



NATIONAL HEALTH
LABORATORY SERVICE



PROFICIENCY TESTING SCHEMES
PARTICIPANT INSTRUCTIONS
2022/2023

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A. GENERAL INFORMATION

1. Introduction

Thank you for participating in the National Health Laboratory Service (NHLS) Proficiency Testing Schemes (PTS). We hope that your participation will be beneficial to your laboratory, as well as enjoyable. We would like to welcome any new participants to the Programme. (National Health Laboratory Service Proficiency Testing Schemes)

2. What is a Proficiency Testing Scheme?

A Proficiency Testing Scheme (PTS) is the practice of testing samples of unknown values sent from an external PT scheme. These samples are shipped to a laboratory at various times throughout the year. The samples are analysed within a specified time frame by testing personnel who must treat them like a patient sample. Once the samples have been tested, results are sent to the PTS for evaluation. The evaluated results are sent back to the laboratory in a report that compares the results obtained with the actual results and compares your laboratory to other laboratories using identical or similar methodology. Participation in PTS allows a laboratory to identify procedural problems and take corrective action before patient results are affected. Successful completion of proficiency testing can serve as a benchmark for quality.

[\(http://www.cms.gov/CLIA/\)](http://www.cms.gov/CLIA/), [\(http://wwwn.cdc.gov/dls/waivedtests/\)](http://wwwn.cdc.gov/dls/waivedtests/)

3. Aim

The NHLS PTS aims to determine the laboratory policy on handling specimens including complete testing and results interpretation. Participants are encouraged to perform testing on all samples. An approach to fulfilling this requirement is to utilise the products and services offered by the NHLS PTS provider.

4. Provider

The NHLS is the sole provider for the proficiency testing schemes. Practice number: 5200296

5. Scope

The NHLS PTS endeavours to assess all aspects of specimen-management, such as turn-around time, accuracy of reports, specimen handling, etc. Rapid turn-around time is an essential element of specimen-management.

B. GENERAL ENROLMENT REQUIREMENTS

Laboratories must enrol on an annual basis. It is mandatory for the NHLS laboratories to enrol on the relevant PTS.

Please take note of below requirements for enrolling for PT Schemes:

Follow the link <https://webpts.nhls.ac.za/login> to enrol.

1. First time enrolment with NHLS PT schemes.

- The Signed Credit Agreement
- Valid Company Registration Document

For the Credit Agreement the following documents **must** be submitted:

- Bank letter not older than 3 months when applying
- Valid Company Registration Document
- Company Letterhead
- Valid Tax Clearance Certificate – South African applicants only.

2. Applicants previously registered on NHLS PT schemes.

The following documentation **must** be submitted:

- Valid Tax Clearance Certificate – South African applicants only
- Bank Letter not older than 3 months – all applicants

3. Payment

The NHLS Finance department will issue a tax invoice; it will be available on the enrolment system to make payment.

4. Enrolment Certificates

The NHLS processes each participant's enrolment and generates an invoice that is sent to participants. For private participants once the invoice is paid in full the enrolment certificate will be available on the system. For non-private participant's certificates are available after enrolments. Table 1 below shows the description of private and non - private laboratories

Table1: Laboratory Categories

CATEGORY	DESCRIPTION
Private	Non NHLS laboratories
Non Private	NHLS laboratories and Funded facilities

5. Cancellations/Refunds

Cancellations, refunds and/or adjustments after enrolments and orders been processed will be handled on a case by case basis. All requests must be submitted in writing to ptsadmin@nhls.ac.za.

6. Changes to existing PT scheme enrolments

All correspondence relating to changes regarding participation to PTS must be forwarded to, ptsadmin@nhls.ac.za, at the NHLS Quality Assurance Department no later than four weeks prior to the scheduled sample shipping date.

7. Confidentiality

To protect the confidentiality of each participant on enrolment, a unique participant number is assigned to each laboratory and/or primary health care facility. The laboratory and/or primary health care facility's name will also be used as an identifier for the internal control of the individual laboratory and/or primary health care facility unless the laboratory and/or primary health care facility does not require this. This unique number identifies each laboratory that participates across all surveys. This number remains associated with that participant indefinitely.

Note: Participants can elect to waive confidentiality within the proficiency testing scheme for the purpose of discussion and mutual assistance, e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the testing provider, the affected participants shall be notified of this action in writing.

8. Participation

Participation of the NHLS Proficiency Testing Schemes is open to all NHLS laboratories. Private laboratories, both local and international may participate. This includes primary health care facilities.

C. SHIPMENTS AND RECEIPT OF SAMPLES

NHLS PT schemes outsource the shipping of samples to courier companies that comply with the IATA regulations. The courier brokerage is charged separately from the cost of the PT samples, and it is not included in the cost of the PT samples. Samples that fall under the UN3373 Category B Hazardous samples are shipped with a special courier that complies with IATA regulations

1. Packaging

Specimens are transported in IATA 650 compliant packaging and ADR road packaging. All packaging complies with the IATA Dangerous Goods Regulations. Your subscription package should include the following items:

- Unique participant code
- Please find master copies of results sheets on the following link:

<http://ptschemes.nhls.ac.za>

1.1 Sample transportation and storage

Proficiency testing scheme material is transported at ambient (18°C-25°C) temperature and on arrival in your laboratory the following; Malaria RDT, Bacteriology, Serology, Haematology, Flow Cytometry, Chemical Pathology, EID, Viral Load and SARS- COV 2 scheme samples must be stored at 2°C-8°C until analysed except all slides, CrAg, Mycology, LPA and Mycobacteriology Culture. Qualitative BhCG samples are shipped in the month that it is due

1.2 General sample storage

Refer to the relevant PTS instructions for proper storage requirements e.g. either between 2 – 8 °C or room temperature before examination. Identify a separate storage space for already analysed PT samples to decrease the possibility of a mix-up with current PT samples.

2. Shipping dates for the 2022/23 cycle

shipment dates and due dates for submission of results for all schemes have been published on the intranet/internet.

Samples are shipped at **ambient temperatures**. Customers must make arrangements to accept delivery and have package routed immediately to the appropriate location for proper handling and storage as indicated for different schemes. Should you not receive your shipment within 5 days post the scheduled shipment date or the condition of the samples is unsuitable, please contact the scheme manager/coordinator.

3. Receipt of samples

Inspect contents of package immediately on arrival in the laboratory.

Inspect for any breakages, possible deterioration during transportation.

Store the samples as per storage instructions until the samples are tested.

Verify that all samples are present (no duplicate or missing samples).

Inspect for sample integrity (adequate volume, cracked or leaking, haemolysis, etc.).

Verify package received corresponds with your enrolment and shipping schedule.

Contact Scheme Manager/Coordinator **within 5 working days** after receipt of samples if samples have not been received. If there are any issues after inspecting package contents replacement samples are available only as long as quantities are available and sample integrity is maintained.

Failure to request for replacement samples is not considered a valid excuse for non-submission of results.

4. Actions to be taken if sample was not received

Should you not receive your PT samples contact the Scheme

Manager/Coordinator **within 5 working days** post the shipment date. A

“tracking of parcel” will then be instituted with the courier company and the participant will be duly informed of the findings.

5. Sample handling precautions

Because no test method can offer complete assurance that HIV, HCV, Hepatitis B Virus (HBV), or other infectious agents are absent it is thus required that all PT samples be treated as potentially infectious and thereby universal safety precautions must be followed as Proficiency testing (PT) samples may be prepared from blood or other human or animal source material. For Quantitative tests each donor unit used in the preparation of material is tested by an approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV-1, HIV-2) and Hepatitis C Virus (HCV) as well as the Hepatitis B surface antigen (HBsAg) and found to be negative (were not repeatedly reactive). The laboratories should use good laboratory practice when handling PT samples.

a) Instructions on returning of proficiency test items.

Not applicable for all NHLS Proficiency Testing Schemes unless discussed with the PT Scheme Manager.

D. PROFICIENCY TESTING SAMPLES

1. Selection of sample

Samples included in the NHLS PTS are characterized on a selection of methods to ensure that a correct interpretation of final result is attained. However, since PT samples may not always behave exactly like patient samples due to the matrix used, the NHLS PTS provider cannot guaranty compatibility with every test system available on the market.

Prior to distribution samples are subjected to one or more of the following processes to ensure suitability:

- Quality control
- Characterization
- Verification processes

All laboratories shall receive a selection of identical samples. The composition of the test samples may vary with each survey.

2. Homogeneity and stability

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the PTS Internal Quality Control (IQC) process.

Chemical Pathology PTS - All testing material are tested and guaranteed for homogeneity and stability by the manufacturers of the material.

3. Treatment and analysis

Please note that for schemes that are live on the web based system, the clinical details will be on the system.

For schemes that are not yet live clinical details will be sent with samples or they can be found on the NHLS internet. Follow the specific sample handling instructions that accompany your shipment. Do not assume that all samples within a shipment are handled in the same manner.

Samples shall be analysed using your own standard operating procedures.

Samples should be treated in the same manner as routine samples.

The specimens should be tested with the laboratory's regular patient workload by staff that routinely performs the testing in the laboratory.

Do not send PT samples to another laboratory for testing.

4. Factors that could influence the testing of samples

Refer to the relevant PT scheme section for further clarity.

Factors could include the following:

Haemolysis

Contamination

Conditions of storage

Samples not brought to ambient temperature before testing

Whole blood samples not mixed adequately before testing

Morphology peripheral blood smears not stored at ambient temperature.

Reticulocyte smears not stored at ambient temperature.

Plasma/serum not stored at -20°C for long term storage.

E. REPORTING PROFICIENCY TESTING SCHEME RESULTS

Please note that for schemes that are live on the web based system, participants are required to enter results on the web based system.

Please use the link below for entry of results:

<http://ptschemes.nhls.ac.za>

For schemes that are not yet live the results form is available electronically and can be found on the NHLS internet and intranet for NHLS participants.

To access the instructions, response forms, specific scheme information including clinical scenarios/information, code booklets, Chemical pathology method questionnaires, receipt checklists and appeal forms on the internet, follow the steps below:

- Go to the web site (Chrome browser preferably)
<https://www.nhls.ac.za>
- Click on **Our Services**
- Go to **Quality Assurance**
- Select **Proficiency Testing**
- Scroll down to find the specific documents

To access the instructions, response forms, specific scheme information including clinical scenarios/information, code booklets, Chemical pathology method questionnaires, receipt checklists and appeal forms on the intranet, follow the steps below:

- Go to the NHLS intranet
<https://intranet.nhls.ac.za>
- Click on **Corporate Departments**
- Go to **Academic Affairs Research and Quality Assurance**
- Select **Proficiency Testing**
- Scroll down to find the specific documents

1. Review analyte/parameter and instrument information

Review/update your analytes/parameters and instrument/method/reagent prior to submitting results. If all information is correct, no changes are required.

If instrument, method, or reagent is incorrect contact scheme manager/coordinator to request an update.

If you need to remove or add an analyte/parameter contact scheme manager/coordinator.

If you are unable to report an analyte/parameter or sample result, you will need to provide reason.

Analyte/parameter and instrumentation/method/reagent changes requested after the due date will not be accepted for the current survey but will be changed for subsequent surveys.

Participants may register more than one instrument. Where samples cannot be shared where laboratories have more than one instrument for the same scheme, the Proficiency Testing Scheme Manager must be informed how many instruments the laboratory needs samples for.

If a participating laboratory has more than one instrument, the results must be submitted on separate result sheets (which your laboratory has made copies from the master result sheet).

Please note: The above is not applicable if the scheme is live on the web based system

Instructions for web based process will be provided for individual schemes.

For the Chemical Pathology PTS, a test selection or method questionnaire forms will be available electronically on the web based system.

2. Report in requested units

Report results in the units as provided in the results submission form.

3. Report in requested decimal places

Do not exceed the number of decimal places indicated. Follow your laboratory SOP if rounding or truncating is necessary.

4. Out of range results (Quantitative Schemes)

Results above reportable range: If proficiency testing results exceed the highest reportable range of your instrument upon initial testing, treat them as you do your patient samples.

If you dilute patient samples, then dilute PT samples

If you do not dilute patient samples, record the highest numeric limit of the instrument as your result including the “greater than” (>) sign.

Results below reportable range: If proficiency testing results exceed the lowest reportable range of your instrument upon initial testing, record the lowest numeric limit of the instrument as your result Including the “less than” (<) sign.

5. Miscalculations, transpositions and other gross errors

Test results that are found to be inappropriate for evaluation due to miscalculations, transpositions or other gross errors will not be included in the evaluation. Incorrect results will be evaluated as such.

F. MANUAL SUBMISSION OF PTS RESULTS

Please note! Manual submission will only be accepted for schemes that are not yet live on the web based system unless indicated otherwise by the PT Scheme Manager.

Return the survey result form to the PTS provider via post/email or fax. Result forms must be completed in full, Laboratory Code must be stated. Please do not

use other email addresses for results submission other than those provided and **DO NOT** redesign the form. All test results, requests for exempted status (temporary suspension of testing), and/or discontinued analyte/parameter testing notification must be submitted until midnight of the due date. Results submitted after the due date will not be evaluated.

Amended results are accepted until midnight of the due date.

Submission address details will be found in the specific PT scheme response form.

G. EVALUATION PROCESS

1. Parametric/ Quantitative data

i. Consensus mean with standard exclusion criteria

After input data, is managed programmatically in a standard manner. The software is programmed to calculate a mean using all raw data. Once this mean has been calculated, each result is measured against the mean. Results that exceed a preset limit such as (4s, 3s or 2s- PT Scheme dependent) are flagged and excluded from the data. The mean is then recalculated and each laboratories' z- score is calculated. This data together with the total sample size and overall coefficient of variation is stored for printing on the report. Any result which exceeds the allowable limits of error for the particular assay is flagged. Where it is known that there are consistent differences in methodology which have a significant influence on the results, results are partitioned accordingly. Separate means are then calculated for each group and the participant is measured against their group mean. A minimum number of samples for this calculation is set at 10.

ii. Consensus mean with exclusion criteria based on Chauvenet's criterion

Data is handled in the same way as above. However, the statistical outliers in each group are identified using Chauvenet's criterion instead of using multiples of s as the cutoff. This means that with small sample sizes such as individual method groups, outliers are identified more effectively. A minimum number of samples for consensus mean with this type of exclusion is 5.

iii. Defined target value

In some instances, it is necessary to use material which has been analysed and assigned a target value. In this case a direct comparison is made between the result submitted and the target value. Any results outside predetermined limits are flagged. The difference between the target value and the laboratories' result is expressed as a percentage bias. No rejection criteria are required as the mean is calculated simply as a method of determining the overall range of results.

iv. Robust analysis compliant with ISO: 13528 Algorithm A

Robust statistics are based on the assumption that the data are a sample from an essentially normal distribution contaminated with heavy tails and a small proportion of outliers. Insensitive to the presence of outliers and heavy tails to avoid undue influence from poor results, and this is why the median or a robust mean is valuable. The median, however, is more robust when the frequency distribution is strongly skewed.

There are two choices:

- Remove statistical outliers
- Use statistical techniques that are robust to these values

Robust techniques are preferred.

NHLS as a PT provider needs to mitigate the effect of extreme results, because not all participants are competent, and extreme results are always possible.

These results have a strong effect on consensus statistics. We have two choices; remove statistical outliers or use statistical techniques that are robust to these values. Robust techniques are preferred. International PT Schemes use this method. With the new web NHLS will be using robust techniques; Robust analysis compliant with ISO: 13528 Algorithm A.

2. Peer group

Peer group consists of specific test systems (same instrument/kit, same reagent, same measurement principle).

3. All methods group

All methods group consists of all methods of all participants. All methods may not be an option in situations where there is excessive result variation among peer groups for a particular analyte/parameter or procedure.

4. z-score

The assessment of individual performance for proficiency testing schemes using parametric (numeric) data is most commonly estimated by using the z score. This is a simple calculation that enables an accurate measure of the degree of bias (error) encountered when carrying out a specific test measurement. The comparative or target value is usually a consensus mean (average) that is calculated from all the participant's results after trimming out all outliers.

5. Bias

Bias is expressed as a percentage. It indicates your result in relation to the target result expressed as a percentage.

6. Evaluation for qualitative schemes

Evaluations for Qualitative schemes are described in relevant scheme sections.

H. REPORTS

1. Postal service

Due to the ongoing problems and delays with the postal service deliveries in both South Africa and Africa, all reports will be couriered together with the next survey samples. Refer to the shipping dates for the schemes and shipping dates for results. If you require your results before receiving the next surveys samples, contact the scheme manager/coordinator with your request. Important, your **participant code number** must be included with all correspondence. Reports are available approximately 5-6 weeks after the closing date for schemes that are not on the web based system.

2. Amended report

Amended reports will be issued on investigation of a written dispute or appeal. The amended reports will not be issued if the source of the transcription error was the participant.

3. Re-issue of Report

The NHLS PTS does not accept responsibility for reports lost or misplaced by the participant. Reports will only be re-printed if a request is done in writing prior to the next survey shipment.

NHLS participants' performances may be disclosed to a restricted list of individuals, their Regional QA managers and QA Coordinators as per NHLS Policy.

I. CPD POINTS

Not Applicable

J. CORRECTIVE ACTION

The onus is on the laboratories concerned to review evaluation reports, identify corrective actions, and to implement corrective and preventative measures, where applicable. If any assistance is required from the NHLS PTS Department, please contact the PTS Managers.

K. PROCEDURE FOR RESOLVING DISCREPANCIES, DISPUTES, APPEALS, COMPLAINTS

Within 5 working days of receiving any proficiency evaluation reports, the participant may dispute the decision to the relevant Proficiency Testing Scheme Manager and shall be limited to investigating whether or not the PTS providers' procedures were followed. All disputes and appeals shall be in writing, clearly stating in detail the nature of the dispute/appeal, and shall provide adequate information as supporting evidence. Participants may submit an appeal for transcription errors only when the NHLS PTS provider is the source of the transcription errors in their preparation of the report. The NHLS PTS provider does not accept responsibility for results faxed/emailed to the wrong fax numbers or email address.

The form to lodge a dispute, appeal and/or complaint is available on the internet/intranet and must be filled in and submitted by the participant to the relevant PT Scheme mailbox.

1. Definitions

- i. Appeal –the process in which results are reviewed, where participants request a formal change to an official decision.
- ii. Anomalies - deviations from what is standard, normal or expected.
- iii. Complaint - a statement expressing dissatisfaction with a particular situation
- iv. Deviations - activities not conforming to procedures and processes. These are actions departing from an established cause or accepted standard.
- v. Feedback - information or criticism about prior action or behaviour from an individual, communicated to another individual (or group) that can be used to adjust and improve current and future actions or behaviour. It is used as a basis for improvement
- vi. Incidents - events or occurrences that are not part of normal operations that disrupts operational processes.
- vii. Observation - a statement based on something one has seen, heard, or noticed
- viii. Query - a question, especially one expressing doubt or requesting information.
- ix. Technical error - an error occurring in the technique of a method. It is a deviation from accuracy or correctness.

L. COMMUNICATION PROCEDURES

1. **Return of results** (relevant to PT Schemes where results have to be submitted manually). Results are to be submitted to the relevant PT email addresses. Refer to **Table 13** for contact details of individual PT Schemes.

