Registration No. 2000/026390/08

1. Program Contact Information

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2. General Information

The SANBS Program is under the guidance of an Advisory Committee. The SANBS Proficiency Advisory Committee consists of Heads of Units and/or Laboratory Managers of the following units at SANBS.

- Issuing.
- Donation Testing.
- Specialised Laboratory Services.
- Donor Collections.
- Statistics.
- ICT.
- Quality Systems.
- Quality Control.
- Research and Development.

3. SANBS Proficiency Program Office (PPO)

The SANBS Proficiency Program office is located in the Quality Control Department, SANBS Head Office Building in South Africa,
Physical address: Quality Control Department, SANBS, 2 Constantia Boulevard, Constantia Kloof, Ext 22, 1709.
Practice Number: 2000/026390/08.

The office is responsible for the day-to-day delivery of all aspects of the Proficiency programs including design of surveys, sample selection and preparation, to summary reports and assessment.

The identity to all participants is kept confidential and details will not be released without the written permission of the participant. The SANBS Proficiency Program will however consider all reasonable requests for information and support when requested.

The SANBS Proficiency Program is managed by a full-time Scheme Manager, a full time Scheme Second in Charge, a full time Program Co-ordinator and a full-time Administration Assistant with the support and consultation of the SANBS Proficiency Advisory Committee. If participants have a query, they can contact the Program office by e-mail on proficiency@sanbs.org.za , phone (+27) 011 761 9226.

4. Application Process

All SANBS participants have access to the *Tranfusion Service Proficiency Program: Information Booklet* (INF-QCL-005) on SAP which contains all the relevant information pertaining to SANBS PTS. The handbook is issued to all external participants on registration or as it is updated.
The scope of the SANBS- PTS is described in INF-QCL-005.
SANBS Laboratories are not charged for their participation, whereas external laboratories are charged a nominal service fee.

The participation of all SANBS Laboratories is governed by *Proficiency Testing Program for SANBS* (SOP-QCL-002). Criteria for participation in the PTS are that all SANBS Laboratories that perform the relevant testing are registered on the electronic system for the relevant PTS by their managers. (www.proficiency@sanbs.co.za).

External laboratories register and enroll online.
On receipt of a registration external participants are issued with a *Proficiency External* Quotation (FRM-QCL-094).

On receipt of an accepted quotation, the QC staff accepts the enrolment online and forward quotation to accounts department.

Proof of review is captured on available electronically and/or on Proficiency *Programme Enrolment* (FRM-QCL-085).

The SANBS PTS manager electronically requests an updated participants list 2 weeks prior to shipment of a survey, which is then filed on the server in the relevant survey folder.
A confidentiality statement is communicated in INF-QCL-005 and on the participants report.

5. Proficiency Program (PP) Certificates

5.1 The SANBS Proficiency Program certificates of enrolment are processed and issued by the SANBS Proficiency Office after payment has been received.
The Proficiency Program Office is located in the Quality Control department, South African National Blood Service, Constantia Boulevard, Constantia Kloof, Roodepoort and enrolment, for assistance with PT staff can be contacted on telephonically: 011 761 9226 or e-mail (proficiency@sanbs.org.za).

5.2 The SANBS PP Certificates of Participation are processed and issued by the PP office. A Certificate of Participation is issued to participants for each program your laboratory is enrolled with. Certificates are provided after the final survey for the year has been analysed and assessed.

6. Confidentiality

Participant numbers are used to identify participants on the electronic system. Should a participant not require their name to appear on the report, this must be submitted in writing to the PTS office to waive the confidentiality clause.
All SANBS-PTS staff and members of the advisory committees have signed a confidentiality statement and are made aware of the importance of confidentiality.

Only authorised personnel have access to the data entry facilities via usernames and passwords.
All performance data is treated as confidential and is disclosed to a restricted list of individuals their managers and QC coordinators.
Should a regulatory authority or any other 3rd party require PTS results, then the affected participant shall be required to submit written consent to the PTS Manager.

