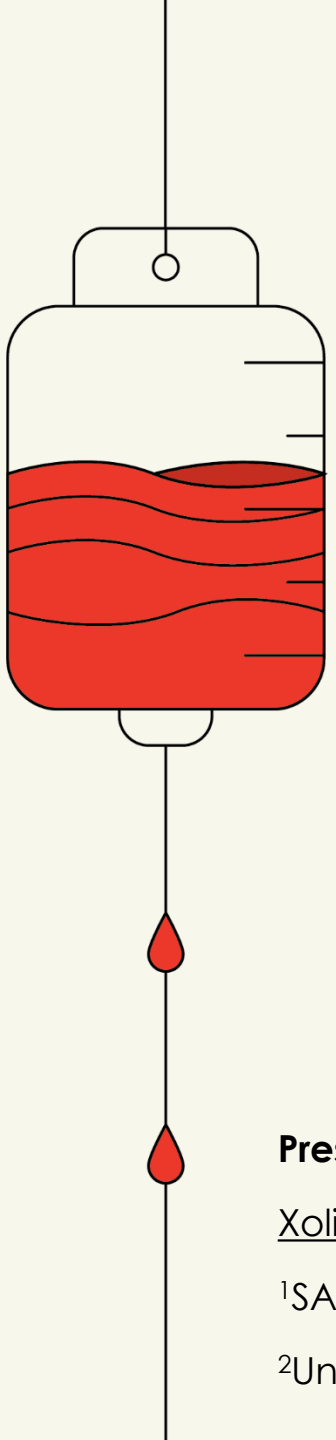

36th South African NATIONAL BLOOD Transfusion Congress

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SHAPING A SUSTAINABLE FUTURE

Establishment of a stable microbiology proficiency testing matrix in transfusion microbiology

Presenter:

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Introduction

- Proficiency testing (PT) assists in detecting laboratory errors, verifying laboratory processes and provides interlaboratory performance comparison.
- Participation in PT is an accreditation requirement for ISO 15189:2012.
- Medical laboratories should enroll in PT programmes that cover their scope, however, this not always possible in transfusion microbiology due unavailability of PT matrix samples.
- PT matrices mimic clinical samples in terms of composition, viscosity, turbidity and colour.
- The suitable PT matrix for transfusion microbiology is blood product based

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Introduction

- Quality control department in SANBS screens blood products in microbiology using bacterial culture methodologies.
- There is no formal PT programme available for these methods.
- Aim of the study
  - ❖ To develop and evaluate a stable matrix-equivalent microbiology PT programme using pooled platelets (PP) and red blood cells (RBC) as the basis matrix.

BacT/ALERT 3D (Culture)

BD FX400 (Culture)

Vitek II compact (ID and AST)

Study design and methodology

- Approval was obtained from SANBS and University of Johannesburg.
- A prospective cross-sectional study approached in 2 phases;
  - ❖ matrix preparation and preparation of samples for testing
  - ❖ sample testing .
- Samples were tested in 2 stages over 3 months.
  - ❖ Testing by the researcher to establish reference results and stability of the PT matrix.
  - ❖ Testing by the participating laboratories for evaluation purposes.
- Methods: Gram staining, Bacterial culture, Bacterial identification and Antimicrobial Susceptibility Testing (AST) in both testing stages.
- Bacterial culture was performed using the BacT/ALERT 3D and Bactec 9120 while Vitek II compact was used for AST.
- Cohen's kappa was used for statistical analysis (>0.75 indicating the high level of agreement).