Note well: results sent to any other email address will not be accepted and a non-return issued

Table 13: Contact details for individual PT Schemes

Category	Proficiency Testing Scheme	PT Scheme Manager	Email	Telephone
Chemistry	Blood Gases	Thokozile Zulu	chempath@nhls.ac.za	+27 (0)11 555-0582
	Cardiac Markers	Zazi Molebatsi	chempath@nhls.ac.za	+27 (0)11 885 5353
	CRP	Bongiwe Mofokeng	chempath@nhls.ac.za	+27 (0)11 386-6148
	Endocrinology	Esther Tsheola	chempath@nhls.ac.za	+27 (0)11 555 0563
	General Chemistry	Bongiwe Mofokeng	chempath@nhls.ac.za	+27 (0)11 386-6143
	TDM	Mahlatse Maleka	chempath@nhls.ac.za	+27 (0) 11 386 6159
	Qualitative BhCG	Bongiwe Mofokeng	chempath@nhls.ac.za	+27 (0)11 386-6148
Haematology	Automated Differential counts	Thokozile Zulu	cd4pts@nhls.ac.za	+27 (0)11 555-0582
	Coagulation: D-Dimer	Zazi Molebatsi	cd4pts@nhls.ac.za	+27 (0)11 885 5353
	Coagulation: INR and APTT	Zazi Molebatsi	haempts@nhls.ac.za	+27 (0)11 885 5353
	Erythrocyte Sedimentation Rate (ESR)	Bongiwe Mofokeng	haempts@nhls.ac.za	+27 (0)11 386-6148
	Full Blood Count	Esther Tsheola	haempts@nhls.ac.za	+27 (0)11 555 0563
	Manual Reticulocyte counts	Bongiwe Mofokeng	cd4pts@nhls.ac.za	+27 (0)11 555-0413
	Morphology-Peripheral blood slides	Bongiwe Mofokeng	cd4pts@nhls.ac.za	+27 (0)11 555-0413
Immune Monitoring	CD4	Mahlatse Maleka	cd4pts@nhls.ac.za	+27 (0) 11 386 6159
	CD4 POCT	Mahlatse Maleka	cd4pts@nhls.ac.za	+27 (0) 11 386 6159
Microbiology	Bacteriology	Zazi Molebatsi	bactpts@nhls.ac.za	+27 (0)11 885 5353
	CrAg LFA	Thokozile Zulu	mycopts@nhls.ac.za	+27 (0) 11 555 0582
	Malaria RDT	Zazi Molebatsi	parapts@nhls.ac.za	+27 (0)11 885 5353
	Mycobacteriology Culture	Esther Tsheola	tbpts@nhls.ac.za	+27 (0)11 555 0563
	Mycobacteriology Microscopy	Esther Tsheola	tbpts@nhls.ac.za	+27 (0)11 555 0563
	Mycology Mould	Thokozile Zulu	mycopts@nhls.ac.za	+27 (0) 11 555 0582
	Mycology Yeast Basic	Esther Tsheola	mycopts@nhls.ac.za	+27 (0)11 555 0563
	Mycology Yeast Advanced	Esther Tsheola	mycopts@nhls.ac.za	+27 (0)11 555 0563
	Non Treponemal Serology	Thokozile Zulu	seropts@nhls.ac.za	+27 (0) 11 555 0582
	Parasitology Blood	Zazi Molebatsi	parapts@nhls.ac.za	+27 (0)11 885 5353
	Parasitology Stool	Thokozile Zulu	parapts@nhls.ac.za	+27 (0) 11 555 0582
	Specific Treponemal Serology	Zazi Molebatsi	bactpts@nhls.ac.za	+27 (0)11 885 5353
Molecular Biology	SARS – CoV - 2	Mahlatse Maleka	seropts@nhls.ac.za	+27 (0) 11 386 6159
	Early Infant Diagnosis (EID) of HIV	Mahlatse Maleka	seropts@nhls.ac.za	+27 (0) 11 386 6159
	Mycobacteriology Line Probe Assay	Esther Tsheola	tbpts@nhls.ac.za	+27 (0)11 555 0563
	Viral Load (HIV)	Mahlatse Maleka	seropts@nhls.ac.za	+27 (0) 11 386 6159
Virology	HBsAg Serology	Mahlatse Maleka	seropts@nhls.ac.za	+27 (0) 11 386 6159
	HIV POCT	Mahlatse Maleka	hiv.poctpts@nhls.ac.za	+27 (0) 11 386 6159
	HIV Serology	Mahlatse Maleka	seropts@nhls.ac.za	+27 (0) 11 386 6159

When submitting results via email, participants are to indicate the laboratory code, scheme and survey no. on the title of email.

e.g. 000 Mycobacteriology Culture Results 0121

2. General PTS Administration

For correspondence with NHLS PT Schemes regarding general queries, comments, suggestions, compliments, enrolments, please send email to ptsadmin@nhls.ac.za

3. Correspondence

Participants are able to contact the PTS manager to discuss any issues related to the scheme.

Physical address:

1 Modderfontein Road
Sandringham
NHLS
2192

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M. PROFICIENCY TESTING SCHEMES INSTRUCTIONS

NHLS Immune monitoring CD4 Proficiency Testing Scheme

This is a detailed documented participant instruction for NHLS Immune Monitoring CD4 Proficiency Testing Scheme participants. All relevant information regarding this proficiency testing scheme is contained in this document which must be read prior to processing the proficiency testing scheme samples.

Please read the information provided. Important dates for dispatch and return of results are indicated.

Your subscription package should include the following items:

- Unique participant code number
- Two proficiency testing samples. (This material is transported at ambient (18°C-25°C) temperature and on arrival in your laboratory or primary health care facility the material must be stored at 2°C-8°C until analysed. The whole blood material is ready for use once brought to ambient temperature).

The Immune Monitoring scheme issues stabilised whole blood in which participants are required to determine the lymphocyte subsets within the preparation. Participants are required to return absolute counts and/or percentage values depending on which the participant is registered for:

- CD4+ (CD3+CD4+) Absolute count
- CD3+CD8+ Absolute count
- CD3+ Absolute count
- CD4+ (CD3+CD4+) Lymphocyte percentage
- CD3+CD8+ Lymphocyte percentage
- CD3+ Lymphocyte percentage
- CD19⁺ B cells Absolute count
- CD3⁺/CD16⁺/CD56⁺ Natural killer cells Absolute count
- CD19⁺ B cells Lymphocyte percentage
- CD3⁺/CD16⁺/CD56⁺ Natural killer cells Lymphocyte percentage

1. Participation

Participation is open to all laboratories and primary health care facilities who offer Immune Monitoring by flow cytometry and CD4 point of care testing.

2. Important registration for more than one flow cytometer/methodology

- Participants may register more than one flow cytometer.
- If your laboratory has more than one flow cytometer and/or different methodologies, submit results on separate result sheets.

- Use the allocated participant number for each result sheet and the Immune monitoring CD4 PTS manager will allocate a sub number/letter for each new flow cytometer/methodology.
- These sub numbers/letters will then be sent to the participant to be used for all further trials.
- Please submit the flow cytometer serial number with each result.

3. Methodology

The NHLS CD4 laboratories use the Single Platform Pan/*leucogated* CD4 method. All other participants use their method of choice.

CD3, CD4, CD8, CD19⁺ and CD3⁺/CD16⁺/CD56⁺ samples

- Two samples are sent out per trial.
- These samples are stabilised material with an expiry date.
 - This material is transported at ambient temperature and on arrival in your laboratory the
 - material must be stored at 2°C-8°C until analysed.
 - All samples should be allowed to attain ambient temperature before testing.
 - All samples should be thoroughly mixed before use.
 - Process the stabilised human blood product as if you were handling routine blood samples (observing associated safety precautions).
 - It is recognised that some minor adjustment of forward and side scatter gains may be required on some flow cytometers as an inevitable consequence of any stabilisation process.

4. Result sheet

- Copies are to be made from the master result sheet.
- The participant's laboratory and/or primary health care facility's name and unique participant code number (and sub code number/letter if registered more than one instrument) must be written in.
- Please note: If the above is not complied with, no results will be generated and a non-return result will be sent to the participant.
- The survey number and trial number must be written in.
- The date received and the date of analysis should be included.
- The flow cytometer (instrument) serial number must be written in.

- Information required from participants includes:
 - Monoclonal antibody panel used
 - Flow cytometer used
 - Basic methodology single platform dual platform
 - Bead product
 - Red cell lysing method
 - Results absolute counts and/or lymphocyte percentages
 - Name, signature, telephone number and email address

5. Interpretation of cumulative SDI/z score graph results

- Individual cumulative SDI/z-score graph on report:
- On the report form, a participants' standard deviation index (SDI)/z-score result is graphically represented.
- On the y-axis, the SDI/z-score is reported.
- On the x-axis, the survey and trial is reported.

6. Laboratory performance showing the Standard Deviation Index (z-score)

- Acceptable performance is ± 2 SDI (z-score):
- A Standard Deviation Index (SDI) (z-score) of less than 0.5 denotes excellent performance
- A SDI (z-score) between 0.5 and 1.0 is satisfactory
- A SDI (z-score) between 1.0 and 1.5 is acceptable
- A SDI (z-score) between 1.5 and 2.0 is border-line
- A SDI (z-score) of greater than 2.0 requires immediate attention

7. Point of care testing (POCT)

- Application of proficiency testing blood via glass capillary instructions:
- Bring proficiency testing sample tubes to room temperature.
- GENTLY mix sample tube.
- Do not shake or vortex to avoid generating air bubbles.
- Once well mixed, proceed with your POCT method.
- Run both tubes labelled "Sample A" and "Sample B".
- Enter CD4 results on the result sheet provided.

8. Important registration for more than one flow cytometer/methodology

- Participants may register more than one flow cytometer.
- If your laboratory has more than one flow cytometer and/or different methodologies, submit results on separate result sheets (which your laboratory has made copies from the master result sheet).
- Use the allocated participant number for each result sheet and the Immune monitoring CD4 PTS manager will allocate a sub number/letter for each new flow cytometer/methodology.
- These sub numbers/letters will then be sent to the participant to be used for all further trials.
- Please submit the flow cytometer serial number with each result.

Appendix 1: Graphical interpretation of NHLS Immune Monitoring CD4 Proficiency Testing report. A cumulative z-score graphical representation of performance, which illustrates the laboratory's z-score value, within the group distribution.

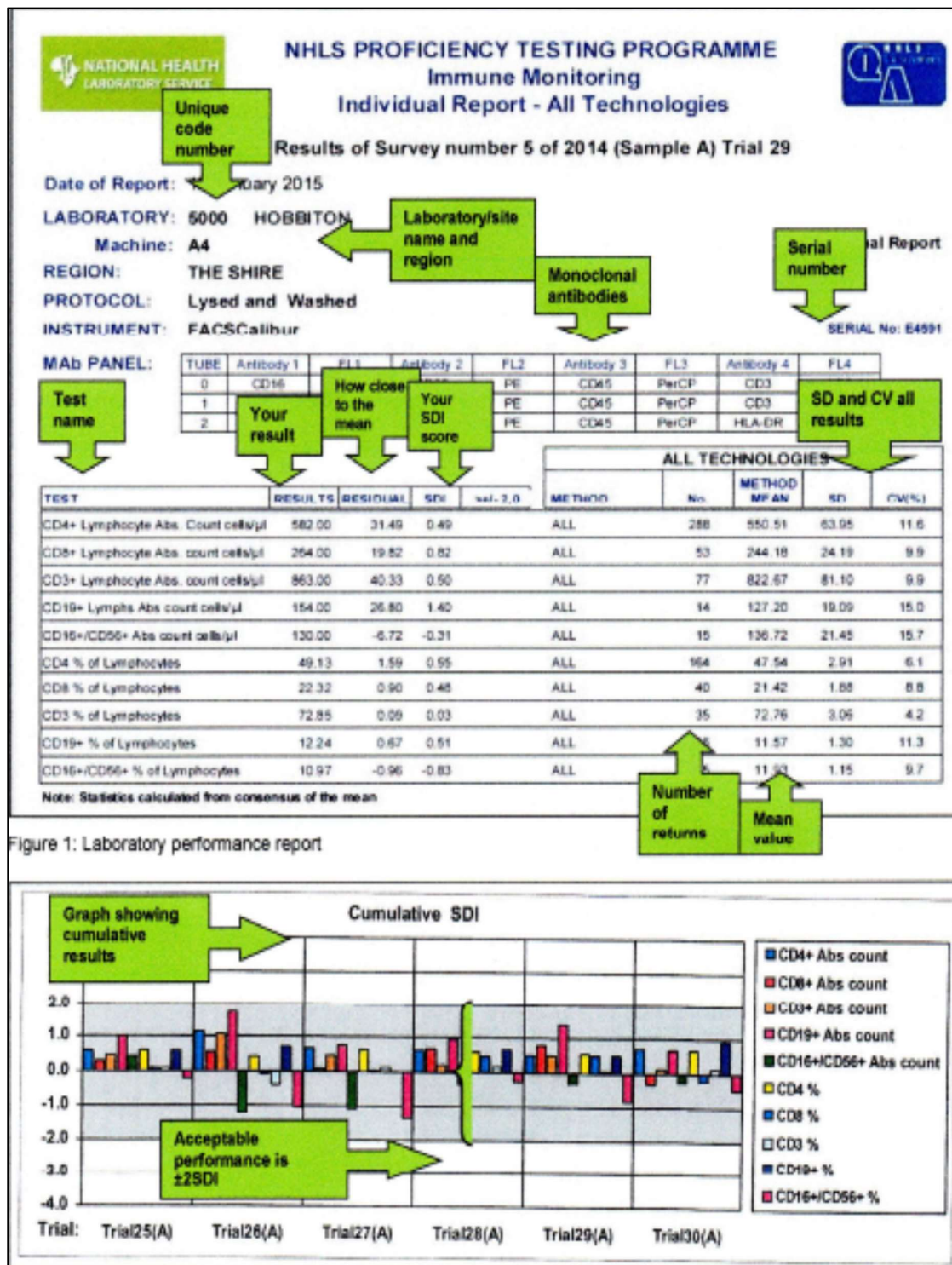


Figure 1: A cumulative SDI graphical representation of performance, which illustrates the laboratory's SD/z-score value, within the group distribution.

NHLS D-Dimer Proficiency Testing Scheme

This detailed document contains participant instructions for the National Health Laboratory Service (NHLS) D-Dimer Proficiency Testing Scheme (PTS). All relevant information regarding this proficiency testing scheme is contained in this document which must be read prior to processing the proficiency testing scheme samples.

Please read through the information provided. Important dates for dispatch and return of results are indicated.

Your subscription package should include the following items:

- Unique participant code number.
- Two proficiency testing samples. (This material is transported at ambient (18°C-25°C) temperature and on arrival in your laboratory the material must be stored at 2°C-8°C until analysed).
- The D-Dimer scheme issues unreconstituted lyophilized plasma in which participants are required to determine the D-Dimer levels within the preparation.

1. Participation

Participation is open to all laboratories and primary health care facilities who offer D-Dimer testing.

2. Methodology

All participants use their method of choice.

a) Reconstitution

1. For proper reconstitution the vial must reach room temperature before adding the water.
2. Dissolve the contents of each sample with exactly 1ml distilled water.
3. Leave the sample for 5 minutes then swirl the sample gently to mix and leave for a further 25 minutes for complete reconstitution.
4. Before use mix the sample again gently.

b) Storage of reagents and controls

1. Unreconstituted lyophilized plasma should be stored at 2-8°C.
2. Reconstituted plasma should preferably be used within 8 hours after reconstitution.
3. Plasma should be kept at room temperature after reconstitution.

c) Reporting unit of the D-Dimer assay

1. The NHLS D-Dimer PTS pilot study was referenced to D-Dimer unit milligrams per liter (DDU mg/mL).
2. All laboratories used the normal reference of 0.00 – ≤ 0.25 mg/L.

d) Result sheet

1. The participant's laboratory name and unique participant code number must be written in.
2. Please note: If the above is not complied with, no results will be generated and a non-return result will be sent to the participant.
3. The survey number must be written in.
4. The date received and the date sent back to QA to be included.
5. All participants are required to submit 4 results:
 - a) the numerical value for sample 1 and sample 2
 - b) the interpretation of "above cut-off" or "below cut-off" for sample 1 and sample 2.
6. Methodology section must be filled in.
7. Fill in "comments/suggestions/queries/complaints" if required.
8. Date, name, signature, telephone number and email address must be filled in.

e) Criteria of acceptance

1. Acceptable limits of error
 - a) The Negative (normal) range should be 0.00 – ≤ 0.25 mg/L with the interpretation indicating below cut off.
 - b) The Positive (high) range should be >0.25 – 0.50mg/L with the interpretation indicating above cut off.
2. The standard deviation index (SDI)/z-score
For proficiency testing results the acceptable SDI/z-score performance is ± 2 SD.

f) The report includes the following:

1. Results of survey number, sample 1 and sample 2.
2. A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and SDI (z-score).
3. Interpretation of results which include “above cut-off” or “below cut-off”
4. Individual cumulative z-score graph
5. A table of “Summary methods”
6. Graphical representation of “Above cut off” and “Below cut off”

g) Interpretation of PTS test results

1. Each laboratory performance report includes the performance of all laboratories (all methods).
2. Results are reported in D-Dimer mg/L units.
3. All participants are required to **submit 4 results**:
 - the numerical value for sample 1 and sample 2
 - the interpretation of “above cut-off” or “below cut-off” for sample 1 and sample 2.
4. The report includes the following:
 - Results of survey number, sample 1 and sample 2.
 - A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and SDI (z-score).
 - Interpretation of results which include “above cut-off” or “below cut-off”
 - Individual cumulative z-score graph
 - A table of “Summary methods”
 - Graphical representation of “Above cut off” and “Below cut off”

h) Evaluation of D-Dimer results

NHLS D-Dimer Proficiency Testing Scheme use the consensus mean and SD calculations along with Chauvenet’s criterion to exclude outliers.

Laboratory performance showing the Standard Deviation Index (z-score)

Acceptable performance is ± 2 SDI (z-score):

A Standard Deviation Index (SDI) (z-score) of less than 0.5 denotes excellent performance

- A SDI (z-score) between 0.5 and 1.0 is satisfactory
- A SDI (z-score) between 1.0 and 1.5 is acceptable
- A SDI (z-score) between 1.5 and 2.0 is border-line
- A SDI (z-score) of greater than 2.0 requires immediate attention

Cut off points

Reference ranges for proficiency testing material and patient's samples in D-Dimer units:

- Negative (normal) range: 0.00 – ≤0.25mg/L
- Interpretation: Below cut off
- Positive (high) range: >0.25 – 0.50mg/L
- Interpretation: Above cut off

Until further notice from the D-Dimer PTS advisory panel the following scoring system will be used

Scoring system:

Sample 1 (if low negative):

- Acceptable performance is ± 2 SDI /z-score
- Score 50%

Cut off points

Negative (normal) range: 0.00 – ≤0.25mg/L

- Interpretation: Below cut off
- No score will be allocated if the interpretation is given

Sample 2 (if high positive):

- Acceptable performance is ± 2 SDI /z-score
- Score 50%

Cut off points

Positive (high) range: >0.25 – 0.50mg/L

- Interpretation: Above cut off
- No score will be allocated if the interpretation is given

Total score 100%

Please note that samples 1 and 2 will be mixed around, that is, sample 1 may be a negative low or a positive high and visa versa.