7. Program Instruction and Result Sheets

7.1 Crossmatch Proficiency Program

Crossmatch Proficiency Test Instruction sheet (FRM-QCL-026).
Proficiency Test-Crossmatch sheet (FRM-QCL-006).
Proficiency Test Antibody Investigation Worksheet (FRM-QCL-007).

7.2 Antibody Identification and Titration Proficiency Program

Proficiency Test Antibody Identification and Titration Instruction Sheet (FRM-QCL-032).
FRM-QCL-007.
Antibody Titration Worksheet (FRM-QCL-097).

7.3 Donation Testing Proficiency Program

Proficiency Test Worksheet-Donation Testing (FRM-QCL-008).
Donation Testing Proficiancy Instruction Sheet (FRM-QCL-111).

7.4 Virology Proficiency Program

Virology Proficiency Test Instruction sheet (FRM-QCL-106).
Virology Proficiency Test Program (FRM-QCL-096).

7.5 Specialised Laboratory Services (SLS) Proficiency Program

SLS Proficiency Test Instruction (FRM-QCL-079).
SLS Proficiency Result Sheet (FRM-QCL-080).

7.6 HemoCue Proficiency Program

HemoCue Proficiency Test Package Insert (FRM-QCL-101).

Instruction sheets and Result Sheets for the different surveys can be downloaded from the website. Survey results are submitted online.

8. PP Survey Samples

Note: External participant samples are issued with a *Proficiency External Delivery Note* (FRM QCL-095).

8.1 Sample Matrix

All samples are prepared from human blood.

8.2 Sample Transport

The SANBS PP survey samples are transported at ambient temperature (Temperature of surrounding environment) or as indicated by the stability testing validation results. Stability testing procedures for the different schemes are included in the relevant operating procedures.
Transportation and packaging of participants' samples are subcontracted.

8.3 Sample Testing

All transfusion Medicine proficiency survey samples are non-reactive for the following markers excluding the Virology Testing program.
HbsAg.
HIV and HCV.
TTI markers for samples for the other schemes are not available.

In keeping with safe laboratory practices, the SANBS PPO recommends that all samples are handled as potentially infectious and appropriate personal protective equipment is recommended.

9. Instructions for Participant:

9.1 Treat all Proficiency samples as "routine samples" and follow own procedures for testing to obtain required results.

9.2 The following factors could influence the testing:

- Temperature: Samples to be stored between (2°C - 6°C) or as indicated on the package insert.
- Environmental conditions: Tests should be performed at Room Temperature.

9.3 Only tests required and resulted will be assessed per program. No additional marks will be allocated for additional testing.

9.4 Closing date for each program will be stated in the package insert provided.

9.5 Sample preparation is included in the package insert.

9.6 Special handling and safety requirements:
Samples should be treated as potentially infectious and appropriate PPE is recommended.

9.7 Recording and Reporting of results: All possible answers are predefined in dropdown menu on the system
Worksheets are available on the website; results must be submitted electronically before the due date.

Availability of reports and Memo will be communicated to participants once reports are approved. Report will be available within 5 working days of the due date & released on the website. Delays will be communicated.

9.8 Closing date for submission of results and consequence of late submission or no returns:
Closing due date will be included in the package insert, results submitted after the due date will not be evaluated.
It is the responsibility of the participants to do root cause analysis and implementation of corrective actions.

9.9 Contact details of PTS coordinator available on PT report and in the INF-QCL-005.

9.10 Instructions on returning of proficiency test items: Available on package insert and Information Booklet.

9.11 Sample Reception:
Sample dispatch notification and actions to be taken if sample were not received or are unsuitable for use:
A communication via email will be sent out to notify participants that samples were issued.
Communicate to the SANBS Proficiency Lab if samples were not received within 5 days from issue via email and telephone.
Perform visual inspection on samples on receipt and record on worksheets under sample integrity. Checks should include temperature monitoring, checking for haemolysis, leaking samples, labels attached properly and information printed must be readable.
Discard unsuitable samples (leaking, not labelled, and unusable) as bio hazardous material; inform the Proficiency office via email.
Samples must be treated and discarded as Biohazardous material.
Complete worksheet, indicating unsuitable samples and email to Proficiency@sanbs.org.za and request new samples. Update samples on electronic system as unsuitable.