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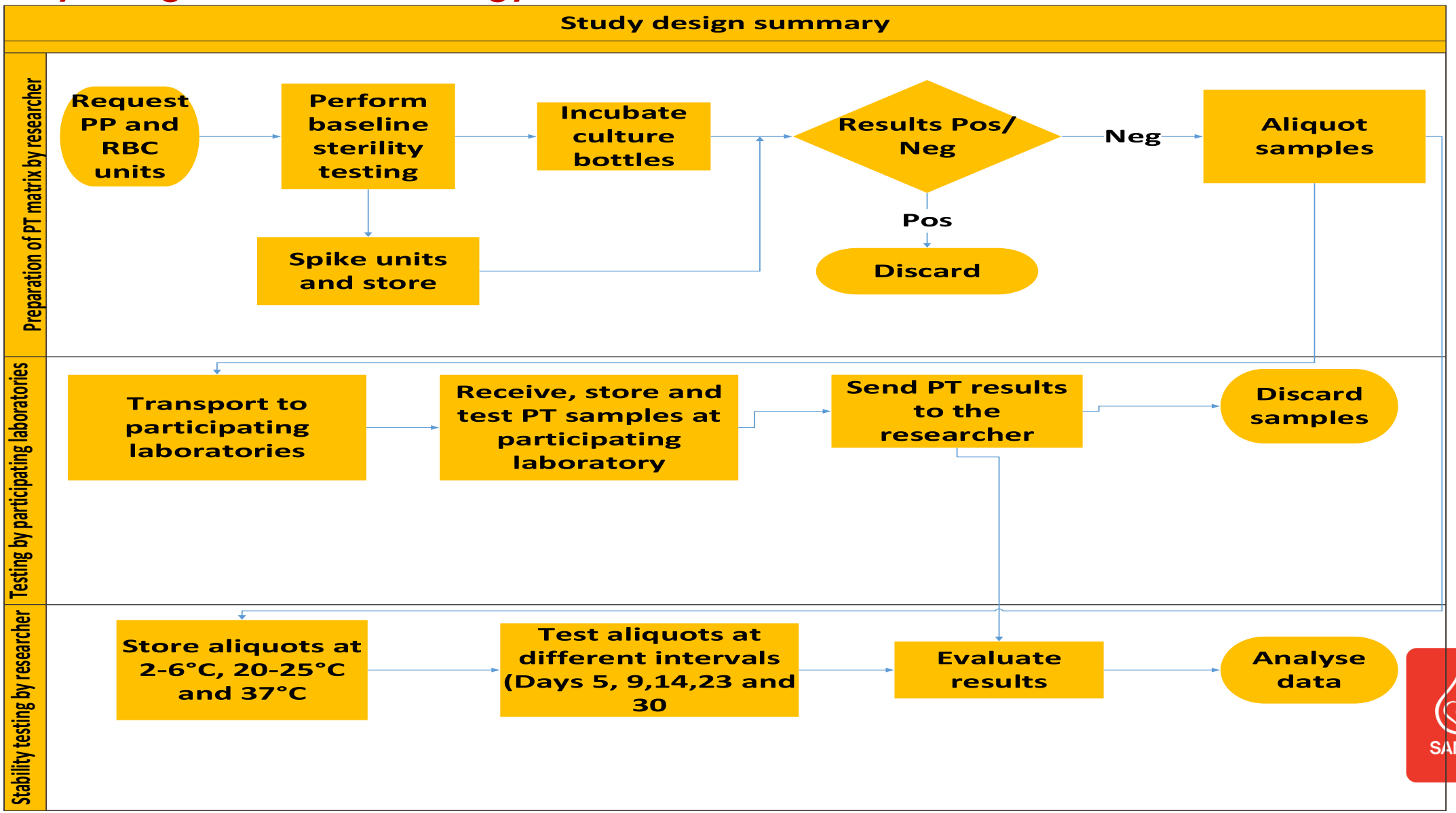
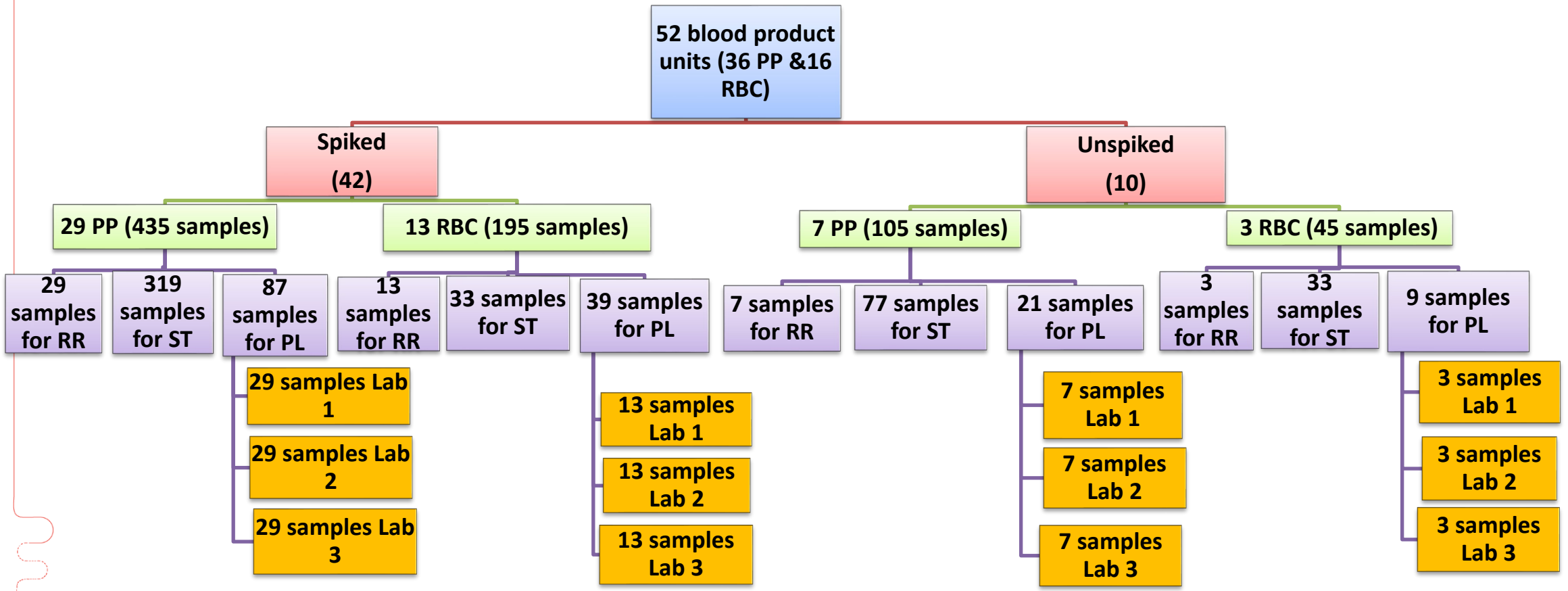
Study design and methodology