Only the ± 2 SDI /z-score will apply for % compliance of 80%, flagging and non-conformances for NHLS coagulation laboratories.

Appendix 1: Graphical interpretation of NHLS D-Dimer proficiency testing scheme report. A cumulative z-score graphical representation of performance, which illustrates the laboratory's z-score value, within the group distribution.

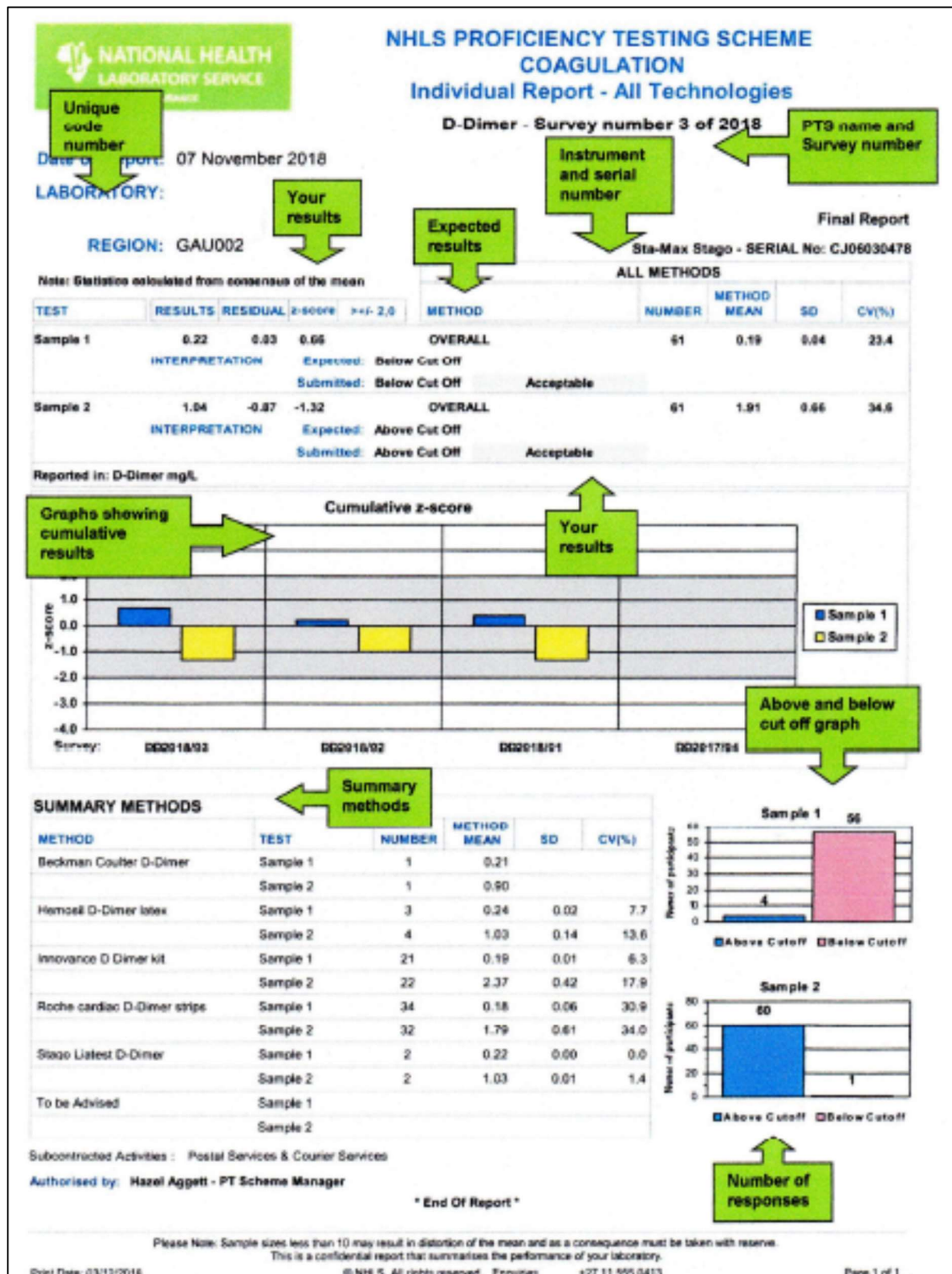


Figure 2: D-Dimer report

NHLS Morphology and Manual Reticulocyte Count Proficiency Testing Scheme

This is a detailed documented participant instruction for NHLS Morphology and Manual Reticulocyte Count Proficiency Testing Scheme participants. All relevant information regarding this proficiency testing scheme is contained in this document which must be read prior to processing the proficiency testing scheme sample

1. Morphology

Twelve surveys per cycle are sent out.

One stained blood film for differential cell counts, morphology and interpretative comments.

2. Reticulocyte Count

Three surveys per cycle are sent out.

One stained blood film is provided for the determination of reticulocyte counts.

3. Peripheral blood slide assessment

3.1 Clinical information

- a) Clinical information with a relevant full blood count and platelets will be given with each slide to be assessed.
- b) This information helps to get an idea of the pathology even before looking at the peripheral blood slide.

3.2 Performance score

- a) All slides will be given a marked score out of 10, which will be deemed either acceptable or not acceptable.
- b) All laboratories will need to obtain a score of 8 or above to be regarded as acceptable. Any score below 8 will be regarded as not acceptable.
- c) The following are required for scoring purposes:
 - a. Differential white cell count, white cell morphology, red cell morphology, platelet morphology, interpretative comment, diagnosis/differential diagnosis and suggest further investigations.
- d) Please note: Normal and abnormal slides will be scored according to the following criteria:

	Score
Differential white cell count	1
White cell morphology	1
Red cell morphology	1
Platelet morphology	1
Interpretative comment	4
Diagnosis/ differential diagnosis	1
Suggested further investigations	1
Total	10

3.3 Interpretation

This is to explain the meaning of the morphological findings and clinical presentation of the patient. For example, the presence of toxic granulation, neutrophilia and thrombocytosis are in keeping with an infective process.

3.4 Diagnosis or differential diagnosis

This is to identify the disorder or disease causing the morphological findings and clinical presentation. Where a number of diseases or disorders can be the cause of the morphological and clinical findings, this list should be given. This is called the differential diagnosis.

4. Manual Reticulocyte Count

On the clinical information sheet a full blood count result will be given together with information required from participants.

4.1 Required:

- Uncorrected reticulocyte count percentage.
- Corrected reticulocyte count percentage (the 0.45 figure is taken as a normal haematocrit).
- Reticulocyte production index.
- The formula, the calculation and the result must be shown
- The reticulocyte count result sheet must be used

For the purposes of the Manual Reticulocyte Proficiency Testing Scheme the following maturation time (index) shall be used:

The maturation time (Index) of the reticulocyte is taken as:

- 1 day at a haematocrit of 0.45
- 1.5 days at a haematocrit of 0.35
- 2 days at a haematocrit of 0.25
- 3 days at a haematocrit of 0.15

4.2 Scored results

All laboratories will need to obtain a mark of 8 or above to be regarded as acceptable. Any mark below 8 will be regarded as not acceptable.

- a) Uncorrected reticulocyte count percentage (4 marks: 2 marks for the reticulocyte count percentage, 1 mark for the formula and 1 mark for the calculation).
- b) Corrected reticulocyte count percentage (3 marks: 1 mark for the formula, 1 mark for the calculation and 1 mark for the correct haematocrit)
- c) Reticulocyte production index (3 marks: 1 mark for the formula, 1 mark for the calculation and 1 mark for the correct maturation index).

Appendix 1: Graphical interpretation of NHLS Morphology and Manual Reticulocyte Count proficiency testing scheme report. A cumulative z-score graphical representation of performance, which illustrates the laboratory's z-score value, within the group distribution.

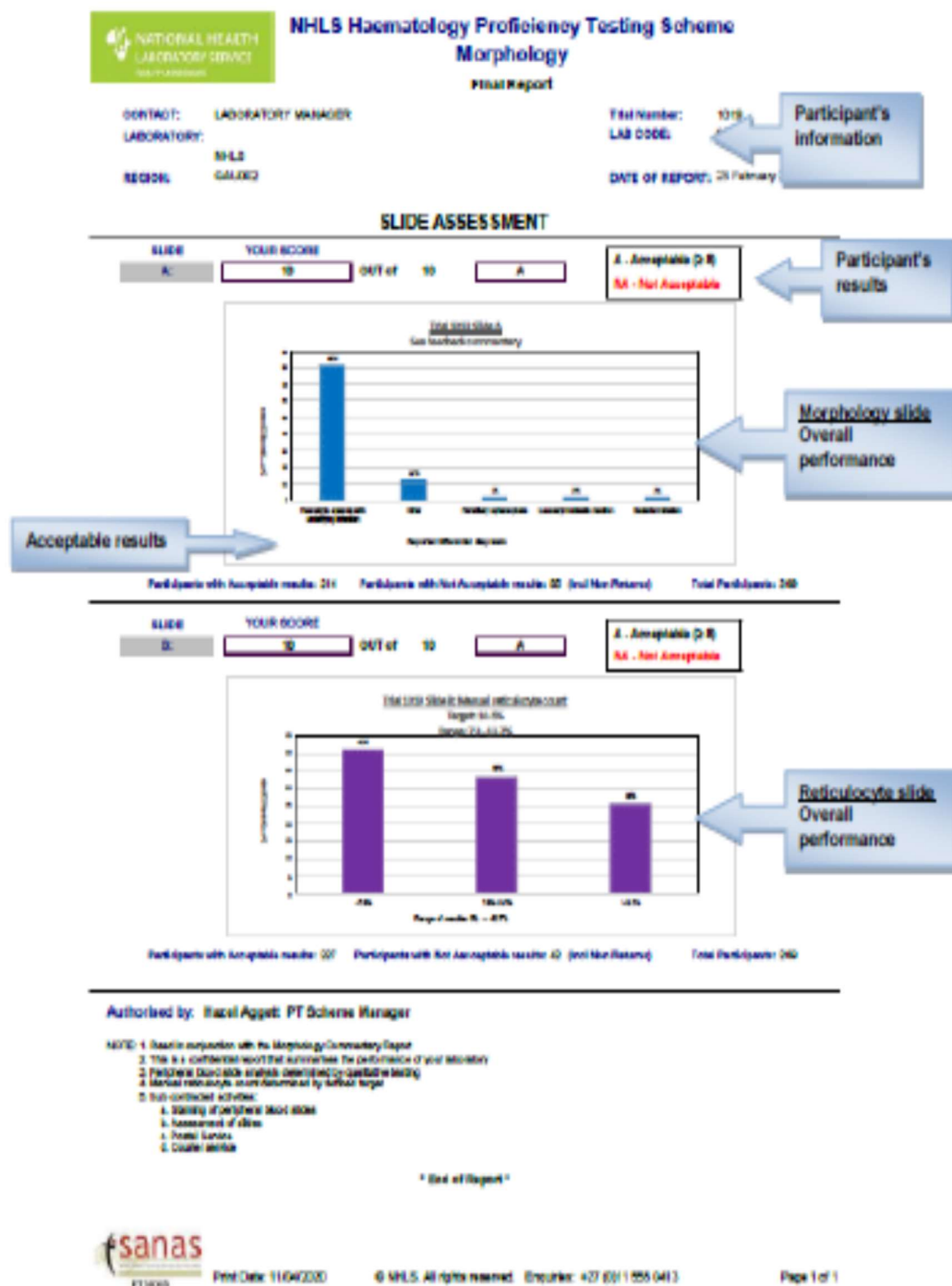


Figure 3: Morphology and Manual Reticulocyte Count reports

NHLS Automated Differential Count Proficiency Testing Scheme

This is a detailed documented participant instruction for NHLS Automated Differential Count (5-part differential) Proficiency Testing Scheme participants. All relevant information regarding this proficiency testing scheme is contained in this document which must be read prior to processing the proficiency testing scheme samples.

Please read the information provided. Important dates for dispatch and return of results are indicated.

Your subscription package should include the following items:

- Unique participant code number
- One proficiency testing sample. (This material is transported at ambient (18°C-25°C) temperature and on arrival in your laboratory the material must be stored at 2°C-8°C until analysed. The whole blood material is ready for use once brought to ambient temperature).
- Process the stabilised human blood product as if you were handling routine blood samples (observing associated safety precautions).

IMPORTANT

Make sure you have the correct sample for the type of haematology analyser used in your laboratory.

The NHLS Automated Differential Count (5-part differential) scheme issues stabilised whole blood in which participants are required to determine the 5-part differential count within the preparation. Participants are required to return absolute counts and percentage values.

Parameter	Percentage (%)	Absolute (10⁹/L)
White cell count (Only absolute result required)		
Neutrophils		
Lymphocytes		
Monocytes		
Eosinophils		
Basophils		

1. Participation

Participation is open to all laboratories who offer Haematology full blood counts and differential counts.

2. Important registration for more than one haematology analyser

- Participants may register more than one haematology analyser.
- If your laboratory has more than one haematology analyser and/or different methodologies, submit results on separate result sheets (which your laboratory has made copies from the master result sheet).
- Use the allocated participant number for each result sheet and the PTS manager will allocate a sub number/letter for each new haematology analyser /methodology.
- These sub numbers/letters will then be sent to the participant to be used for all further surveys.
- Please submit the haematology analyser serial number with each result.

3. Methodology

The laboratories are to use the haematology analyser method for their laboratory. Methodology for the following user groups:

- Coulter Act 5Diff series
- Coulter LH and DxH series
- Advia series
- Sysmex series
- Mindray series

4. Homogeneity and stability

The samples have been tested and found to be homogeneous and stable for this scheme.

5. Stability and storage

Store the tubes vertically in their original package at 2 to 8°C when not in use. DO NOT FREEZE.

6. Reconstitution

No reconstitution required, the sample is stabilised whole blood.

- Remove the tube of blood from the refrigerator and allow to warm at room temperature (18 to 25°C) for 15 minutes before mixing.
- To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.
- Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
- Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing,
- Gently invert the tube 8 - 10 times immediately before sampling.
- Return tube to the refrigerator within 30 minutes of use.

7. Instructions to participants for the following user groups

a. Coulter Act 5 diff

- Whole blood material compatible with Act 5diff OV, Act 5diff CP and AcT 5diff AL instruments.
- Analyse the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
- This product should be sampled as QC material.
- Please report UNCORRECTED WBC.

b. Coulter LH Series and DxH instruments

- Whole blood material compatible with Coulter LH series, DxH 600, 800, 900 instruments.
- Analyse the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
- Please report UNCORRECTED WBC.

c. Advia 2120i

- Whole blood material compatible with Advia instruments.
- Analyse the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
- Please report UNCORRECTED WBC.

d. Sysmex

- Whole blood material compatible with Sysmex instruments.
- Analyse the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
- This product should be sampled as QC material.
- Sysmex XN: Please ensure TNC-N (Total Nuclear Cell Count (WBC#+NRBC)) value is reported.
- Sysmex XE/XT: Please report your impedance count for all parameters.

e. Mindray

- Whole blood material compatible with Advia instruments.
- Analyse the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
- Please report UNCORRECTED WBC.

8. Result sheet

- Copies are to be made from the master result sheet.
- The participant's laboratory name and unique participant code number (and sub code number/letter if registered more than one instrument) must be written in.
- Please note: If the above is not complied with, no results will be generated and a non-return result will be sent to the participant.
- The survey number must be written in.
- The instrument name and serial number must be written in.
- Information required from participants includes:
- Results absolute counts and/or lymphocyte percentages
- Name, signature, telephone number and email address

9. Laboratory performance report

- The results which have been sent by the participating laboratories are analysed and documented in a report.
- Each laboratory performance report includes the performance of technology group.
- The report includes the following:
- Results of survey number and date of report

- A automated differential count report sheet that summarises the information submitted by the participant and identifies the institution, laboratory participant number, haematology analyse with serial number.
- A summary table of statistics that includes reported value (laboratory submitted result), aggregate group mean value (method mean), residual, SD, %CV and z-score.
- Results include:
 - a) White cell count (Only absolute result required)
 - b) Percentage (%)
 - Neutrophils
 - Lymphocytes
 - Monocytes
 - Eosinophils
 - Basophils
 - c) Absolute counts ($10^9/L$)
 - Neutrophils
 - Lymphocytes
 - Monocytes
 - Eosinophils
 - Basophils

10. Evaluation of Automated Differential Count results

NHLS Automated Differential Counts Proficiency Testing Scheme use the consensus mean and SD calculations along with Chauvenet's criterion to exclude outliers.

A cumulative z-score graphical representation of performance, which illustrates the laboratory's z-score value, within the group distribution.

11. Interpretation of cumulative SDI/z score graph results

Individual cumulative SDI/z-score graph on report:

- On the report form, a participants' standard deviation index (SDI)/z-score result is graphically represented.
- On the y-axis, the z-score is reported.
- On the x-axis, the survey and trial/survey is reported.

12. Criteria of acceptance with the z-score

Acceptable performance is ± 2 z-score:

- A z-score of less than 0.5 denotes excellent performance
- A z-score between 0.5 and 1.0 is satisfactory
- A z-score between 1.0 and 1.5 is acceptable
- A z-score between 1.5 and 2.0 is border-line
- A z-score of greater than 2.0 requires immediate attention

Note

Sample sizes less than 10 may result in the distortion of the mean and as a consequence must be taken with reserve.

Appendix 1: Graphical interpretation of NHLS Automated Differential Count (5-part differential) proficiency testing scheme report. A cumulative z-score graphical representation of performance, which illustrates the laboratory's z-score value, within the group distribution.

