TRANFUSION SERVICE PROFICIENCY PROGRAM: INFORMATION BOOKLET

SANBS
Registration No. 2000/026390/08

1. Program Contact Information:

SANBS
Private Bag X 14
Weltevreden Park
1715
Tel: +27 11 761 9226
Fax: +27 86 682 8505

SANBS Proficiency Program Private Bag X14 Weltevreden Park 1715	Telephone No Fax No E-mail	+27 11761 9000 +27 86 682 8505 proficiency@sanbs.org.za

SANBS Proficiency Program Manager	Telephone No Fax No E-mail	+27 11 7619265 +27 11 7619259 Truscha.Niekerk@sanbs.org.za

SANBS Transfusion QAP Program Second in Charge	Telephone No Fax No E-mail	+27 11 7619297 +27 11 7619259 Pontsho.Simelane@sanbs.org.za

SANBS Proficiency Coordinator	Telephone No Fax No E-mail	+27 11 7619226 +27 86 6828505 Christelle.Bothma@sanbs.org.za Yvette.McGorrell@sanbs.org.za Tiisetso.Masitha@sanbs.org.za Nondumiso.Ndlovu@sanbs.org.za

SANBS Transfusion QAP Administration Assistant	Telephone No Fax No E-mail	+27 11 7619218 +27 11 7619259 Ntefo.Lekotlopo@sanbs.org.za Naomi.Mampuru@sanbs.org.za

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
- Statistics
- ICT
- Quality Systems
- Quality Control

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 permanent employed staff. The team includes Second in Charge, Program Co-ordinator and Administration Assistant and supported by the SANBS Proficiency Advisory Committee. If participants have a query, they can contact the Program office by logging a ticket on the website proficiency@sanbs.org.za , phone (+27) 011 761 9226. If no response received in 24 hours, they should email the office.

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.

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 and available electronically and/or on Proficiency *Programmer Enrolment* (FRM-QCL-085).

The SANBS PTS Coordinator electronically generates an updated Distribution list 2 weeks prior to the production date 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 participant's report.

Registration of an institution can be done at any time during the cycle. Enrolment needs to be entered 2 weeks prior to the production date the Proficiency. PT Coordinators will review enrolment request and approve or reject based on availability of requested material. It is recommended that all participants enrol prior January to avoid request being rejected.

5. Proficiency Program (PP) Certificates

5.1 The SANBS Proficiency Program certificates of enrolment are initiated by the SANBS Proficiency Office and issued by the SANBS Proficiency system, after receipt of an accepted quotation from the external participants. The Proficiency Program Office is located in the Quality Control department, South African National Blood Service, Constantia Boulevard, Constantia Kloof, Roodepoort.

5.2 The SANBS PP Certificates of Participation are initiated the PP office. A Certificate of Participation is issued to participants for each program your laboratory is enrolled with by the SANBS Proficiency system. 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 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:
Note: The Proficiency Test Instruction Sheet will be sent to the participants as an attachment to the "Proficiency Set Ready" e-mails sent by the SANBS Proficiency System on the day of issue.
Result Sheets for the different surveys can be downloaded from the website. Survey results are submitted online.
   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 DAT Proficiency Test Program:
   DAT Proficiency Instruction Sheet (FRM-QCL-147).
   Proficiency Test – DAT Worksheet (FRM-QCL-146).
   7.7 PCR Aneuploidy Screening Proficiency Test Program
   PCR Aneuploidy Screening PT Program Workssheet (FRM-QCL-162).
   PCR Aneuploidy Screening PT Program Instruction (FRM-QCL-163).
   PCR Proficiency Testing Memorandum (FRM-QCL-164).
   PCR Aneuploidy Screening Proficiency Checklist (FRM-QCL-165)
   7.8 Proficiency Testing Program Manual Report.
   In the event of software error, reports will be generated manually using *Proficiency Testing Program report* (FRM-QCL-170).

8. PP Survey Samples
Note: External participant samples are issued with a *Proficiency External Delivery Note* (FRM-QCL-095) and *Proficiency Testing (PT) Dangerous Goods Declaration* (FRM-QCL-161).
   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. If this is not the case, then the respective packages are clearly marked with the specific transport temperature requirements.
   - All participants are notified once the PT item has been dispatched and are instructed to contact SANBS-PTS if the PT items are not received as per the schedule or the dispatch notification.
   - Participants are to follow the transport temperature guidelines provided on their PT consignments. In the event that the receiver will be re-distributing the PT samples, the hampers must be stored at 1-10°C immediately on receipt until further transportation. Transport according to the hamper label.
   - 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.

- HIV; HBV; HCV; TPHA
- 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 on the package insert provided via e-mail on the Proficiency issue date. It is also available on the "Proficiency distribution dates" document under the Information Tab on the PT website.

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. A N/A option exists to instances where test are not performed by participants results submitted as N/A will not be evaluated.
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 cannot be submitted after the due date.
It is the responsibility of the participants to do root cause analysis and implementation of corrective actions for non-submissions

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 using "Log a Ticket "functionality.
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 log a ticket.
Samples must be treated and discarded as Biohazardous material.
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 Crossmatch, antibody identification, donation testing, SLS, Virology, DAT and PCR is done electronically. Manual evaluation is only allowed in instances where system errors occur and notification are logged to investigate and correct errors.

9.13 Corrective action managed by participants:
Corrective actions should be taken for all results that are not acceptable.

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) 0800119031or via log a tick.
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.
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 Crossmatch Program comprises Blood Grouping (ABO and Rh), 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. Patient's 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 are allowed for the range based on results obtained by participants. In the event that 2 modes are calculated, the titer

results obtained in QC during production will be added to the participant results. A new mode will be calculated using *antibody Titre consensus* (FRM-QCL-115). 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. A variation between methods is 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. HLA and Proficiency Test Program
    13.1 Survey Requirements-Plasma
    This module is designed for laboratories that perform HLA & Platelet antibody testing. There are 4 surveys per year from January to December.
    13.2 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.
    13.3 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.
    13.4 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. Compliance is based on a comparison of the original results with the Proficiency results.

14. Virology Proficiency Test program
    14.1 Survey Requirements
    This module is designed for Laboratories and areas that routinely perform HIV, HBsAg, HCV and TPHA testing including rapid HIV testing.
    14.2 Sample specifications
    There are 4 surveys per year consisting of 6 serum samples per analyte.
    14.3 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.
    14.4 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.

15. DAT Proficiency Test Program
    15.1 Survey Requirements
    This module is designed for laboratories that perform DAT testing.
    15.2 Sample specifications

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

15.3 Selection criteria
Samples include Positive and Negative samples.

15.4 Reports and Assessment
DAT targets are pre-determined based on results obtained during production. 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.

16. PCR Aneuploidy Screening Proficiency Test Program

16.1 Survey Requirements-Plasma:
This module is designed for laboratories that perform PCR Aneuploidy Screening testing. There are 4 surveys per year from January till December.

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

16.3 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.

16.4 Reports and Assessment:
The PCR Aneuploidy Screening 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.

Revision Summary

VERSION NUMBER	REVISION DETAILS
11	• The Proficiency Test Instruction Sheet will be sent to the participants as an attachment to the "Proficiency Set Ready" e-mails sent by the SANBS Proficiency System on the day of issue. • Result Sheets for the different surveys can be downloaded from the website. Survey results are submitted online.