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 Operating hours	+27 11761 9000 +27 86 682 8505 proficiency@sanbs.org.za Monday to Friday; 08H00 – 16H00 (CAT)

SANBS Proficiency Scheme Manager	Telephone No Mobile E-mail	+27 11 7619265 +27 0828962420 Truscha.Niekerk@sanbs.org.za

SANBS Transfusion PT Scheme Manager	Telephone No E-mail	+27 11 7679872 Xoliswa.mpumlwana@sanbs.org.za

SANBS Proficiency Coordinator	Telephone No WhatsApp Line E-mail	+27 11 7619226/9288 082 450 4781 Tiisetso.Masitha@sanbs.org.za Mashudu.nevhungwili@sanbs.org.za Sinetemba.Ntlontlo@sanbs.org.za Ntsako.Manganye@sanbs.org.za

SANBS Transfusion QAP Administration Assistant	Telephone No E-mail	+27 11 7619218 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.
   - Learning 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 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 /9288. 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 available on the PT website under the information tab for all participants.
   The scope of the SANBS- PTS is described in INF-QCL-006.
   SANBS Laboratories are not charged for their participation, whereas external laboratories are charged a nominal service fee.

   Criteria for participation in the PTS
   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. Applications are reviewed according *to Proficiency Program Enrolment* (FRM-QCL-085).

   Coordinators will review enrolment request and approve or reject based on availability of requested material. Review of enrolment are done according to the criteria on FRM-QCL-085

   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 *Program Enrolment* (FRM-QCL-085).

   The SANBS PTS Coordinator electronically generates an updated Distribution list 2 weeks prior to the production date of a survey.
   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 updated 2 weeks prior to the production date of the Proficiency.
   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 and Impartiality:
   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 Worksheet (FRM-QCL-162).
   PCR Aneuploidy Screening PT Program Instruction (FRM-QCL-163).
   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 2-6°C immediately on receipt until further transportation. Transport according to the hamper label.
      - Transportation and packaging of participants' samples are subcontracted.
      - Validation of the stability of samples were performed and are available on the document management system.
   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 on receipt.
      - 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 or comments.
   9.4. Due date for each program will be stated on the Instruction Sheet provided via e-mail on the Proficiency issue date. The Instruction sheet is also available on the "Instruction Sheet" Tab found on the Information page.
   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 is 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. Due date for submission of results and consequence of late submission or no returns:
   Due due date will be included in the package insert; results cannot be submitted after the due date.
   A Due Date reminder for the submission of results will be electronically sent out by the Proficiency system, five days after the Issue date and one day before the final day.
   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 the instruction sheet and the Information Booklet under the sample reception section.
   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 predetermined. 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 evaluation of results and generating of reports are done electronically. Manual evaluation is only allowed in instances where system errors occur and notification/disputes are logged to investigate and correct errors.

9.13. Corrective actions are 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 via the "Log a Ticket process".
External participants: logging a ticket.
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.
Validation reports to confirm the stability of all samples are available
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 on the due 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 clinically significant 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.
Compatible (YES/NO): Refers to serological compatibility. IF a positive reaction (Agglutination) is observed in Coombs, the expected answer is NO, if a negative reaction (NO Agglutination) is observed the answer is YES
Transfuse YES/NO: Refers to the participants decision to transfuse the unit (YES) or not transfuse the unit (NO) based on the information available.
10.3. Sample specifications.
There are 10 surveys per year consisting of patient red cell sample, patient serum sample and 4 donor red cell 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 day before issue 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 10 surveys per year running from February to November.
    12.2. Sample specifics-ACD/P.
    Each survey consists of 10 whole blood samples.
    12.3. Selection Criteria.
    Samples should include: A, B, O, AB, and Rh positive and negative as well as at least 1 high titre sample where possible.
    12.4. Reports and Assessment.
    The Donation testing proficiency targets and acceptable responses are pre-determined based on results reported for the donation on the IT system.

13. SLS - Human Platelet Antibody (HPA) Proficiency Test Program.
    13.1. Survey Requirements-Plasma.
    This module is designed for laboratories that perform Human 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 HPA 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, HBV, HCV and TPHA testing. Samples are suitable for rapid HIV testing methods.
    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. The final acceptable response is at the discretion of the Proficiency Advisory Committee (PAC). Variation between methods is taken into consideration.
    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 Direct Antiglobulin Test - 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
14	• Added point 10.2 for Compatibility Yes/No and Transfuse Yes/No added • Amended Donation Testing Surveys from February to November • Updated Coordinator Details and WhatsApp contact number