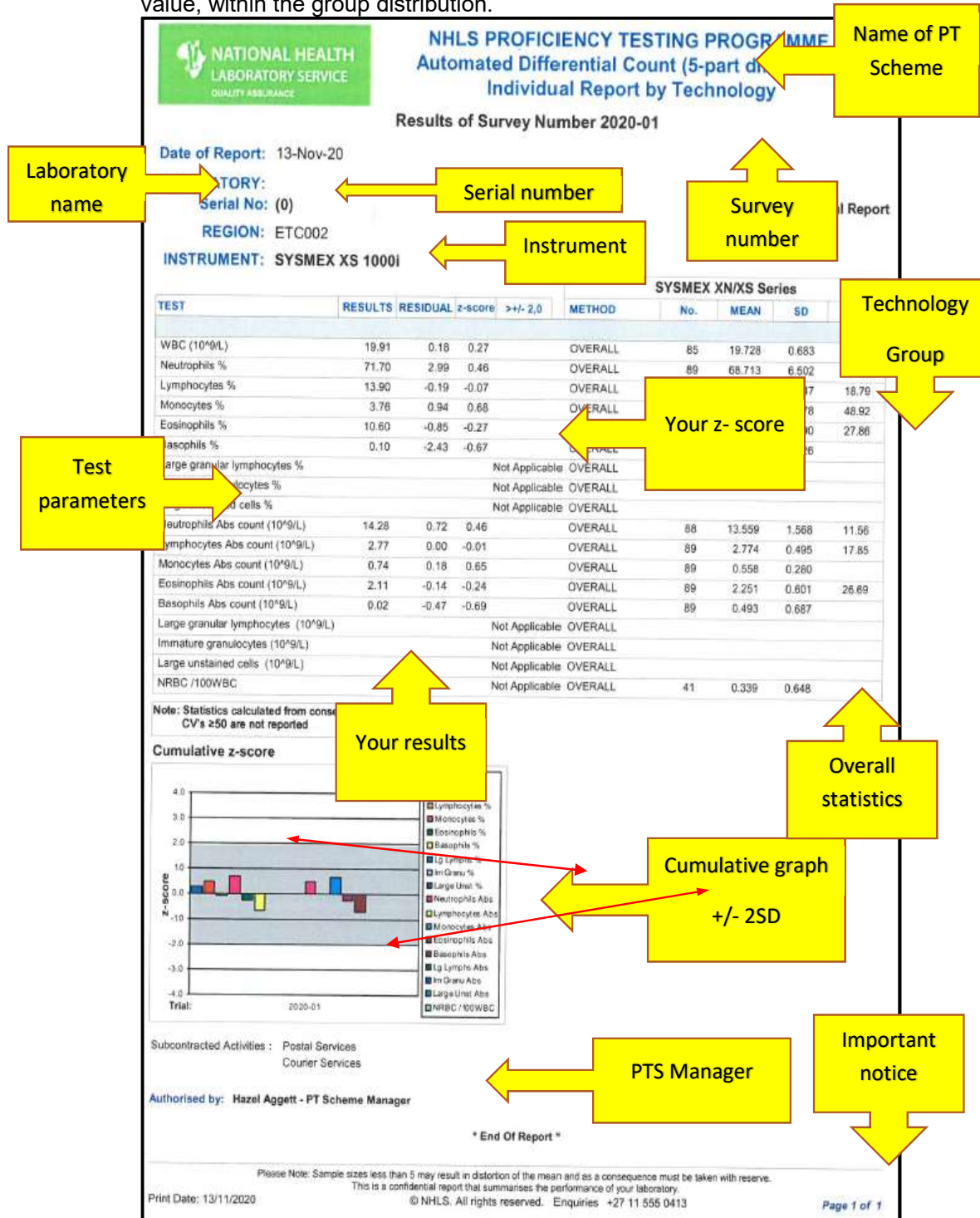


Figure: NHLS Automated Differential Count (5-part differential) report

NHLS Bacteriology Proficiency Testing Scheme Instructions

a) Scope

The NHLS PTS for Bacteriology aims to determine the laboratory policy on handling specimens including complete identification, antimicrobial susceptibility testing and recommendations to clinicians. Participants are encouraged to perform all of the survey challenges.

b) Selection of sample

Isolates that are included in the NHLS PTS for bacteriology are carefully characterised to ensure that typical features are present to facilitate identification. Prior to distribution, phenotypic methods are used to test the isolates. The design of the NHLS PTS for bacteriology is reviewed annually at the advisory committee meetings.

c) Homogeneity and stability

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the NHLS PTS internal quality control process.

d) Sample reception

Each survey consists of four samples; **Sample A, Sample B, Sample C and Sample D**, unless otherwise stated. Please open package and inspect for any breakages, possible deterioration during transportation or missing samples. Please keep all samples **refrigerated** until time of testing.

e) Reconstitution and inoculation of lyophilized culture

Aseptically rehydrate the freeze-dried material by adding 1ml of a suitable broth e.g. nutrient broth or BHI broth, to the vial using a sterile syringe. Gently swirl the vial to dissolve the material. Allow to stand for 10-15 minutes before sub-culturing the material. Inoculate the suspension onto media appropriate for the type of sample supplied. Keep the reconstituted vial at room temperature until you have identified the organisms fully.

f) Proficiency test item –treatment and analysis

Read the clinical details and processing instructions for each sample. Samples shall be analysed using your own standard operating procedures. All participants are required to use the test method of their choice.

g) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are refrigerated prior to processing. When ready to start processing bring samples to room temperature and keep them at room temperature at all times until final identification.

Stability: Some of the simulated specimens have a limited viability; therefore, your laboratory should process the samples as soon as they are received in the laboratory.

h) Special handling instructions and safety requirements

If the package contains broken samples, sterilize (autoclave) the container and contents immediately. Dispose broken samples as per safety protocols used in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

i) Specific environmental conditions that the tests must be performed

Please keep all processed samples at room temperature until you have final identification of the organism/s.

j) Recording and submission of PTS results

Print a response form, clinical scenarios and code booklet from www.nhls.ac.za. If an answer code is not provided in the table, please write out the answer in the comment space. If any other format is used to, report results other than that requested by NHLS PTS provider, then the result will not be evaluated. Please adhere to the format in which we request antimicrobial susceptibility results to be reported. Return the completed survey response form by the survey deadline via email to bactpts@nhls.ac.za or fax to 086 225 2460. Responses will not be evaluated if instructions are not followed.

NHLS MYCOBACTERIOLOGY CULTURE

a) Scope

The NHLS PTS for Mycobacteriology Culture aims to determine the laboratory policy on handling specimens and to obtain an objective measure of the diagnostic ability of participating laboratories and build capacity in the field of human diagnostic tuberculosis in Africa. Participants are encouraged to perform all of the survey challenges.

b) Proficiency Test Item –Treatment and analysis

Read the clinical details and processing instructions per sample. Instructions and response forms are available on the NHLS internet www.nhls.ac.za. Instructions on how to access the information was sent with first survey samples. Samples shall be analysed using your own standard operating procedures. All participants are required to use the test method of their choice unless otherwise stated for culture.

c) Survey Requirements;

The NHLS PTS for Mycobacteriology Culture endeavours to assess all aspects of specimen-management, such as turn-around time, accuracy of reports, clinical relevance of results, specimen handling, *etc.* Rapid turn-around time is an essential element of specimen-management.

If a laboratory code is not completed on the survey questionnaire or results are received after 24h00 on the closing date then these results will not be assessed, this is equivalent to omitting a patient's name on a report.

Please contact NHLS PT if you are unsure of your LABORATORY CODE

e) Factors that could influence the testing e.g. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item.

Temperature: Cultures are shipped at ambient conditions. On receipt in the laboratory, please ensure that cultures are stored and processed at room temperature at all times unless instructions are supplied to the contrary

Stability: Process the samples as soon as they are received in the laboratory.

f) Selection of samples:

All laboratories receive identical test panels. The test panel includes 4 samples whose composition of the test panels may vary with each survey.

g) Homogeneity and stability:

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the NHLS PTS internal quality control process.

h) Mycobacteriology survey contents

The survey consists of 4 samples, 4 Lowenstein Jensen (LJ) samples or a combination of LJ slopes and lyophilized samples.

The composition of the test panels may vary with each survey.

i) Special handling:

If the package contains broken PTS samples, sterilise (autoclave) the container and contents immediately. Dispose of according to normal procedures in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

j) Specific environmental conditions that the tests must be performed at.

All PTS samples should be stored at room temperature and are stable for the period of the programme.

k) Instructions on returning of proficiency test items.

Not applicable for this PTS.

l) Sample reception

Please open package and inspect for any breakages, possible deterioration during transportation or missing samples, inform PTS Co-ordinators in writing if samples were unsuitable and should you require a replacement sample.

m) Reconstitution of samples

Indicated on the response form if needed.

n) Recording and submission of PTS Results.

All responses may be submitted via fax +27 (0) 86 225 2458 or email

tbpts@nhls.ac.za

May you indicate the laboratory code, scheme and survey no. on the title of email when emailing results.

e.g. 000 Mycobacteriology Culture Results 0121

PLEASE DO NOT USE OTHER EMAIL ADDRESSES FOR SUBMISSION OF RESULTS, DO NOT REDESIGN THE RESPONSE FORM.

STATE YOUR LABORATORY CODE ON THE RESPONSE FORM.

RESPONSE FORMS MUST BE COMPLETED IN FULL.

Please note your results will not be evaluated if the above instructions are not adhered to

o) Closing date for submission of results and consequence of late submission or no returns.

Closing dates are indicated under **shipments and receipt of samples** in general information section of the document

Non-returns will be issued for all late submissions.

If the response form is incomplete or results are received after 24h00 of the closing date, then these results will not be evaluated.

p) Evaluation of responses:

The scheme uses either acceptable or unacceptable based on the qualitative results submitted by the participants. All acceptable (correct) results are thus given a score of 4 or 2 depending on test required and all unacceptable (incorrect) results are given a score of 0.

r) Reporting

Final report:

The performance of NHLS participant may be disclosed to a restricted list of individuals; viz: regional QA Managers and QA Co-ordinators as per NHLS Policy. When external parties require the PTS report, a written request shall be submitted to the scheme managers by the participant.

Re-issue of reports:

The PT providers do not accept responsibility for reports lost or misplaced by the participant. Reports will be reprinted if a request is made in writing prior to the shipment of the next survey.

Genotype Line Probe Assay (LPA) of Mycobacterium Strain

a) Scope

The NHLS PTS for LPA aims to determine the laboratory policy on handling specimens including complete testing and final results interpretation. Participants are encouraged to perform testing on all samples.

b) Survey Requirements

The NHLS PTS for LPA endeavors to assess all aspects of specimen-management, such as turn-around time, accuracy of reports, specimen handling, etc.

Rapid turn-around time is an essential element of specimen-management. Incomplete laboratory codes on response forms will result in non-assessment.

Response forms received after 12:00 midnight on the closing date will also result in non-assessment. This is equivalent to omitting patient details on a report and not meeting turn-around times (TAT).

c) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored and processed at room temperature at all times unless instructions are supplied to the contrary.

d) Sample reception

Please open package and inspect for any breakages, possible deterioration during transportation or missing samples. Inform PTS Manager/s in writing if samples are unsuitable and whether you require a replacement sample.

e) Special Handling instructions and safety requirements.

Dispose of broken samples as per safety protocols used in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

f) Specific environmental conditions that the tests must be performed at.

Samples should be stored at ambient conditions before processing, and must be examined by routine methods.

g) Instructions For Analysis of Proficiency Test Item

1. Samples shall be analyzed using your own standard operating procedures.
2. **Include controls**, record results and **attach PCR** strips on the Genotype MTBDR plus response sheet.
3. **Sample Details**: The package contains 5 Heat Inactivated MGIT Culture samples (**LPA 01 - 5**) with +-2.5ml of culture

h) Instructions on returning of proficiency test results.

Instructions and response forms are available on the NHLS internet www.nhls.ac.za. Instructions on how to access the information was sent with first survey samples.



Please send the original PCR strips for evaluation – fax or photocopies will NOT be scored or evaluated. [HAIN Genoscan results, if available, are also acceptable]

Record all sample numbers on the response form, for both MTBDRplus and CM


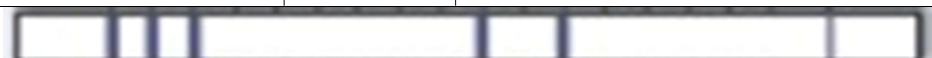
i) **Recording of results**

Please record results as in the example below:

MTBDRplus

SAMPLE NO. 1	TUB BAND	<i>rpoB</i>	<i>katG</i>	<i>inhA</i>	INTERPRETATION	PLAN
RESULTS	present	WT7 absent MUT3 present	WT absent MUT1 present	WT1,2 present	RIF: RESISTANT INH: RESISTANT	-
ATTACH LPA STRIP HERE						
SAMPLE NO. 2	TUB BAND	<i>rpoB</i>	<i>katG</i>	<i>inhA</i>	INTERPRETATION	PLAN
RESULTS	absent	-	-	-	NEGATIVE FOR MTBC	CM
ATTACH LPA STRIP HERE						

CM

SAMPLE NO. 3	CONTROLS	BANDS	INTERPRETATION
RESULTS	CC, UC, GC - present	4	<i>Mycobacterium avium</i>
ATTACH CM STRIP			
	CONTROLS	BANDS	INTERPRETATION
RESULTS	CC, UC, GC - present	10, 12	<i>Mycobacterium kansasii</i>
ATTACH CM STRIP			

Result forms must be completed in full, Laboratory Code must be stated.

j) **Submission of PTS Results.**

Please indicate the laboratory code, scheme and survey no. on the title of the email when submitting results.
e.g. 000 LPA results 0120

k) **Closing date for submission of results and consequence of late submission or no returns.**

Closing dates are indicated under **shipments and receipt of samples** in general information section of the document.

Non-returns will be issued for all late submissions.

If the response form is incomplete or results are received after 24h00 of the closing date, then these results will not be evaluated.

I) Reporting

Final Report: Hard copies are sent via post prior to the shipment of the next survey.

All performance data is treated as confidential. NHLS participants' performances may be disclosed to a restricted list of individuals, their regional QA managers and QA Coordinators as per NHLS Policy.

When sponsors require the PTS report a written request must be submitted to the PTS Manager.

Should a regulatory authority or any other 3rd party require participants PTS results, and then the affected participant shall be required to submit written consent to the PTS Manager.

Amended Report: Amended reports will be issued on investigation of a written dispute or appeal. Amended reports will not be issued if the source of the transcription error was the participant.

MYCOBACTERIOLOGY MICROSCOPY

a) Scope

The NHLS PTS for TB Microscopy aims to determine the laboratory policy on handling specimens including microscopy and quantitation of the acid fast bacilli present in the smears and to obtain an objective measure of the diagnostic ability of participating laboratories and build capacity in the field of human diagnostic tuberculosis in Africa. Participants are encouraged to perform all of the survey challenges.

b) Proficiency Test Item –Treatment and analysis

Samples shall be analyzed using your own standard operating procedures. All participants are required to use the test method of their choice.

c) Survey Requirements

The NHLS PTS for Mycobacteriology Microscopy endeavors to assess all aspects of specimen-management, such as turn-around time, accuracy of reports, clinical relevance of results, specimen handling, *etc.*

Rapid turn-around time is an essential element of specimen-management.

A laboratory must be registered with the NHLS Quality Assurance Department and be in possession of a laboratory code.

If a laboratory code is not completed on the survey questionnaire or results are received after 12am on the closing date then these results will not be assessed, this is equivalent to omitting a patient's name on a report.

Please contact NHLS PTS provider (PTSP) if you are unsure of your
LABORATORY CODE

d) Factors that could influence the testing for examples: nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item.

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored and processed at room temperature at all times unless instructions are supplied to the contrary.

e) Selection of samples:

All laboratories receive identical test panels. The test panel includes slides with different grades of positivity in order to evaluate the ability of the technicians to properly grade positive slides. The composition of the test panels may vary with each survey. Prior to distribution, the smears are quality controlled by using standard staining and microscopy methods.

The design of the NHLS PTS for Mycobacteriology/(TB) Microscopy is reviewed annually at the advisory committee meetings.

f) Homogeneity and stability:

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the NHLS PTS internal quality control process.

g) Clinical Details and Sample preparation

The package contains 2 slide mailers labeled TB slides unstained. Each test panel includes ten slides which have been heat fixed. **All the slides are unstained**

h) Special Handling instructions and safety requirements.

If the package contains any broken slides or unsuitable slides, please dispose of them according to normal procedures in your laboratory and if available participants can request repeat slides. Please follow universal safety precautions at all times.

i) Specific environmental conditions that the tests must be performed at.

Please keep all processed smears at room temperature until you have received either the final evaluation of the survey

j) Instructions on returning of proficiency test items.

Laboratory results forms and smears (if necessary) are returned for evaluation to the Academic Affairs Research and Quality Assurance (AARQA) at the NHLS. It is to be noted that the returning of slides is not mandatory for the laboratories.

Returned slides are reviewed only should there be a major error (High False negative/ High False positive) on evaluation.

k) Sample reception

Please open package and inspect for any breakages, possible deterioration during transportation or missing samples, inform PTS Managers in writing if samples were unsuitable and should you require a replacement sample.

Please keep all processed smears at room temperature until you have received either the interim results or final evaluation of the survey.

l) Instructions for completing the survey

Slides A-J:

Slides A-J have been made using concentrated sputum and fixed. Stain the slides using your laboratories routine procedure. Record the staining procedure used. Report on the presence of acid-fast bacilli and if present, supply a quantitative result

For all slides:

Use the slide quantification scheme recommended by the International Union against Tuberculosis and Lung Disease (Refer to table 2)
Laboratories using Auramine O are requested to use an appropriate conversion factor to convert their results into a ZN format:

For Auramine slides read using 400x (40x) objective use the conversion table below:

Table 1. Conversion table

NO. OF AFB	FIELDS	REPORT	ENTER RESULTS AS:
0	In entire smear	No AFB seen	0
1 – 9	In entire smear	Scanty AFB	SC (1 - 9)
10 – 399	Per 100 fields	1+ AFB/ P1	1
4 – 40	Per field	2+ AFB/ P2	2
> 40	Per field	3+ AFB/ P3	3

m) Recording and submission of PTS Results.

Instructions and response forms are available on the NHLS internet www.nhls.ac.za. Instructions on how to access the information was sent with first survey samples.

All responses may be submitted via fax +27 (0) 86 225 2458 or email tbpts@nhls.ac.za

May you please indicate the laboratory code, scheme and survey no. on the title of the email when emailing results.

e.g. 000 Mycobacteriology Microscopy 0121 results

PLEASE DO NOT USE OTHER EMAIL ADDRESSES FOR SUBMISSION OF RESULTS,

DO NOT REDESIGN THE RESPONSE FORMS.

STATE YOUR LABORATORY CODE ON THE RESPONSE FORM.

RESPONSE FORMS MUST BE COMPLETED IN FULL.

Please note your results will not be evaluated if the above is not complied to.

n) Closing date for submission of results and consequence of late submission or no returns.

Closing dates are indicated under **shipments and receipt of samples** in general information section of the document.

Non-returns will be issued for all late submissions.

If the response form is incomplete or results are received after 24h00 of the closing date, then these results will not be evaluated.

o) Evaluation of submitted results

Participants are allowed to stain the slides with a method of choice (ZN or Auramine O).

The scheme uses the International Union Against TB and Lung Disease IUATLD grading system for grading slides as in Table 1 below. A target value is assigned for all smears.

In the event of a lack of referee laboratory and participant consensus for a challenge, the sample will not be assessed.

Errors are classified using Table 3. Major discrepant results returned from the participating laboratory to the PT providers are confirmed by the PTS staff. Each result is allocated a score using Table 3. The scores are totalled.

A total score of 80% or more is deemed to be an acceptable performance.

Table 2: IUATLD grading system for TB microscopy slides

Carbol-fuchsin stain under oil	Report
- No AFB -	No acid-fast bacilli observed/ negative
1 to 9 AFB/100 fields	record exact number (scanty)
10 to 99 AFB/100 fields	1+
1 to 10 AFB/field	2+
>10 AFB/field	3+

Table 3: Classification of errors

Result of participating laboratory	Result as deemed by QA				
	Negative	Exact /Scanty	1+	2+	3+
Negative	Correct	LFN	HFN	HFN	HFN
Exact no/Scanty	LFP	Correct	Correct	QE	QE
1+	HFP	Correct	Correct	Correct	QE
2+	HFP	QE	Correct	Correct	Correct
3+	HFP	QE	QE	Correct	Correct

Interpretation

QE = Quantification Error	Minor error
LFN = Low False Negative	Minor error
LFP = Low False Positive	Minor error
HFN = High False Negative	Major error
HFP = High False Positive	Major error

Table 4: Scoring system

Classification	Interpretation	Score
Correct response	No error	10 points
QE	Minor error	5 points
LFN, LFP	Minor error	5 points
HFN, HFP	Major error	0 points

p) Reporting

Final Report:

Hard copies are sent via post prior to the shipment of the next survey.