Study design and methodology



RR - Reference results
ST- Stability testing
PL - Participating laboratories

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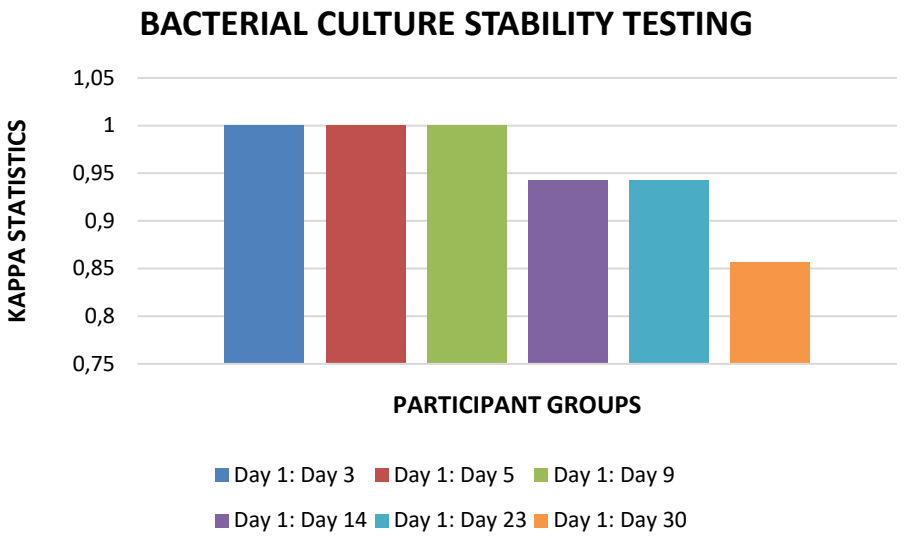
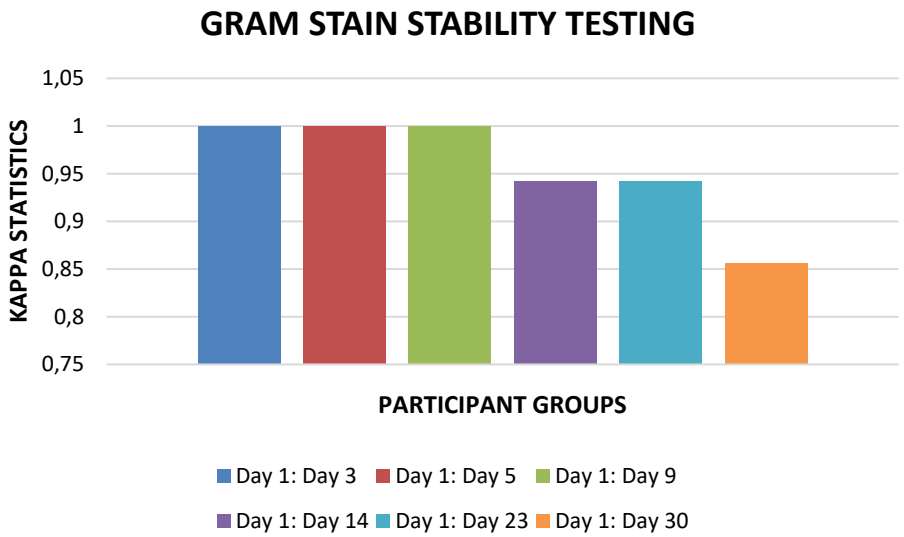
Results by researcher