9.12 Evaluation of submitted results.
Acceptable responses are either predetermined or based on statistical analysis using Z scores (which is the measurement of bias relative to the overall mean).
Evaluation of predetermined results will be determined by QC during production.
Results obtained by QC during production and results obtained on the due date must correspond. The final acceptable response is at the discretion of the Proficiency Advisory Committee (PAC).
The reporting and evaluation of Crossmatching, antibody identification, donation testing, SLS, and virology is done electronically.

9.13 Corrective action:
Corrective actions should be taken for all results that are not acceptable.
For external participants root cause analysis and implementing corrective actions is the responsibility of the participant.

9.14 Disputes and appeals:
Participants should submit Disputes in writing by logging a customer complaint:
External participants: by telephoning the toll free number (+27) 0800119031.
Internal participants: by logging a notification on SAP.
The final acceptable response is at the discretion of the Proficiency Advisory Committee.

10. Sample Integrity

Participants must check and record sample integrity on receipt of samples.
Methods for Stability testing procedures for the different schemes are included in relevant operating procedures.
Stability Samples are tested by the staff and results reviewed by the Scheme Manager or Second in Charge on the closing date.

Five days is the average time determined for delivery of Proficiency samples.

10.1 Crossmatch Proficiency Test Program

The Cross-match Program comprises Blood Grouping (ABO and Anti-D), Antibody Screen, Antibody Identification and Compatibility testing. The Crossmatch Proficiency Program includes manual as well as automated testing.

10.2 Survey Requirements

This module is designed for Laboratories that routinely prepare blood for transfusion as well as for labs that perform patient blood groups and DAT. Patients sample can be with or without allo-antibodies.

Any specific tests that are outside the scope of the laboratory and would normally be referred to a central or reference laboratory will not affect the performance assessment.

Only those tests required for the transfusion of compatible units will be assessed.

10.3 Sample specifications

There are 10 surveys per year consisting of patient red cell sample, patient serum sample and 4 donor samples.

10.4 Selection Criteria

Availability of blood stock determines the specificity of tests sent out for the surveys. This may or may not include antibody positive plasma as well as antigen positive or negative red blood cells.

In addition, customer satisfaction questionnaires are distributed annually to provide the SANBS Proficiency Test program with participant feedback regarding the Proficiency programs.

10.5 Reports and Assessment

The Crossmatch Proficiency Test program targets and acceptable responses are pre-determined. Results obtained by QC during production and results obtained during and at the due date must correspond. The final acceptable response is at the discretion of the Proficiency Advisory Committee (PAC). Variation between methods is taken into consideration during the evaluation.

11. Antibody and Titration Proficiency Test Program

11.1 Survey Requirements

This module is designed for laboratories that routinely perform Antibody identification and Titration tests. There are 10 surveys per year running from February to November. The Antibody and Titration Proficiency Test Program includes manual as well as automated testing.

11.2 Sample specifications

There are 10 surveys per year consisting of a patient serum sample.

11.3 Selection Criteria

Availability of blood stock determines the specificity of tests sent out for the surveys. Clinically significant antibodies (IgG) able to cause HDN and or Transfusion reactions are selected for this program.

11.4 Reports and Assessment

The Antibody Identification acceptable range consensus ±2 titres is allowed for the range based on results obtained by participants. The final acceptable target is at the discretion of the Proficiency Advisory Committee.

In addition, customer satisfaction questionnaires are distributed annually to provide the SANBS Proficiency Test program with participant feedback regarding the Proficiency programs. Variations between methods are taken into consideration during evaluation.