All performance data is treated as confidential.

The performance of NHLS participant may be disclosed to a restricted list of individuals; viz: regional QA Managers and QA coordinators as per NHLS Policy.

When external parties require the PTS report, a written request shall be submitted to the scheme managers by the participant.

Amended Report:

Amended reports might be issued where it is found the participant was unfairly assessed following a written dispute or appeal. Amended reports will not be issued if the source of the transcription errors was the participant.

Re-issue of Reports:

The PT providers do not accept responsibility for reports lost or misplaced by the participant. Reports will be reprinted if a request is made in writing prior to the shipment of the next survey.

MYCOLOGY YEAST

a. Introduction

This PT Scheme is coordinated by the Microbiology PT Scheme Managers at NHLS Academic Affairs, Research and Quality Assurance (AARQA). Samples for the scheme are prepared with assistance from National Institute for Communicable Diseases, a Division of the National Health Laboratory Service. Please refer to the most recent correspondence from the Microbiology PT Scheme Managers for their contact details.

b. Scope

The NHLS PTS for Mycology (Yeasts) aims to teach participants to identify pathogenic yeasts. Participants are encouraged to perform all of the survey challenges, even if their laboratories do not usually perform them routinely.

c. Selection of samples

Isolates which are included in the NHLS PTS for Mycology (Yeasts) are carefully characterized to ensure that typical features are present to facilitate identification. Prior to distribution, the organisms are tested using standard phenotypic methods and a part of the fungal genome is sequenced to confirm the final identity.

d. Proficiency Test Item –Treatment and analysis

The package contains sample **E** (slide) and **F** (culture suspended in water). Laboratories that perform antifungal susceptibility testing receive sample **H** (culture suspended in water). If the package contains broken samples, sterilize (autoclave) the container immediately. Dispose of according to normal procedures. Guard against the production of aerosols.

Inoculation of culture suspended in sterile water

After gently swirling, inoculate approximately half of the suspension directly onto media appropriate for the type of sample supplied. Keep the vial at room temperature until you have identified the isolate completely.

Instructions for samples

Read the clinical scenarios provided with each survey samples. Examine the provided slide/ simulated specimen (sample **E**) for evidence of yeasts. Identify the culture suspended in water (sample **F**) using standard operating procedures. *If your laboratory routinely performs antifungal susceptibility testing*, identify the culture suspended in water (**sample H**) and perform testing for the listed antifungal agents using standard operating procedures.

Please complete the survey questionnaire using the provided answer codes or by marking the appropriate tick box. If an answer code is not provided in the table, please write the full answer in the questionnaire. Return the survey questionnaire before the return deadline: email mycopts@nhls.ac.za or fax +27 (0) 86 225 2458

e. Survey Requirements;

The NHLS PTS for Mycology (Yeasts) endeavors to assess aspects of specimen management, such as turn-around time, accuracy of reports, clinical relevance of results, specimen handling, *etc.* Rapid turn-around time is an essential element of specimen management, so any survey questionnaires which are received after the return deadline will be penalized and those received after the preliminary survey answers are distributed will not be assessed. If a laboratory name and number is not completed on the survey questionnaire, it is considered equivalent to leaving a patient's name off a laboratory report. These results will not be assessed, even if a covering fax sheet is sent with them.

Please contact NHLS PT if you are unsure of your LABORATORY CODE

- f. Factors that could influence the testing e.g. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item.**

Temperature: Samples are shipped at ambient conditions. On receipt in the laboratory, please ensure that samples are stored and processed at room temperature at all times unless instructions are supplied to the contrary

- g. Homogeneity and stability:**

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the NHLS PTS internal quality control process.

h. Sample Dispatch and actions to be taken if sample was not received.

Should you not receive your shipment or the condition of the shipment is unsuitable, please contact the scheme coordinators within **5 working days** of receipt.

i. Specific environmental conditions that the tests must be performed at.

All PTS samples should be stored at room temperature and are stable for the period of the programme.

j. Instructions on returning of proficiency test items.

Not applicable for this PTS

k. Sample reception

Please open package and inspect for any breakages, possible deterioration during transportation or missing samples, inform PTS Co-ordinators in writing if samples were unsuitable and should you require a replacement sample

l. Recording and submission of PTS Results.

All responses may be submitted via fax +27 (0) 86 225 2458 or email mycopts@nhls.ac.za

May you indicate the laboratory code, scheme and survey no. on the title of email when emailing results.
e.g. 000 Mycology yeast 0121 results.

PLEASE DO NOT USE OTHER EMAIL ADDRESSES FOR SUBMISSION OF RESULTS,

DO NOT REDESIGN THE RESPONSE FORM.

STATE YOUR LABORATORY CODE ON THE RESPONSE FORM.

RESPONSE FORMS MUST BE COMPLETED IN FULL.

Please note your results will not be evaluated if the above instructions are not adhered to.

m. Corrective Action (CA)

The onus is on the participant to review evaluation reports, identify corrective actions, and to implement corrective and preventative measures, where applicable. If any assistance is required from the PT providers, the regional manager may contact the PTS Manager.

n. Response forms

Read the clinical details and processing instructions per sample. Instructions and response forms are available on the NHLS internet www.nhls.ac.za. Instructions on how to access the information was sent with first survey samples.

o. Survey Grading

The survey questionnaires are graded by one person using a model answer framework and moderated by a second person. The model answer framework is reviewed by the NHLS PTS Microbiology Advisory Committee.

NHLS Parasitology Blood Proficiency Testing Scheme Instructions

a) Scope

One of the main objectives of the Blood Parasites PT Scheme is to teach and participants are encouraged to perform all of the survey challenges, even if their laboratories do not perform them routinely. Participants are encouraged to keep survey specimens. Survey specimens can be used in the future as teaching aids, used as reference material or as controls for tests by participants.

The NHLS PTS for Parasitology Blood aims to assess other aspects, such as turn-around time, accurate result reports, clinical relevance of results, specimen handling etc. Rapid turn-around time is an essential element of PTS. PTS survey samples should be treated in the same way as routine patient specimens.

The NHLS PT Scheme procedure is that all late returns, received after the result deadline, or those submitted with incorrect/incomplete laboratory details on the PTS response form will not be assessed, even if a covering fax sheet is sent with it.

a) Survey requirements

Selection of sample

This survey contains 5 challenges. Identify any parasite(s) present, even if not pathogenic and write the answer codes. Only the answer codes will be assessed, not parasite names (except for code 33). More than one answer code can be reported for mixed infections. Do not report artefacts. The response form below will be sent with each shipment of samples with the clinical scenarios relevant to that survey.

c) Homogeneity and stability

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the Parasitology Blood Internal Quality Control Process.

c) Actions to be taken if sample was not received

Should you not receive your shipment or the condition of the shipment is unsuitable, please contact the scheme Managers within the scheduled shipment week. Return of PTS items to the PT provider is not applicable for this PT scheme.

!!!!Important!!!!

PTS sample donation

We are always in need of blood parasite-positive specimens to use in this PT scheme. Ideally fresh EDTA blood (<8 hours old) is needed for preparation of good quality blood films; it is important for laboratories close to NHLS Sandringham to contact us, by telephone, immediately when they get a positive specimen so that we can arrange for collection.

b) Proficiency test item –treatment and analysis

Read the clinical details and processing instructions for each sample. Samples shall be analyzed using your own standard operating procedures. All participants are required to use the test method of their choice.

c) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored and processed at room temperature at all times.

d) Special handling instructions and safety requirements

If the package contains broken samples, sterilize (autoclave) the container and contents immediately. Dispose broken samples as per safety protocols used in your laboratory.

e) Specific environmental conditions that the tests must be performed

N/A

f) Recording and submission of PTS results

Print a response form, clinical scenarios and code booklet from www.nhls.ac.za. All responses may be submitted via fax 086 225 2460 or email parapts@nhls.ac.za. Complete the response form using the appropriate answer codes provided.

NHLS Haematology Full Blood Count Proficiency Testing Scheme

1. Scope

The FBC is a group of tests that evaluate the cells that are circulate in blood including red blood cells, white cells and platelets. The FBC can evaluate the overall health and detect variety of diseases and conditions, such as infections, anaemia and leukemia. Blood cells are produced in the bone marrow, and are released into the bloodstream as needed.

The samples are shipped twelve times a year.

2. Sample matrix

- The scheme ships one stabilised whole blood sample every month, in which participants are expected to process the sample , and report FBC parameters: (WCC, RBC, Hb, Hct, MCV, MCH, MCHC, RDW, PLT and MPV)

3. Participation

Participation is open to all Haematology laboratories who offer the tests covered by the NHLS PTS.

For all correspondence the unique identifier must all always be used.

4. Important information.

- If your laboratory has more than one backup instrument, the sample is sufficient to process through up to 3 instruments.
- Use the laboratory QA number for each result sheet submitted.
- Please submit a completed result sheet with instrument serial number and model of the instrument indicated.

5. Sample preparation

Samples are sent to participants according to the survey schedule. The samples have been tested by an FDA approved method for the presence of HIV antigen, hepatitis B surface antigen as well as for hepatitis C antigen and have been found to be negative. As with all preparations of human origin, suitable precautions should be taken in the handling and disposal. After receipt of the samples should be stored at 2-8 °C until analysis.

6. Factors that can influence testing.

- Inadequate mixing of the PT sample.
- Technical errors associated with the assay.
- Improper storage.
- Not allowing the samples to reach the room temperature equilibrium.

7. Homogeneity and stability

All testing material have been tested and found to be homogeneous and stable. For the material that is procured the manufacturer issues the certificate of analysis for each survey.

8. Handling instructions and safety requirements.

- Upon receipt please refrigerate samples at (2-8 °C).
- To ensure consistent and reproducible results, the control material must be thoroughly mixed and handled in the same manner as patient sample.

9. Instruction for use.

- No reconstitution required – the samples contain 2.ml of stabilised whole blood.
- Allow to stand at RT for 15 minutes before testing.
- Mix well before processing.
- To mix, hold vial horizontally between palms of the hands. Do not pre-mix on a mechanical mixer.
- Roll the vial back and forth for 20-30 seconds; occasionally invert the vial. Mix vigorously but do not shake.
- Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may need extra mixing.
- Gently invert the vial 8-10 times immediately before running each sample.
- Return vials to refrigerator within 30 minutes of use.

10. Stability and storage.

Opened tubes/vial are stable for 7 days stored at 2-8°C.

11. Indication of deterioration.

After mixing product should be similar in appearance to fresh whole blood. In unmixed tubes the supernatant may appear cloudy and reddish, this is normal and does not indicate deterioration. Other discolouration, very dark supernatant or haemolysis. Do not use the product if deterioration is suspected.

NHLS Manual Erythrocyte Sedimentation Rate (ESR) Proficiency Testing Scheme

1. Scope

Erythrocyte sedimentation rate is a test that indirectly measures the degree of inflammation present in the body. The red cells settle at a faster rate in the presence of an increased level of protein.

ESR PT material is an assayed level control for evaluating the accuracy and precision of manual Erythrocyte Sedimentation Rate (ESR) methods.

This ESR PT material is intended for use as supplied. Adulteration by dilution or addition of any material to the ESR PT material vial invalidates any diagnostic use of the ESR PT material.

The samples are shipped four times a year.

2. Sample matrix

- The scheme ships one stabilised whole blood sample, in which participants are expected to process the sample, and report the ESR in mm/hr.

3. Participation

Participation is open to all Haematology laboratories who offer the tests covered by the NHLS PTS.

For all correspondence the unique identifier must all always be used.

4. Important information.

- Use the laboratory QA number for each result sheet submitted.
- Please submit a completed result sheet with instrument serial number and model of the instrument indicated.

5. Sample preparation

Samples are sent to participants according to the survey schedule. The samples have been tested by an FDA approved method for the presence of HIV antigen, hepatitis B surface antigen as well as for hepatitis C antigen and have been found to be negative. As with all preparations of human origin, suitable precautions should be taken in the handling and disposal. After receipt of the samples should be stored at 2-8 °C until analysis.

6. Factors that can influence testing.

- Inadequate mixing of the PT sample.
- Technical errors associated with the assay.
- Improper storage.
- Not allowing the samples to reach the room temperature equilibrium.
- Dilution of PT material.

7. Homogeneity and stability

All testing material have been tested and found to be homogeneous and stable as part of the internal quality control processes.

8. Handling instructions and safety requirements.

- Upon receipt please refrigerate samples at (2-8 °C).
- To ensure consistent and reproducible results, the control material must be thoroughly mixed and handled in the same manner as patient sample.

9. Instruction for use.

Manual procedure:

- **Do not dilute ESR PT material-use directly from the vial.**
- **If you have to transfer the sample to another tube, please use a dry tube-no anticoagulant!**
- Remove vial from refrigerator and allow it to equilibrate to room temperature (18-30 degrees) for 20-30 minutes.
- Mix vial through inversion and by gently rolling upright between palms until red cells are completely suspended. Continue to mix for 90 seconds. The samples may also be rotated on a rotator prior to use.
- Follow your laboratory standard operating procedure for processing the manual ESR.

10. Stability and storage.

ESR sample (open vial) is stable for 95 days when stored at 2-30°C.

11. Indication of deterioration.

After mixing product should be similar in appearance to fresh whole blood. In unmixed tubes the supernatant may appear cloudy and reddish, this is normal and does not indicate deterioration. Other discolouration, very dark supernatant or haemolysis. Do not use the product if deterioration is suspected.

NHLS Automated Coagulation (PT/INR and APTT) Proficiency Testing Scheme

1. Scope

1.1 PT and APTT

The central event in the coagulation pathway is the production of the thrombin, which acts upon the fibrinogen to produce fibrin and therefore fibrin clots. This clot is further strengthened by crosslinking action of factor XIII, which itself is activated by thrombin. The two commonly used coagulation tests, activated partial thromboplastin time (APTT) which measures the integrity of the intrinsic system and the common components. The Prothrombin time (PT) along with its derived measure international normalized ratio (INR) are assays collectively evaluate the extrinsic and common pathway of coagulation. The INR is a calculation based results of a PT and is utilised to monitor individuals being treated with blood thinning medication warfarin. The PT and INR are used to monitor the effectiveness of the anticoagulant warfarin.

2. Sample matrix

- The scheme ships two lyophilized material, in which participants are expected to process the sample and report PT in seconds, INR, APTT in seconds and interpretation.

3. Participation

Participation is open to all Haematology laboratories who offer the tests covered by the NHLS PTS.

For all correspondence the unique identifier must all always be used.

4. Important information.

- The clinical information will be included on the insert issued with each survey.
- If your laboratory has more than one backup instrument, the samples are sufficient to process through up to 3 instruments.
- All samples are lyophilised plasma and require reconstitution.
- Use the laboratory QA number for each result sheet submitted.
- Please submit a completed result sheet with instrument serial number and model of the instrument indicated.

5. Sample preparation

Samples are sent to participants according to the survey schedule. The samples have been tested by an FDA approved method for the presence of HIV antigen, hepatitis B surface antigen as well as for hepatitis C antigen and have been found to be negative. As with all preparations of human origin, suitable precautions should be taken in the handling and disposal. After receipt of the samples should be stored at 2-8 °C until analysis.

6. Factors that can influence testing.

- Inadequate mixing of the PT sample.
- Technical errors associated with the assay.
- Improper storage.
- Not allowing the samples to reach the room temperature equilibrium.
- Wrong diluent.
- Incorrect volume.

7. Homogeneity and stability

All testing material have been tested and found to be homogeneous and stable.
For the material that is procured the manufacturer issues the certificate of analysis for each survey.

8. Handling instructions and safety requirements.

- Upon receipt please refrigerate samples at (2-8 °C).
- To ensure consistent and reproducible results, the control material must be thoroughly mixed and handled in the same manner as patient sample.

9. Instruction for use.

- Carefully open the vial of material.
- Add 1 ml of redistilled water into each vial,
- Allow to stand for 10 minutes.
- Gently swirl the control vials.
- Allow to stand again for 15 minutes.
- The samples are ready to be processed.
- Use the material within 8 hours of reconstitution.

10. Stability and storage.

- Reconstituted and stored at 2-8°C stable for 8 hours.
- Reconstituted and frozen at -20°C stable for 48 hours.
- Opened vial stored at 2-8°C stable for 7 days.
- Opened vial stored at -20°C stable for 28 days.
- Unopened vial stored at 2-8°C stable until expiry date.

All PT material to be discarded as per the waste management standard operation procedure.

GENERAL NOTES. (FBC , ESR and PT/APTT)

a) Completion of result sheet

- The survey number be written on the form.
- The QA number.
- Instrument name and serial number.
- Results obtained **please do not submit the instrument raw data.**
- Name of personnel who processed the PT samples.
- Only the current financial year 20XX/20XX result sheets will be acceptable.

Beckman coulter users.

Please report the uncorrected WCC.

Siemens users.

Please report the uncorrected WCC.

Sysmex users

Sysmex XN: Please ensure TNC-N (Total Nuclear Cell Count (WBC#+NRBC)) value is reported.

Mindray users

Analyze the QA material in the QC mode of the instrument in the same manner as you run daily QC, or as instructed in the Quality Control section of the Operator's Manual for your instrument.

b) Laboratory performance report.

A confidential performance report is issued on monthly basis to participating laboratories.

The information provided is as follows.

The overall mean, standard deviation (SD) and coefficient of variation (CV) for each test parameter for all method.

The results outside the 2SDI (z-score) are flagged.

c)Performance evaluation**1. Consensus of the mean (Chauvenet's Criterion)**

Participant results are compared to consensus mean that uses Chauvenet's Criterion.

As an individual performance indicator the Z-score is used. The Z-score indicates the distance between the participants' result and the consensus value expressed as a ratio of the standard deviation.

The Z-score can be either positive or negative depending whether the participants' results is higher or lower than the consensus value.

The z-score is calculated as follows: [(laboratory result) - (mean result of all laboratories)] / (standard deviation of all results)

d)Acceptance criteria

Each participants should carefully evaluate the Z-scores given in the report. In accordance with ISO guideline 17043 and ISO guideline 13528 the following acceptance criteria are used:

- Z score $\leq \pm 2$ the results are acceptable.
- Z score $> \pm 2$ the results are questionable (warning signal).
- Z score $> \pm 3$ the results are unacceptable (action signal).
- A single action signal or two warning signals in consecutive surveys shall be taken as evidence that an anomaly has occurred that requires investigation by the laboratory.

The formula is as follows:

$$Z = \frac{t - \bar{x}}{SD}$$

Where $t = \text{lab result}$

$\bar{x} = \text{overall mean}$

$SD = \text{standard deviation}$

In other words:

$$z \text{ score} = \frac{\text{your result} - \text{method mean}}{\text{standard deviation}}$$

For example:

Your result = 125

Method mean = 130

SD = 5


Z score = -1

Note:

Sample sizes less than 10 may result in the distortion of the mean and as a result must be treated with reserve.

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Appendix B: Example ESR report.