Stability testing





- A high level of agreement for bacterial culture and Gram stain results was obtained throughout all stability detection days with kappa scores of >0.75
- Day 1 = Reference results

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Results by researcher

Stability testing

Bacterial identification stability testing	
Testing days	Kappa value
Day 1 versus Day 3	1,000
Day 1 versus Day 5	1,000
Day 1 versus Day 9	1,000
Day 1 versus Day 14	0,955
Day 1 versus Day 23	0,955
Day 1 versus Day 30	0,842

- A kappa score of 1.000 was obtained on AST results for all bacteria that required AST testing.

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Results by participating laboratories

- Kappa score of 1.000 was obtained on AST results for all bacteria that required AST.

Participants	Bacterial Culture	Gram Stain	Bacterial Identification
Lab 1 vs Reference results	1.000	0.947	0.958
Lab 2 vs Reference results	1.000	0.920	0.958
Lab 3 vs Reference results	1.000	0.920	0.894

- Bacterial culture had 156/156 = 100% compliance
- Gram stain had 151/156 = 97% compliance
- Bacterial Identification had 149/156 = 96% compliance
  - *Staphylococcus epidermidis*
  - *Bacillus cereus*
  - *Staphylococcus aureus*
  - *Listeria monocytogenes*
  - *Streptococcus pyogenes*
- AST had 156/156 = 100%

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Discussion

Stability results

- PT matrices were stable for up to 23 days in all storage conditions between 2°C and 37°C.
- The results obtained during stability testing demonstrated that storage time of up to 23 days was acceptable, except for *Listeria monocytogenes*.
- *Listeria monocytogenes* was stable for 14 days.
- This strains requires certain growth substances which were not provided in the platelet and RBC concentrates.
- The growth substances include amino acids such as leucine and vitamins such as riboflavin.
- *Morganella morganii* could not be identified on day 30.
- This strain was validated by the Paul-Ehrlich-Institut (PEI) for only 7 days in platelets and never validated in red blood cells.

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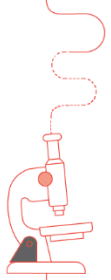
Discussion

Evaluation from participating laboratories

- All positive and negative cases were identified correctly by the participating laboratories on bacterial culture, showing a high level of agreement.
- There were no discrepancies observed between the reference results and the participating laboratories for AST results, 100% compliance was obtained.
- 3% percent of discrepant results were obtained for Gram stain and bacterial identification
- *Listeria monocytogenes* could not be identified by all 3 participants.

Conclusion

- Blood product based matrices provided a possible solution in closing the gap of unavailable PT matrix for transfusion microbiology
- PT matrices are suitable to be sent to areas where delivery can be achieved within seven days from dispatch.
- This matrix covers Gram staining, bacterial screening, bacterial identification as well as antimicrobial susceptibility testing.
- The matrices need to be replicated and validated to see if suitable for shipments to African Blood transfusion services to support blood safety.



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- SANBS Quality Control and Proficiency Testing (PT) teams.
- Research completed as part of my Master's dissertation.
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THANK YOU