12. Donation Testing Module Reports and Assessment

12.1 Survey Requirements

This module is designed for laboratories that routinely perform ABO, Rh, Antibody screen, and Titre tests on donor samples. There are 12 surveys per year running from January to December.

12.2 Sample specifics-ACD/P

Each survey consists of 10 Random ACD/P specimens from the routine racks of samples that have been tested and all results confirmed.

12.3 Selection Criteria

Samples should include: A positive, A negative, B positive, B negative, O positive, O negative, AB positive & AB negative as well as at least 1 high titre sample.

12.4 Reports and Assessment

The Donation testing proficiency targets and acceptable responses are pre-determined based on original data from the instrument and results reported for the donation on the IT system.

13. Hemocue Hb IQAS Proficiency Program

13.1 Survey Requirements

This module is designed for Donor Clinics that routinely perform point of care Hb testing on Blood Donors. The HemoCue IQAS is designed to assist in gauging the performance of the HemoCue instrument by comparison with other centres. There are 12 surveys per year running from January to December.

13.2 Sample Specifics

There are 12 surveys per year consisting of one WB sample per instrument.

13.3 Selection Criteria

Hb value ranges between 10.5 g/dl – 18.5 g/dl.

13.4 Reports and Assessment

Results are submitted electronically by the participant's staff before the due date. Statistical analyses of results are done. Results from participant must be with-in 2 SD (standard deviations) of the mean for the specific batch to be acceptable. The mean and SD is calculated from the results received from all participants. The acceptable range can be calculated as follow:

- Lower limit: Mean – (2xSD).
- Upper limit: Mean + (2xSD).

HemoCue Hb targets and acceptable ranges are based on statistical analysis of submitted results using the Z scores.

Reports are available electronically.

In addition, customer satisfaction questionnaires are distributed annually to provide the SANBS Proficiency Test program with participant feedback regarding the Proficiency programs.

14. HLA and Proficiency Test Program

14.1 Survey Requirements-Plasma

This module is designed for laboratories that perform HLA & Platelet antibody testing. There are 4 surveys per year from January till December.

14.2 Sample specifics

There are 4 surveys per year; each survey consists of 3 frozen serum samples Samples selected must be representative of routine samples and include all possible outcomes.

14.3 Selection Criteria

Random serum samples and a copy of the original results are sent to the QC Department from the SLS Department. The specimens are relabelled by the QC department as Proficiency Test Samples and issued to the respective Laboratories and retested according to their Standard Operating Procedure.

14.4 Reports and Assessment

The HLA proficiency targets and acceptable responses are pre-determined based on original data from the relevant Laboratory.
Results are evaluated electronically against memo. Percentage consistency compares the original results with the Proficiency results.

15. Virology Proficiency Test program

15.1 Survey Requirements

This module is designed for Laboratories and areas that routinely perform HIV, HBsAg, HCV and TPHA testing including rapid HIV testing.

15.2 Sample specifications

There are 4 surveys per year consisting of 6 serum samples.

15.3 Selection Criteria

Samples include Virology reactive and non-reactive samples.
In addition, customer satisfaction questionnaires are distributed annually to provide the SANBS Proficiency Test program with participant feedback regarding the Proficiency programs.

15.4 Reports and Assessment

The HIV Proficiency targets and acceptable responses are pre-determined based on original data from the instrument and results reported for the donation on the IT system.

16. DAT Proficiency Test Program

16.1 Survey Requirements

This module is designed for laboratories that performs DAT testing.

16.2 Sample specifications

There are 4 surveys per year consisting of red cell samples.

16.3 Selection criteria

Samples include Positive and Negative samples

16.4 Reports and Assessment

DAT targets are pre-determined based on results obtained during production.

Revision Summary

VERSION NUMBER	REVISION DETAILS
5	• Removed CP-QMD-015. • Included DAT on point 16. • Removed logging of notifications under 9.8.