**NATIONAL HEALTH
LABORATORY SERVICES**
HEALTH SERVICES

Proficiency Testing Schemes
Academic Affairs Research and
Quality Assurance Department
01 Madderfontein Road
Sandringham, South Africa
2131

National Health Laboratory Services Proficiency Testing Program

HAEMATOLOGY (ESR)

Final Report

Tel : +27 (0)11 386 6148
Fax : +27 (0)11 386 6206

CONTACT: LABORATORY MANAGER

LABORATORY: NHLS

REGION: GAU003

Trial Number: 420

Sample: ES 04-20

ESR METHOD: Manual

LAB CODE: 007

DATE OF REPORT: 22 February 2021

SAMPLE: ES 04-20

ESR (mm/h)

RESULT:

OUT OF LIMITS

z-score

No

MEAN

SD

CV (%)

62

0.78

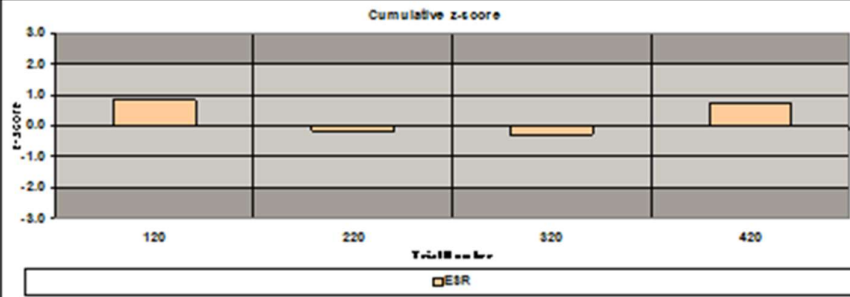
208

38

17.71

48.3

Statistics above calculated from consensus of the mean



Cumulative z-score


z-score

Trial Number

ESR

Authorised by: Bongile Mofokeng - PT Scheme Manager

* End Of Report *



PT50005

Please Note: This is a confidential report that summarises the performance of your laboratory.

Print Date: 25/03/2021 © NHLS. All rights reserved. Enquiries +27 (0)11 386 6148

Page 1 of 1

Note: Coagulation is the new scheme therefore there's no report.

NHLS General Chemical Pathology Proficiency Testing Scheme

Introduction

Welcome to the 2021/22 NHLS Chemical Pathology Proficiency Testing Schemes. We hope that your participation will be beneficial to your laboratory. Please read the information provided. Important dates for shipment and return of results are indicated.

Instructions for recording and reporting of results

Participants will receive a master copy result submission sheet, of which copies must be made in order to submit results.

The participant's unique participant code, survey number and instrument details has to be written in the space provided.

*Please note: If the above is not complied with, the provider takes no responsibility for incorrect information reflected on the reports.

Results must be written as per blocks provided on the result sheet. See below for examples.

Example	Correct				Incorrect			
Glucose - 18.6 mmol/l	1	8	,	6	18,6		,	
Example	Correct				Incorrect			
Chloride – 114 mmol/l	1	1	4				114	

Results to be reported in the units on the form, if a participating laboratory use different units please convert and report in the units on the result sheet

General Chemistry - Web entry

Web address <http://pts.nhls.ac.za/>

General Chemistry results online via the web entry, no results sheets to be emailed to the result mailbox.

For access and user manuals please contact the Chemical Pathology PT scheme manager.

Contact IT helpdesk to reset passwords at 011 386 6125 or helpdesk6@nhls.ac.za

When requesting a password reset please indicate clearly in the subject line the following "Chemistry Proficiency Testing Scheme password reset "

Clearly indicate the laboratory QA number.

Method of evaluation

The Chemical Pathology PTS has two methods of evaluation.

1. Consensus of the mean (Chauvenet's Criterion)

Participant results are compared to consensus mean that uses Chauvenet's Criterion to eliminate outliers. The following schemes are evaluated according to this method

Chemistry

CRP

2. Defined target

The defined target schemes use traceable reference material and the allowable limits are calculated using Rhodes acceptable limits (www.datainvariationsicos.com acceptable limit criteria). The following PT schemes are evaluated according to this method.

Therapeutic Drugs

Endocrinology

Blood gas

Cardiac

3. Direct Qualitative analysis

The Qualitative BhCG results are compared to the expected results and reported as Acceptable or Not-acceptable.

Laboratory performance report Chemical Pathology

The results which have been sent by the participating laboratories are analysed and documented in a report.

The report includes the following:

- Results of survey number, trial number and sample number.
- A summary table of statistics that includes: reported value (laboratory submitted result), aggregate group mean value (method mean), SD, %CV and SDI (z-score).
- A **W** indicates a result more than 3SD (z-score)
- A ***** indicates a result of more than 2SD (z score)/results outside of the acceptable limit.

Reports are sent out before the next survey is due (+/- 4 weeks post submission)

Acceptable criteria for Chemical Pathology

The z-score indicates the laboratories performance in relation to the group mean. The z-score must be applied in the same manner as the QC rules in your laboratory. See acceptable z-score criteria below:

- Z-score < 2 – acceptable result
- Z-score >2 but <3 – questionable result (monitor results)
- Z-score >3 – unacceptable result (needs immediate action)

Defined target interpretation- the result must be within the acceptable limits defined on the report.

Calculations used for Chemical Pathology Schemes

Z-score

The z-score shows how well your result compares with the peer group mean. It is expressed in units as a ratio of the difference between your lab mean and the pool mean to the standard deviation of the pool mean.

$$\text{Z-score} = \frac{\text{Your Lab Result} - \text{Group Mean}}{\text{SD of Group Mean}}$$

Percentage Bias

The percentage Bias indicates your result in relation to the target result express as a percentage.

$$\% \text{bias} = (\text{X} - \text{target value}) / \text{Target value} * 100$$

NHLS Qualitative BhCG Proficiency Testing Scheme

1.Scope

A human chorionic gonadotropin (hCG) urine test is a pregnancy test. A pregnant woman's placenta produces hCG, also called the pregnancy hormone.

2. Material supplied.

The scheme ships two vials of liquid urine, in which participants are expected to process the sample and report the BhCG results.

3. Analysis

The control is to be used in accordance with the directions accompanying the assay procedure being used. Samples to be treated in the same manner as patient specimen.

For in vitro diagnostic use only

CAUTION: Human source material, from which this product has been derived, has been tested at donor level for Human Immunodeficiency Virus (HIV1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg) , and Hepatitis C Virus (HCV) antibody and found to be non-reactive. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases. Dispose of any discarded material in accordance with your laboratory waste regulations.

Samples are ready for use; no reconstitution is required.

4. Limitations of procedure.

- Inadequate mixing of the PT sample.
- Technical errors associated with the assay.
- Improper storage and handling.
- Not allowing the samples to reach the room temperature equilibrium.

For more information, refer to the "Limitations of Procedure" section of the direction insert of the assay procedure being used. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

5. Homogeneity and stability

All testing material have been tested and found to be homogeneous and stable as part of the internal quality control processes.

6. Storage conditions.

The samples are transported at ambient temperature. Once received store at 2-8°C.

7. Completing the result sheet

- After analysis, complete a result sheet by filling in the Laboratory name
- QA lab number,
- Date sample analysed.
- Kit used for testing.
- Results obtained please write the results in block provided.
- The name of the person who processed the PT samples.

NHLS Blood Gas Proficiency Testing Scheme

MATERIALS SUPPLIED

Twelve ampoules of aqueous control material labelled 1A- 6B. (Store at 2 - 25°C)

ANALYSIS

Two ampoules are analysed for each cycle e.g. 1A and 1B.

N.B. Allow a minimum of four hours for the sample to reach room temperature before analysing.

Before sampling, hold the ampoule between the thumb and forefinger and shake for 10 seconds to completely mix the contents, and then gently tap so that any fluid trapped in the top of the ampoule is forced down.

To open, place the ampoule in a piece of paper towel between thumb and forefinger to prevent injury from broken glass, snap open and immediately introduce into the instrument.

The material must be analysed in the same way as patient samples and run in accordance with protocol for the instrument in use.

1. Direct aspiration: Aspirate the contents directly from the opened ampoule as per instrument protocol.
2. Syringe transfer:
 - a) To prime the syringe fill with a small volume (0.2 –0.3ml) of control.
 - b) Remove the syringe from the ampoule, carefully debubble and discard most of the solution leaving the syringe “dead space” filled with control. Do not return any discarded material to the ampoule.
 - c) Aspirate the desired volume with the syringe.
 - d) Expel one or two drops through the needle.
 - e) Remove the needle and immediately inject the sample into the instrument.

STORAGE CONDITIONS

Material - The controls should be stored between 2 to 25°C and are stable for the period of the survey.

The samples are shipped under ambient conditions.

PROCEDURE

The control is to be used in accordance with the directions accompanying the assay procedure being used. While following these directions, the control is to be treated in the same manner as a patient specimen.

LIMITATIONS OF PROCEDURES

The results obtained using the control is dependent upon several factors. Erroneous results can occur from improper storage, reconstitution inaccuracies, inadequate mixing, and technical errors associated with the assay procedure. For more information, refer to the "Limitations of Procedure" section of the direction insert of the assay procedure being used. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

DISPOSAL

Dispose of used vials in a glass disposal container in accordance with your laboratory waste regulations.

COMPLETING THE RESULT SHEET

- After analyzing the samples complete a result sheet by filling in the Laboratory name, QA lab number, date, instrument used and the name of the person who did the assays as well as the results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will result in a corrective action/no return.
- Please do not enter two numbers in a block. Ascertain that your laboratory is reporting the results in the units required.

NHLS Cardiac Markers Proficiency Testing Scheme

MATERIALS SUPPLIED

Six vials of lyophilised serum labelled 1 to 6 (Store at 2-8°C)

ANALYSIS

1. The control is to be used in accordance with the directions accompanying the assay procedure being used.

For in vitro diagnostic use only

CAUTION: Human source material from which this product has been derived has been tested at donor level for HIV-1, HIV-2, HBsAg and HCV antibodies and found to be NON REACTIVE. However, it is recommended that this product be handled with the same precautions used for patient specimens. Dispose of any discarded material in accordance with your laboratory waste regulations.

RECONSTITUTION

Carefully reconstitute each vial of lyophilised serum with exactly 1ml of redistilled water at 15 to 25°C. Close bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

STORAGE CONDITIONS

Unreconstituted material - the samples should be stored between 2 - 8°C. Protect from light.

Reconstituted material – the samples are stable for 5 days at 2 - 8°C and 4 weeks at -20°C if kept capped in original container and free from contamination.

Troponin I is stable for 2 weeks at -20°C if kept capped in original container and free from contamination.

LIMITATIONS OF PROCEDURES

The results obtained are dependent upon several factors. Erroneous results can occur from improper storage, reconstitution inaccuracies, inadequate mixing, and technical errors associated with the assay procedure. For more information, refer to the "Limitations of Procedure" section of the direction insert of the assay procedure being used. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department. Testing has been conducted to assure that this product is sufficiently homogeneous. This program does not assess CK MB Activity

Completing the result sheet

- After analyzing the samples complete a result sheet each month by filling in the Laboratory name, QA lab number, date, instrument used and the name of the person who did the assays as well as the results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will result in a corrective action/no return.
- **Please do not enter two numbers in a block, the correct number of blocks and decimal places are provided for each assay's result.**

NHLS General Chemistry Proficiency Testing Scheme

MATERIALS SUPPLIED

Twelve vials of lyophilised serum labelled 1-12 (Store at 2-8°C)

ANALYSIS

1. The control is to be used in accordance with the directions accompanying the assay procedure being used. .

2. Each sample must be analyzed at the appropriate time, preferably some time before the final date for receipt of results. **It serves no useful purpose to analyse all twelve samples simultaneously or to perform multiple analyses of each parameter to derive a mean result. Results will only be analysed in the month that it is due, no results will be kept by QA when send in the incorrect month.**

3. Please ascertain that your laboratory is classified under the correct method for enzyme assays. If any methods change during the year indicate the changes in the spaces provided on the result sheet.

For in vitro diagnostic use only

CAUTION: Human source material was used in the manufacture of this product. Each donor unit used was tested for and found to be non-reactive for HBsAg, HIV-1, HIV-2 and HCV. Because no test method can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient specimens. Dispose of any discarded material in accordance with your laboratory waste regulations.

RECONSTITUTION

1. Add exactly 5ml of distilled water at 15 - 25°C to the vial.
2. Replace the stopper in the vial and allow standing for 30 minutes out of direct sunlight.
3. Swirl the contents until homogeneous, then remove sample for testing. Avoid formation of foam. Do not shake.
4. Keep material in the refrigerator up to the time of analysis. Prior to reuse, mix sample thoroughly.

STORAGE CONDITIONS

The samples are transported at ambient temperature.

Unopened material - The samples should be stored between 2 - 8°C and are stable for the period of the programme.

Reconstituted material – The samples are stable for 8 hours at 15 - 25°C or 7 days at 2 - 8°C and 28 days when frozen once at -20°C. Do not return any residual product to the original vial.

It is recommended that for Alk Phos the reconstituted serum is allowed to stand for 1 hour at 15 - 25°C before measurement. Total and Direct Bilirubin is stable for 4 days at 2 - 8°C when stored in the dark. Do not store at 15 - 25°C. Do not freeze; analysis should be done on the day of reconstitution.

LIMITATIONS OF PROCEDURES

Glucose, bilirubin and alkaline phosphatase should be analysed on the day of reconstitution.

The results obtained are dependent upon several factors. Erroneous results can occur from improper storage, reconstitution inaccuracies, inadequate mixing, and technical errors associated with the assay procedure. For more information, refer to the "Limitations of Procedure" section of the direction insert of the assay procedure being used. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

Testing has been conducted to assure that this product is sufficiently homogeneous.

COMPLETING THE RESULT SHEET

- After analysing the samples complete a result sheet each month by filling in the Laboratory name, QA lab number, date, instrument used and the name of the person who did the assays as well as the results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will result in a corrective action/no return.
- **Please do not enter two numbers in a block, the correct number of blocks and decimal places are provided for each assay's result.**
- Please complete the method questionnaire form timeously and submit to QA via email, when changing instruments. Results cannot be entered if no method questionnaire is submitted.

RESULT SUBMISSION

All General Chemistry results to be captured online on the General Chemistry web based system.

REPLACEMENT SAMPLES

Please complete the appropriate form when requesting a replacement sample

NHLS C-Reactive Protein Proficiency Testing Scheme

1. Scope

C-reactive protein (CRP) is a blood test marker for inflammation in the body. It is produced in the liver and its level is measured by testing the blood. CRP is classified as an acute phase reactant, which means that its levels will rise in response to inflammation.

3. Material supplied

The scheme ships four vials of liquid serum labelled survey 1 to survey 4 ready for analysis, in which participants are expected to process the sample and report the CRP results.

4. Analysis

The control is to be used in accordance with the directions accompanying the assay procedure being used. While following these directions, the sample is to be treated in the same manner as a patient specimen.

For in vitro diagnostic use only

CAUTION: Human serum was used in the manufacture of this product. Each donor unit used was tested with licensed reagents and found to be non-reactive for HbsAg, HIV1/2 Antibody and HCV Antibody.

Because no test method can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient specimens. Dispose of any discarded material in accordance with your laboratory waste regulations.

Samples are ready for use; no reconstitution is required.

4. Limitations of procedure.

- The results obtained are dependent upon several factors.
- Erroneous results can occur from improper storage.
- Inadequate mixing,
- Technical errors associated with the assay procedure.

For more information, refer to the "Limitations of Procedure" section of the direction insert of the assay procedure being used. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

5. Homogeneity and stability.

All testing material have been tested and found to be homogeneous and stable. For the material that is procured the manufacturer issues the certificate of analysis for each survey.

6. Storage and conditions.

The samples are transported at ambient temperature.

The samples should be stored between 2 - 8°C and. Protect from light and heat.

7. Completing the result sheet.

- After analysing the samples complete a result sheet.
- Laboratory name.
- QA lab number.
- Date of analysis
- Instrument used, please make copies for backup instruments.
- The name of the person who analysed the PT samples.
- The results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will not be marked.
- **Please do not enter two numbers in a block, the correct number of blocks and decimal places are provided for each assay's result.**

NHLS Endocrinology Proficiency Testing Scheme

MATERIALS SUPPLIED

Six vials of lyophilized serum labeled 1-6. (Store at 2 - 8 °C)

ANALYSIS

- All constituents should be analysed on the day of reconstitution.
- Each sample must be analysed at the appropriate time. It serves no useful purpose to analyze all six materials simultaneously or to perform multiple analyses of each parameter to derive a mean result.
- The sample, tightly capped will be stable for 20 days if frozen once and stored at -10 to -20°C.

For in vitro diagnostic use

PRECAUTIONS

This serum is human based and has been tested for the presence of HIV-1/HIV-2 antibody, HBsAg, and HCV and was found to be non-reactive. This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled in the same manner as patient samples. Dispose of any discarded material in accordance with your laboratory waste regulations.

STORAGE CONDITIONS

The samples should be stored between 2 to 8°C and are stable for the period of the program.

The samples are shipped under ambient conditions.

RECONSTITUTION

- Open the vial carefully, avoiding any loss of material.
- Reconstitute with exactly 5 ml distilled water at +15°C to 25°C.
- Replace the rubber stopper and allow standing for 30 minutes.
- Gently swirl gently contents to ensure that the contents are completely dissolved.
- Prior to use, mix the contents by inverting the vial, avoiding the formation of foam
- **. Ensure that no lyophilised material remains unreconstituted.**

Reconstituted vials are stable for 7 days when stored tightly capped at 2 to 8°C and 4 weeks at -20°C.

Do not return residual product to the original vial to avoid contamination.

PROCEDURE

The sample is to be used in accordance with the directions accompanying the assay procedure being used.

LIMITATIONS OF PROCEDURES

The results obtained using the samples are dependent upon several factors. Erroneous results can occur from improper storage, reconstitution inaccuracies, inadequate mixing, and technical errors associated with the assay procedure. If there

is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

Testing has been conducted to assure that this product is sufficiently homogeneous

COMPLETING THE RESULT SHEET

- After analysing the samples complete a result sheet by filling in the Laboratory name, QA lab number, date, instrument used and the name of the person who did the assays as well as the results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will result in a corrective action/no return.
- **Please do not enter two numbers in a block. Please report results in the units on the result form, if different units are used please use the conversion factors.**
- Please complete the form attached to indicate the tests your laboratory would be participating in
- Mark any method changes in the space provided

NHLS Therapeutic Drug Proficiency Testing Scheme

MATERIALS SUPPLIED

Six vials of lyophilized serum labeled 1-6. (Store at 2 - 8 °C)

ANALYSIS

1. All constituents should be analysed on the day of reconstitution.
2. Each sample must be analysed at the appropriate time. It serves no useful purpose to analyze all six materials simultaneously or to perform multiple analyses of each parameter to derive a mean result. **Results will only be analysed in the month that it is due, no results will be kept by QA when send in the incorrect month.**

For in vitro diagnostic use

PRECAUTIONS

This serum is human based and has been tested for the presence of HIV-1/HIV-2 antibody, HBsAg, and HCV and was found to be non reactive. This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled in the same manner as patient samples. Dispose of any discarded material in accordance with your laboratory waste regulations.

STORAGE CONDITIONS

The samples should be stored between 2 to 8°C and are stable for the period of the program.

The samples are shipped under ambient conditions.

RECONSTITUTION

1. Open the vial carefully, avoiding any loss of material.
2. Reconstitute with exactly 5 ml distilled or deionised water.
3. Replace the rubber stopper and allow to stand for 15 minutes.
4. Gently swirl gently contents to ensure that the contents are completely dissolved.
5. Prior to use, mix the contents by inverting the vial, avoiding the formation of foam.
Ensure that no lyophilized material remains unreconstituted.
6. Allow the sample to reach room temperature before use (18 - 25°C). Replace the stopper promptly.

Reconstituted vials are stable for 7 days when stored tightly capped at 2 to 8°C and 4 weeks frozen at -20°C

Do not return residual product to the original vial to avoid contamination.

PROCEDURE

The sample is to be used in accordance with the directions accompanying the assay procedure being used.

LIMITATIONS OF PROCEDURES

The results obtained using the sample is dependent upon several factors. Erroneous results can occur from improper storage, reconstitution inaccuracies, inadequate mixing, and technical errors associated with the assay procedure. If there is visible evidence of microbial growth in a vial do not use that vial and request another vial from the QA Department.

Testing has been conducted to assure that this product is sufficiently homogeneous.

Completing the result sheet

- After analysing the samples complete a result sheet by filling in the Laboratory name, QA lab number, date, instrument used and the name of the person who did the assays as well as the results you obtained. Use the blocks provided for the results.
- Incomplete result sheets will result in a corrective action/no return.
- **Please do not enter two numbers in a block.**
- Please report results in the units on the result form, if different units are used please use the conversion factors
- Please complete the form attached to indicate the tests your laboratory would be participating in
- Mark any method changes in the space provided.

Consensus Mean Report Interpretation



NHLS PROFICIENCY TESTING PROGRAM (CHEMICAL PATHOLOGY)



Mean of results
in method group

Results of Survey number 1 for 2011/12

Devenet's Criterion

Your
instrument

Date of Report: 17 May 2011

LABORATORY:

Final Report

REGION:

INSTRUMENT:

ROCHE MODULAR

				NATIONAL				
TEST	RESULTS	z-score	>+/- 2,0	METHOD	No.	MEAN	SD	CV
SODIUM mmol/L	121	1.37		OVERALL	246	116.695	3.136	2.69
POTASSIUM mmol/L	2.8	1.02		OVERALL	248	2.675	0.122	4.56
CHLORIDE mmol/L	79	-0.61		OVERALL	238	83.071	6.702	8.07
MAGNESIUM mmol/L			No Result	OVERALL	145	0.793	0.061	7.65
UREA mmol/L	5.50	-0.14		OVERALL	262	5.556	0.414	7.45
CREATININE µmol/l	131	1.16		OVERALL	285	116.737	12.300	10.54
CALCIUM mmol/L	2.13	0.76		OVERALL	162	2.054	0.100	4.87
INORGANIC PHOS mmol/L	1.23			Method used → OVERALL	109	1.255	0.086	6.85
				DIMENSION	17	0.651	0.112	17.27
				SYNCHRON CARTRIDGE	19	0.936	0.069	7.41
CHOLESTEROL mmol/L			Not Performed	OVERALL	185	3.889	0.212	5.45
GLUCOSE mmol/L	6.1	-0.23		OVERALL	281	6.175	0.329	5.33
URATE mmol/L	0.25	0.09		OVERALL	211	0.249	0.014	5.70
TOTAL BILIRUBIN µmol/L	30	-0.35		OVERALL	238	32.311	6.683	20.68
DIRECT BILIRUBIN µmol/L	24	1.01		OVERALL	236	19.233	4.698	24.43
TRIGLYCERIDES mmol/L	1.83	5.45	W	OVERALL	154	1.298	0.098	7.52
TOTAL PROTEIN g/L	49	0.21		OVERALL	208	48.188	3.832	7.95
				SYNCHRON CARTRIDGE	38	59.921	1.880	3.14
ALBUMIN g/L	33	0.81		BCG	168	31.548	1.794	5.69
				BCP	87	29.230	1.020	3.49
ALP U/L	135	-0.67		PNP(AMP BUFFER) 37°C	237	148.882	20.634	13.86
				PNP(DEA BUFFER) 37°C	8	394.750	49.161	12.45
AST U/L	56	-1.39		IFCC 37°C (-P5P)	217	60.968	3.575	5.86
					28	60.714	3.789	6.24
ALT U/L	49	-2.41		→ Your Performance Score → 253	31	60.585	4.801	7.92
					51	58.968	7.387	12.53
LDH U/L	591	0.45		DGKC (P-L) 37°C	56	576.036	33.213	5.77
				(LACT.- PYRUV.) 37°C	33	243.121	27.684	11.39
				SFBC (P-L) 37°C	38	705.026	28.516	4.04
				IFCC 37°C	20	288.250	12.916	4.48
					247	32.255	3.322	10.30
GGT U/L	33	0.22		SZASZ 37°C	247	32.255	3.322	10.30
AMYLASE U/L	101	-1.84		PNP-G7 (IFCC) 37°C	121	116.174	8.242	7.09
				PNP-G3 (37°C)	40	123.925	26.216	21.16
				MALTOTETRAOSE 37°C	12	74.250	4.288	5.77
CK U/L	161	0.33		NAC act. (IFCC) 37°C	138	158.181	8.564	5.41
LIPASE U/L	77	-1.26		OVERALL	23	89.130	9.655	10.83
LACTATE mmol/L	1.5	-0.14		OVERALL	91	1.520	0.143	9.42
				POC	25	2.016	0.440	21.84
IRON µmol/l	15.2	0.15		OVERALL	38	15.037	1.094	7.27



Please Note: Sample sizes less than 5 may result in distortion of the mean and as a consequence must be taken with reserve.
This is a confidential report that summarises the performance of your laboratory.

PTS0005

Print Date: 18/07/2011

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Defined Target Result Interpretation



NHLS PROFICIENCY TESTING PROGRAM (ENDOCRINE)



Results of Survey number 1 for 2011/12

Date of Report: 08 June 2011

LABORATORY:

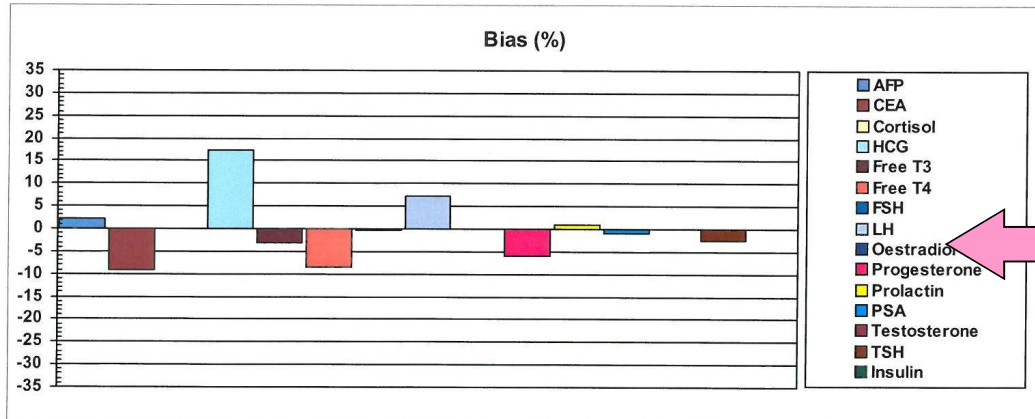
REGION:

INSTRUMENT:

BECKMAN DXI

TEST	RE	BIA %	ACCEPTANCE LIMITS			INSTRUMENT MEAN	No.
			LOW	HIGH	TARGET		
a-Fetoprotein kU/L		2.22	151.00	208.00	180.00	195.57	7
CEA µg/L	39.30 Beckman DXI	-9.03	36.30	50.10	43.20	41.45	8
Cortisol nmol/L		NR	641.00	961.00	801.00	770.00	7
HCG U/L		17.48	119.00	167.00	143.00	122.00	7
Free T3 pmol/L		-3.15	10.20	15.20	12.70	12.20	7
Free T4 pmol/L	49.50 Beckman DXI	-8.67	45.40	63.00	54.20	48.03	9
FSH IU/L	Beckman DXI	-0.46	36.00	50.60	43.30	43.17	7
LH U/L	61.60 Beckman DXI	7.13	48.30	66.70	57.50	61.00	7
Oestradiol pmol/L	Beckman DXI	NR	2036.00	2811.00	2424.00	2542.50	6
Progesterone µg/L	96.80 Beckman DXI	-6.02	84.80	121.00	103.00	94.93	7
Prolactin µg/L	32.60 Beckman DXI	0.93	27.10	37.50	32.30	32.94	7
PSA µg/L	21.20 Beckman DXI	-0.93	18.00	24.80	21.40	20.725	8
Testosterone nmol/L *	Beckman DXI	NR	21.70	30.00	25.90	26.23	4
TSH mIU/L	33.10 Beckman DXI	-2.65	28.60	39.50	34.00	32.800	9
Insulin mIU/L *	Beckman DXI	NR	107.00	147.00	127.00	131.00	2

* - Not accredited by SANAS



* End Of Report *

Authorised by: Ann Higgs - PT Scheme Manager



Please Note: Sample sizes less than 5 may result in distortion of the mean and as a consequence must be taken with reserve. This is a confidential report that summarises the performance of your laboratory.

PT50005

Print Date: 20/07/2011

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NHLS Cryptococcal antigen lateral flow assay Proficiency Testing Scheme

Introduction

Cryptococcal meningitis (CM) is a leading cause of death among individuals with HIV/AIDS. Despite increased availability of ART and appropriate therapy, CM continues to be associated with high mortality rates (20%-70%). Early targeted screening and treatment is a more cost-effective and successful means of reducing CM-related mortality. CrAg is detectable in blood prior to development of meningitis. Prevalence of antigenaemia in HIV-infected populations varies between 6%-20%. Studies suggest that patients with CD4+ T-lymphocyte counts <100 cells/ μ L are at highest risk for developing antigenaemia and cryptococcal disease. Identifying patients with CrAg through screening provides a unique opportunity to treat patients who are at risk for developing CM, and to identify patients with early or unrecognised cryptococcal disease who are at risk for immune reconstitution inflammatory syndrome (IRIS).

Proficiency Test Item-Treatment and analysis

1. This material is transported at ambient temperature and on arrival in your laboratory the simulated samples must be stored at 2°C-8°C until analysed.
2. The simulated samples should be well mixed before analysis.
3. Participants must **not** test the three simulated samples in the same manner as patients' specimens.
4. Participants should test the three simulated samples the same number of times that it routinely tests patients' samples.
5. The three simulated samples should be tested with the regular patient workload by staff members who routinely perform the testing in the laboratory, using the routine methods.

Survey Requirements

1. The NHLS CrAg LFA PTS endeavors to assess all aspects of specimen-management, such as turn-around time, accuracy of reports, specimen handling, etc.
2. Rapid turn-around time is an essential element of specimen-management.
3. **Incomplete participant codes on result sheets will result in non-assessment.**
4. **Result sheets received after 12:00 midnight on the closing date will also result in non-assessment. This is equivalent to omitting patient details on a report and not meeting turn-around times (TAT).**

L. Factors that could influence the testing of samples

1. Although rare, extremely high concentrations (>0.140mg/mL) of CrAg can result in weak test lines or false negatives (due to high-dose hook effect or prozone phenomenon).
2. Drops of diluent adhering to the side of the microcentrifuge tube before the addition of sample.
3. Bubbles in the diluent or prepared test: **do not** shake the tube to mix sample with diluent.
4. Inadequate mixing of sample into diluent by pipette tip.
5. Inadvertently bending the strip when inserting so that damage occurs to the strip wick or membrane or both.

M. Homogeneity and stability

1. All simulated samples are tested and guaranteed for homogeneity and stability as part of the NHLS PTS internal quality control process.

N. Sample reception

1. Open package and inspect for any breakages, leaks, missing samples and possible deterioration during transportation.
2. Inform the PTS manager in writing if samples were unsuitable and should require a replacement sample

S. Methodology

- The NHLS CD4 laboratories currently use the IMMY CrAg Lateral Flow Assay kit.
- The kit lot number and expiry date must be written on the result sheet.
- If your laboratory is using any other CrAg kit, please indicate which one.

i. Cryptococcal antigen screening

- Early detection and pre-emptive treatment of CM saves lives.
- Asymptomatic cryptococcal antigenaemia precedes the onset of CM by a median of 3 weeks; this provides a window of opportunity for screening.
- Patients with antigenaemia can be identified by reflexively screening blood specimens using a CrAg detection test.
- Newly-diagnosed CrAg+ patients should be urgently followed up and started on antifungal treatment followed by antiretroviral treatment (ART).

ii. The CrAg test

CrAg can be detected by several test formats:

- Latex agglutination (LA),
- Enzyme immunoassay (EIA)
- Lateral flow assay (LFA).

However, only the LFA format is used in the NHLS CD4 laboratories to reduce specimen preparation time. This is the only method acceptable for the CrAg PTS.

The CrAg PTS uses the LFA method:

- The CrAg LFA is a dipstick sandwich immunochromatographic assay (Immuno-Mycologics, Inc., Norman, OK). The test uses specimen wicking to capture gold-conjugated, anti-CrAg monoclonal antibodies and gold-conjugated control antibodies deposited on the test membrane.
- If CrAg is present in the specimen, it binds to the gold-conjugated, anti-CrAg antibodies.
- The gold-labelled antibody-antigen complex forms a sandwich with capture antibodies at the test line resulting in a visible test line.

iii. Equipment and Materials

- IMMY CrAg Lateral Flow Assay kit, 50 strips

- 1.5 ml disposable micro centrifuge tubes
- 40µl pipette (50 or 100µl pipette to dispense 40µl) and pipette tips
- Timer capable of accurately measuring 10 minutes
- A rack suitable for the micro centrifuge tubes
- Class II biohazard cabinet (if available)
- Centrifuge with 5 ml adaptors

iv. Preparation and Storage of reagents and controls

The kit comprises:

- 50 test strips
- 1 bottle of positive control
- 1 dropper bottle of specimen diluent

No preparation is necessary and the kit is stored at room temperature (22°C - 25°C)

v. Procedure

CrAg PTS tests should be performed on CrAg PTS simulated samples C, D and E.

- Label one micro centrifuge tube for the positive control and one for the negative control.
- Add 1 drop of specimen diluent using the dropper bottle to each PTS sample's micro centrifuge tube (Samples C, D and E) and to the positive control tube.
- Ensure that the drop is centrally placed in the tube.
- Add 2 drops of specimen diluent using the dropper bottle to the negative control tube.
- Add 40µl of the CrAg PTS simulated sample using a pipette to the corresponding labelled micro centrifuge tube and mix the diluent and CrAg PTS simulated sample with the same pipette and tip by aspirating and dispensing the total volume at least twice.
- Add 1 drop of the positive control to the corresponding labelled micro centrifuge tube and mix using a pipette as above.
- Submerge the white end of a CrAg LFA strip into each micro-centrifuge tube
- Set the timer for 10 minutes
- Read the reaction immediately after 10 minutes has elapsed and record the results on the CrAg PTS result sheet.

vi. Interpretation of PTS test results

- The presence of two lines (test and control) regardless of the intensity of the lines (bright or faint), indicates a positive result.
- A single control line only indicates a negative result.
- Ensure that the positive control has two lines and the negative control has one line.
- If the control line does not appear on either a control or patient test sample, the results are invalid and the test must be repeated.

T. Potential biohazardous material

Laboratories should use good laboratory practice when handling this reagent.

U. Laboratory safety

- Use universal precautions with all specimens.
- Follow standard laboratory safety operating procedures.
- Wear a laboratory coat, gloves, and safety glasses when handling simulated whole blood samples.
- Decontaminate all working surface with 70% alcohol and wipe spills with sodium hypochlorite.
- Document and report any laboratory accidents immediately.

V. Result sheet

- Three results are required to be entered, Sample C, Sample D and Sample E.
- The LFA method is semi-quantitative but only qualitative results should be reported: negative, positive or indeterminate. **CrAg titres need not be checked and reported for positive CrAg results.**
- **If you record an indeterminate result you must give an explanation. If no explanation is given, the result will be flagged.**
- Fill in “comments/suggestions/queries/complaints” if required.
- Date, name, signature, telephone number and email address must be filled in.

W. Laboratory performance report

Test results that are found to be inappropriate for statistical evaluation due to miscalculations, transpositions or other gross errors will not be included in the evaluation. They will be marked as not evaluated and unacceptable. If the test is not done or a no response they will be marked as not evaluated and unacceptable. PT items that were distributed but were found to be unsuitable for performance evaluation due to non-homogeneity, instability, damage or contamination are cancelled for evaluation. Such PT items are exempted from evaluation and full scores are assigned. Basic statistics are used for this scheme. Method of data evaluation is no-parametric (qualitative, positive/negative). A cumulative graph is generated for each trial with the number of responses. Statistics include:

- Number of laboratories participating
- Laboratories with acceptable responses
- Laboratories with not acceptable responses.
- Laboratories that did not respond at all.

X. Evaluation of performance

The laboratories are currently using the IMMY CrAg Lateral Flow Assay kit. Three proficiency testing samples, Sample C, Sample D and Sample E are sent to the participants. The participants are graded qualitatively for this scheme (non-parametric), that is negative and positive. In order for performance to be deemed acceptable the participant has to get all three results correct. All surveys and statistic results are automatically generated by the Access data base. Methods of evaluating PTS performance is described in tables 1 and 2.

Table 1: CMPT grading system for scoring participants acceptable results

Sample	Qualitative evaluation	Score	Percentage	Evaluation
C	Correct response	4	33.33	Acceptable
D	Correct response	4	33.33	Acceptable
E	Correct response	4	33.33	Acceptable

Table 2: CMPT grading system for scoring participants unacceptable results

Sample	Qualitative evaluation	Score	Percentage	Evaluation
C	Incorrect response	0	0	Not acceptable
D	Incorrect response	0	0	Not acceptable
E	Incorrect response	0	0	Not acceptable

Acceptable: Report is technically correct and clinically appropriate.

Unacceptable: Report contains errors that could result in incorrect interpretation and actions.

The method of evaluation is referenced to:

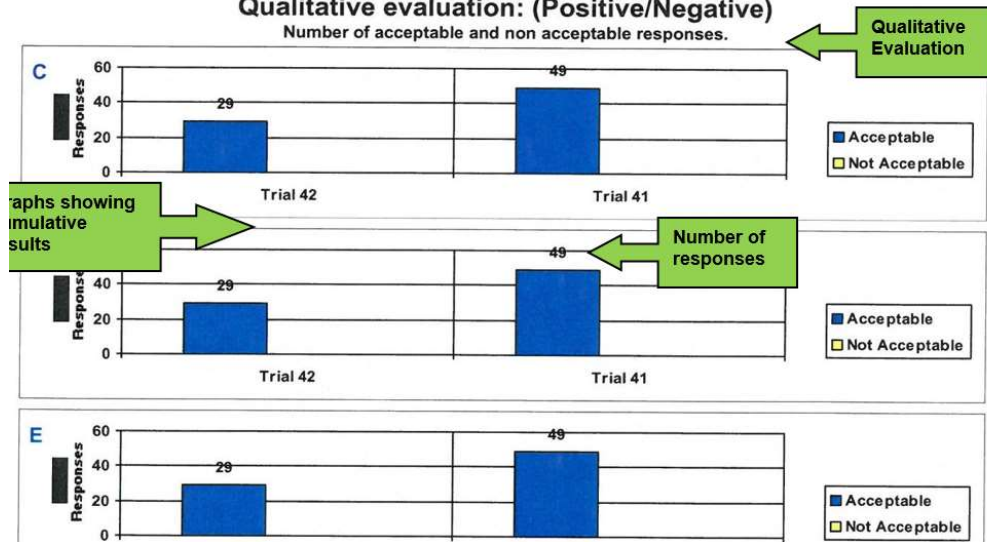
- Clinical Bacteriology numeric grading system guidelines CMPT grading system ([http://cmpt.ca/eqa-programs/mycology/External Quality Assessment for Mycology Laboratories](http://cmpt.ca/eqa-programs/mycology/External%20Quality%20Assessment%20for%20Mycology%20Laboratories)).
- Management of the NHLS Proficiency Testing Scheme for Mycology QASY0009.

Participants are issued with a report detailing their performance compared with that the expected result. A cumulative graph represents the number of responses that are acceptable and not acceptable. A table of statistics is given per survey.

Laboratory performance report

Qualitative evaluation: (Positive/Negative)

Number of acceptable and non acceptable responses.



National Health Laboratory Services
Proficiency Testing Scheme

CrAg LATERAL FLOW ASSAY
Survey : Trial 42

Unique code number: [] PTS name and Trial number: []

Individual report: Final Report Test kit Survey Print Date: 27 Feb 2017

LABORATORY: []

METHOD: []

Kit expiry date: 2019/01/13

SAMPLE	Your Result	Expected Result	Evaluation
C Weak Positive (10 µl CrAg)	Positive	Positive	Acceptable
D Negative (0 µl CrAg)	Negative	Negative	Acceptable
E Strong Positive (30 µl CrAg)	Positive	Positive	Acceptable

COMMENT:

NHLS MYCOLOGY MOULDS

Selection of samples: Isolates which are included in the NHLS PTS for Mycology (Moulds) are characterised to ensure that typical features are present to facilitate identification. Prior to distribution, the organisms are identified using standard phenotypic methods and a part of the fungal genome is sequenced to confirm the final identity.

Survey Requirements: The NHLS PTS for Mycology (Moulds) endeavours to assess aspects of specimen-management, such as turn-around time, accuracy of reports, clinical relevance of results, specimen handling, *etc.* Rapid turn-around time is an essential element of specimen-management, so any survey questionnaires which are received after the return deadline will be penalised and those received after the preliminary survey answers are distributed will not be assessed. If a laboratory name and number is not completed on the survey questionnaire, it is considered equivalent to leaving a patient's name off a laboratory report. These results will not be assessed, even if a covering fax sheet is sent.

Preliminary Survey Answers: The identity of the samples distributed through the NHLS PTS for Mycology (Moulds) will be emailed to NHLS quality Assurance (QA) Managers and non-NHLS laboratories a week after the deadline for return of the survey questionnaire. Therefore, survey questionnaires which are received late cannot be assessed. Please email the above address to be added to the distribution list.

Survey Grading: The survey questionnaires are graded by one person using a model answer framework and moderated by a second person. The model answer framework is reviewed by the NHLS PTS Microbiology Advisory Committee.

INSTRUCTIONS FOR SURVEY

The package contains samples **A, B, C** and **D** (cultures suspended in sterile water). If the package contains broken samples, sterilize (autoclave) the container immediately. Dispose of according to normal procedures. Guard against the production of aerosols.

Inoculation of culture suspended in sterile water

After gently swirling, inoculate approximately half of the suspension directly onto media appropriate for the type of sample supplied. Keep the vial at room temperature until you have identified the isolate completely.

Instructions for completing the survey questionnaire

Read the clinical scenarios provided with each survey samples. Identify the provided samples (**A to D**), using standard operating procedures. Note – sample **D** is provided as a “difficult identification challenge” and will not be graded.

Please complete the survey questionnaire using the provided answer codes. If an answer code is not provided in the table, please write the full answer in the questionnaire.

Grading system for NHLS PTS for Mycology (Moulds)

Score	Result	Definition	Performance assessment
4	Completely correct result	A result which is accepted as the most correct and clinically relevant result.	Acceptable
3	Almost completely correct result	A result which is not technically correct, but the error or omission has little or no clinical impact; a deviation from what is considered the most clinically relevant result.	Acceptable
	<i>Separator</i>	<i>To divide acceptable from unacceptable responses.</i>	N/A
1	A significantly incorrect result	A clinically relevant result which could lead to a minor diagnostic or treatment error.	Unacceptable
0	Completely incorrect result	A clinically relevant result which could lead to a major diagnostic or treatment error.	Unacceptable
0	No result	No result submitted by participant.	Unacceptable

NHLS Parasitology Stool Proficiency Testing Scheme Instructions

Scope

One of the **main objectives** of the Stool Parasites PT Scheme is to **teach** and participants are encouraged to perform all of the survey challenges, even if their laboratories do not perform them routinely. Participants are encouraged to keep survey specimens. Survey specimens can be used in the future as teaching aids, used as reference material or as controls for tests by participants.

Selection of sample

a) Proficiency Testing Schemes involve more than a positive or negative answer to a survey sample and this PT Scheme aims to assess other aspects, such as turn-around time, accurate result reports, clinical relevance of results, specimen handling, etc. Rapid turn-around time is an essential element of PTS. PTS survey samples should be treated in the same way as routine patient specimens. This survey contains 5 challenges. Identify any parasite(s) present, even if not pathogenic and write the answer codes. Only the answer codes will be assessed, not parasite names (except for code 33). More than one answer code can be reported for mixed infections. Do not report artefacts.

b) Homogeneity and stability

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the Parasitology Stool Internal Quality Control Process.

PTS sample donation:

We are always in need of 3+ parasite positive specimens to use in this PT scheme and all contributions are welcome. Please ensure that stool specimens are sent in 10% formalin. You can contact us at the numbers above for any further instructions.

a) Proficiency test item –treatment and analysis

Read the clinical details and processing instructions for each sample. Samples shall be analyzed using your own standard operating procedures. All participants are required to use the test method of their choice.

b) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored and processed at room temperature at all times.

c) Special handling instructions and safety requirements

If the package contains broken samples, sterilize (autoclave) the container and contents immediately. Dispose broken samples as per safety protocols used in your laboratory.

d) Specific environmental conditions that the tests must be performed

N/A

e) Provisional results

Provisional results are e-mailed to regional managers and participants who request them, one week after the result deadline. Please e-mail us at the above e-mail address to be added to the mailing list.

NHLS Malaria RDT Proficiency Testing Scheme

a) Scope

The NHLS PTS for Malaria RDT aims to assess the correct interpretation of the various Malaria RDT kits that participants are using.

b) Selection of sample

This survey contains three challenges. Participants are required to test for the presence or absence of malaria antigens from the samples given.

c) Proficiency test item –treatment and analysis

Samples shall be analysed using your own standard operating procedures. All participants are required to use the test method of their choice.

d) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage, whether the PTS is limited to selected methods and timing of the PT Item

Temperature: Shipment of samples is at ambient conditions. Please ensure that samples are kept **frozen** prior to testing, thaw and bring to room temperature before testing.

e) Special handling instructions and safety requirements

If the package contains broken samples, sterilize (autoclave) the container and contents immediately. Dispose broken samples as per safety protocols used in your laboratory.

f) Specific environmental conditions that the tests must be performed

N/A

g) Recording and submission of PTS results

Print a response form from www.nhls.ac.za. Submissions can be made via fax 086 225 2460 or email parapts@nhls.ac.za. Complete the response form using the appropriate answer codes provided

NHLS Specific Treponemal Serology Instructions

a) Scope

The NHLS PTS for Specific Treponemal Syphilis Serology aims to determine the laboratory policy on handling specimens including complete testing and results interpretation. Participants are encouraged to perform testing on all samples.

b) Selection of sample

All laboratories receive identical test panels. The test panel includes both positive and negative samples. The composition of the test panels may vary with each survey. Prior to distribution, the samples are quality controlled by external referee laboratories using standardized methods.

c) Proficiency Test Item –Treatment and analysis

Samples shall be analysed using your own standard operating procedures.

All participants are required to use the test method of their choice.

d) Homogeneity and stability:

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the Specific Treponemal Syphilis Serology Internal Quality Control Process.

e) Sample reception

The package contains three serum samples (**ST01, ST02, and ST03**) - the samples are derived from human plasma converted into serum by a process of recalcification. Please open package and inspect for any breakages, possible deterioration during transportation or missing samples.

f) Factors that could influence the testing i.e. nature of the PT items, conditions of storage

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored at 2-8°C upon receipt and at -20°C for long-term storage.

g) Special Handling instructions and safety requirements.

If the package contains broken samples, sterilize (autoclave) the container and contents immediately. Dispose of broken samples as per safety protocols used in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

h) Specific environmental conditions that the tests must be performed.

Samples should be stored between 2 – 8 °C before examination. Bring samples to room temperature and test using routine methods.

i) Recording and submission of PTS Results.

Print a response form from www.nhls.ac.za. Submissions can be made via fax 086 225 2460 or email bactpts@nhls.ac.za. Please complete the survey result form by recording results either as reactive or non-reactive.

j) Evaluation of submitted results

The results are graded as in Table 1 below

Table 1 Evaluation of Specific Treponemal Serology PTS

Sample	Qualitative Evaluation	SCORE
ST01	Correct Response	4
ST02	Correct Response	4
ST03	Correct Response	4

A total score of 12 is possible, all incorrect responses will receive zero.

NHLS NON SPECIFIC TREPONEMAL SEROLOGY

b) Factors that could influence the testing ie. Nature of the PT items, conditions of storage

Temperature: Samples are shipped at ambient conditions. Please ensure that samples are stored at 2-8°C upon receipt and at -20°C for long term storage.

c) Selection of sample

All laboratories receive identical test panels. The composition of the test panels may vary with each survey. Prior to distribution, the samples are quality controlled by external referee laboratories using standard methods.

d) Homogeneity and stability:

All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the Non-Specific Serology Internal Quality Control Process.

e) Sample Details

The package contains 3 sera samples (**S01, S02, and S03,**) - the samples are derived from human plasma converted into serum by a process of recalcification.

f) Special Handling instructions and safety requirements.

If the package contains broken samples, sterilise (autoclave) the container and contents immediately. Dispose of broken samples as per safety protocols used in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

g) Specific environmental conditions that the tests must be performed.

Samples should be stored between 2 – 8 °C before examination, and must be examined by routine methods.

h) Sample reception

This package contains 3 sera samples labeled with sample number, department name and year of survey.

Please open package and inspect for any breakages, possible deterioration during transportation or missing samples. Inform PTS Coordinators in writing if samples are unsuitable and whether you require a replacement sample.

i) Recording and submission of PTS Results.

Print a response form from www.nhls.ac.za. Submissions can be made via fax 086 225 2460 or email seropts@nhls.ac.za. Please complete the survey result form by recording results either as reactive or non-reactive.

j) **Evaluation of submitted results**

The scheme uses a grading method for the allocation of a score for each of the 3 samples, as in Table 1 below.

Table 1

Sample	Qualitative Evaluation	Score	Quantitative Evaluation/Titre	Score
S01	Correct Response	4	Correct Response	1
S02	Correct Response	4	Correct Response	1
S03	Correct Response	4	Correct Response	1

A total score of 15 is possible, all incorrect responses will receive zero.

NHLS HIV EARLY INFANT DIAGNOSIS

a) Selection of sample

Prior to distribution, the samples are examined by external referee laboratories using standard methods and then further subjected to pre-distribution testing by the provider. All laboratories shall receive identical panels consisting of a selection of negative and/or positive samples. The composition of the test panels may vary with each survey.

b) Sample reception

Sample contents detailed in the instructions and process checklist.

Please open package and inspect for any possible deterioration during transportation or missing samples. Inform the PTS Provider in writing if samples are unsuitable and whether you require a replacement sample.

c) Evaluation of submitted results

The scheme uses a grading method for the allocation of a score for each of the 5 Dried Blood Spots, as in Table 1 below.

Table 1

SPECIMEN CATEGORY	PARTICIPANTS' RESPONSE	SCORE
HIV-1 Detected	HIV-1 Detected	1
	HIV-1 Not Detected	0
HIV-1 Not Detected	HIV-1 Not Detected	1
	HIV-1 Detected	0

d) Recording and submission of PTS Results.

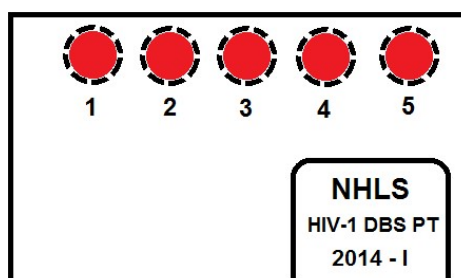
Print a response form from www.nhls.ac.za.

HIV-1 Proficiency Testing Program for Early Infant Diagnosis

Instructions and Process Checklist

In this PT testing event, a DBS PT Panel for each Survey is included. Please process 5 samples. With the card oriented upright, please process the DBS from the left to the right as numbered in the diagram below. Report the sample IDs as follows: 20XX-1, 20XX-2, 20XX-3, 20XX-4, and 20XX-5.

DBS PT Panel



Checklist

Please indicate with the date and your initials when Proficiency Testing materials were received. Your test kit should include:

Initial	Date	Item
		2 NHLS DBS PT Panel card (5 Spots on card) – 2 sets (Survey 1 and 2)
		1 NHLS Positive Quality Control Card (10 DBS)
		1 NHLS Negative Quality Control Card (10 DBS)
		Instructions and Process Checklist

Testing Instructions

Initials	Date	Action
		Perform PT testing according to your laboratory's Standard Operating Procedure

Result Form Instructions

Initials	Date	Action
		Complete blank fields on the top portion of the form.
		Provide your laboratory's final interpretation for each specimen in the table. (HIV-1 Detected, HIV-1 Not-detected, Equivocal, or Invalid)
		Provide CT values for all specimens including Kit and NHLS controls.
		Review Result Form and check for transcription errors. Verify that all result fields are complete.
		Submit results electronically by due date online as per login details submitted or alternatively, submit a hard copy to NHLS at seropts@nhls.ac.za . It is not necessary to sign the electronic copy of the Report Form.
		The HIV-1 EID Proficiency Testing Program Result Form must be signed by the laboratory's director and retained in your laboratory for review by regulatory and accrediting agencies.

NHLS HIV SEROLOGY

a) Selection of sample

Samples included in the NHLS PTS for HIV Serology are characterized on a selection of both HIV ELISA and Rapid test methods to ensure that a correct interpretation of final result is attained. Prior to distribution, the samples are examined by external referee laboratories using standard methods and then further subjected to pre-distribution testing by the provider. All laboratories shall receive identical panels consisting of a selection of negative and/or positive samples. The composition of the test panels may vary with each survey.

b) Sample reception

The package contains 6 sera samples (**H01, H02, H03, H04, H05 and H06**) - the samples are derived from human plasma converted into serum by a process of recalcification. The samples are labeled with sample number, department name and year of survey. Please open package and inspect for any breakages, possible deterioration during transportation or missing samples. Inform PTS Coordinators in writing if samples are unsuitable and whether you require a replacement sample.

c) Evaluation of submitted results

The scheme uses a grading method for the allocation of a score for each of the 6 samples, as in Table 1 below.

Table 1

SPECIMEN CATEGORY	PARTICIPANTS' RESPONSE	SCORE
Anti-HIV positive	Positive	2
	Negative	0
Anti-HIV negative	Positive	0
	Negative	2

d) Recording and submission of PTS Results.

Print a response form from www.nhls.ac.za.

NHLS HBsAg SEROLOGY

a) Selection of sample

Samples included in the NHLS PTS for HBsAg Serology are characterized on a selection of both HBsAg ELISA and Rapid test methods to ensure that a correct interpretation of final result is attained. Prior to distribution, the samples are examined by external referee laboratories using standard methods and then further subjected to pre-distribution testing by the provider. All laboratories shall receive identical panels consisting of a selection of negative and/or positive samples. The composition of the test panels may vary with each survey.

b) Sample reception

The package contains 6 sera samples (**HB01, HB02, HB03, HB04, HB05 and HB06**) - the samples are derived from human plasma converted into serum by a process of recalcification. The samples are labeled with sample number, department name and year of survey. Please open package and inspect for any breakages, possible deterioration during transportation or missing samples. Inform PTS Coordinators in writing if samples are unsuitable and whether you require a replacement sample.

c) Proficiency Test Item –Treatment and analysis

Samples positive for HBsAg have been heat inactivated at 56°C for 60 minutes.

d) Special Handling instructions and safety requirements.

If the package contains broken samples, sterilise (autoclave) the container and contents immediately. Dispose of broken samples as per safety protocols used in your laboratory. Guard against the production of aerosols. Please follow universal safety precautions at all times.

e) Evaluation of submitted results

The scheme uses a grading method for the allocation of a score for each of the 6 samples, as in Table 1 below.

Table 1

SPECIMEN CATEGORY	PARTICIPANTS' RESPONSE	SCORE
HBsAg Positive	Positive	2
	Negative	0
HBsAg Negative	Positive	0
	Negative	2

f) Recording and submission of PTS Results.

Print a response form from www.nhls.ac.za.

NHLS HIV-1 VIRAL LOAD

a) Factors that could influence the testing i.e. Nature of the PT items, conditions of storage

Temperature: Samples are shipped at ambient conditions. Store specimens at 2-30°C until day of testing. Do not use past expiration date on vial. Specimens must be at room temperature before opening vials. Each vial should be tested once and then discarded.

b) Sample Details

- 10 single use vials [two identical sets of 5 Dried Tube Specimens (DTS)]
- One tube (13 ml) reconstitution buffer.

c) Sample preparation and testing

- Add 1.1 ml reconstitution buffer to each DTS specimen and vortex for 10 seconds.
- Reconstituted specimens should be red in color, free of particulate matter and used immediately. If needed, the rehydrated specimens of DTS can be stored at 4°C for 24 hours or -20 °C or colder for up to one week, with no more than one freeze-thaw.
- Perform testing according to your laboratory's Standard Operating Procedure along with your patients' specimen into your daily workflow, so test results are truly indicative of your lab's daily performance.

d) Recording and submission of PTS Results.

- Print a response form from www.nhls.ac.za.
 - Please note that Results must be reported in log₁₀ copies/ml

Results must be submitted online to the PTS Provider before the return deadline. Login details have been emailed to individual laboratories but the PT Coordinators can be contacted for more information.

NHLS SARS-COV-2

a) Scope

The PTS for SARS-COV-2 aims to determine the facility's policy on handling specimens including complete testing and final results interpretation. Participants are encouraged to perform testing as directed.

b) Sample Details

- Each pellet/swab contains human respiratory epithelial cells.

c) Sample preparation and testing

Pellet

- a. Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water.
- b. Vortex the rehydrated pellet for 10 seconds or until pellet is dissolved.
- c. Use the appropriate volume of the rehydrated pellet for the assay being performed and follow laboratory protocols or manufacturer instructions for processing the sample.

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

Swab

- d. Tear open the foil pouch containing the quality control swab at the notch.
- e. Remove the swab from the pouch.
- f. Rehydrate the swab in a method appropriate to the assay and follow laboratory protocols or manufacturer's instructions for processing the sample.

Note: Each swab is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

d) Recording and submission of PTS Results.

- We have supplied one hard copy of the result response forms and an electronic copy will be made available if required.

e) Recording and submission of PTS Results.

Print a response form from www.nhls.ac.za .