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SHAPING A SUSTAINABLE FUTURE

Quality Control Testing on Leukodepleted Blood products

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Introduction

- Removal of leucocytes from various blood products to $<5 \times 10^6$ ul cells in a blood component has the following benefits:
 - Minimizes febrile non-hemolytic transfusion reactions
 - Minimizes HLA alloimmunization and platelet refractoriness in multi-transfused patients.
 - Prevents transmission of leukotropic viruses such as EBV and CMV.
- Currently the best leukoreduction can be achieved by the two method below:



1. Apheresis instrument used at donor clinics.



2. Leukofilters, used both in laboratory processing of blood product and at patient bed side during transfusion



Introduction

- Trima and Heamonetics apheresis instrument are used in SANBS apheresis clinics.
- SANBS Processing laboratories use Kanbarrier erythrocyte leukocyte Filters laboratory model (with Sepacell Filter) to leukodeplete RBC products
- The QC lab performs white cell count (WCC) test with two different instrument that have different principles to measure leukocytes. We compared these in terms of sensitivity and accuracy.
- At least one percent of all units processed is sent to QC laboratory for testing.



Aim

- The aim of the study was to establish if the two testing methods used in QC department namely,
 - Haematology Advia 2120i and the
 - Flow Cytometry FC500,are able to detect leukocytes of $<5 \times 10^6$ ul cells per unit on leukodepleted units.



SANBS QC Lab





Method

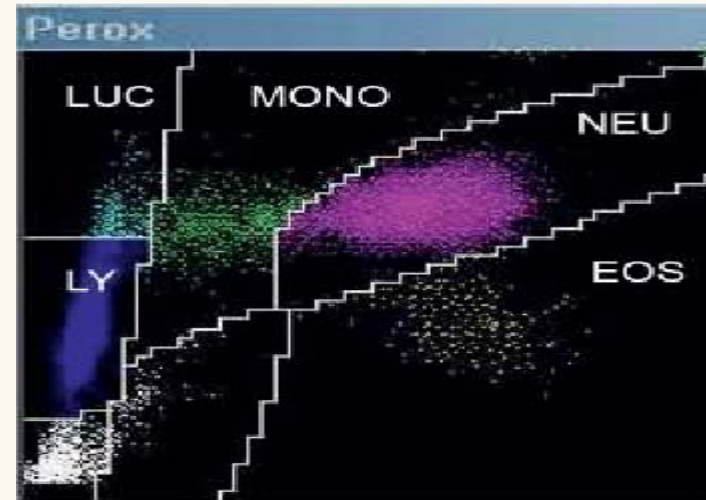
- A retrospective review of quantitative laboratory data of leukodepleted product samples for the year 2021 was performed.
- Samples included leukodepleted red cell products (RBCFL) and Apheresis platelets products (PLCA)
- QC laboratory uses two analyzers to test for white cell count (WCC) on samples, a Haematology and Flow cytometry instrument.
- Both methods use the laser technology with different principles which are sensitive and accurate in counting white blood cells.
- Statistical data was analyzed using the p value to determine if there was significant difference between test results obtained by the two methods.



Method



- Siemens Advia 2120i, this flow cytometry-based system uses light scatter, differential white blood cell (WBC) lysis, and myeloperoxidase and oxazine 750 staining to provide a complete blood cell count, a WBC differential, and a reticulocyte count.



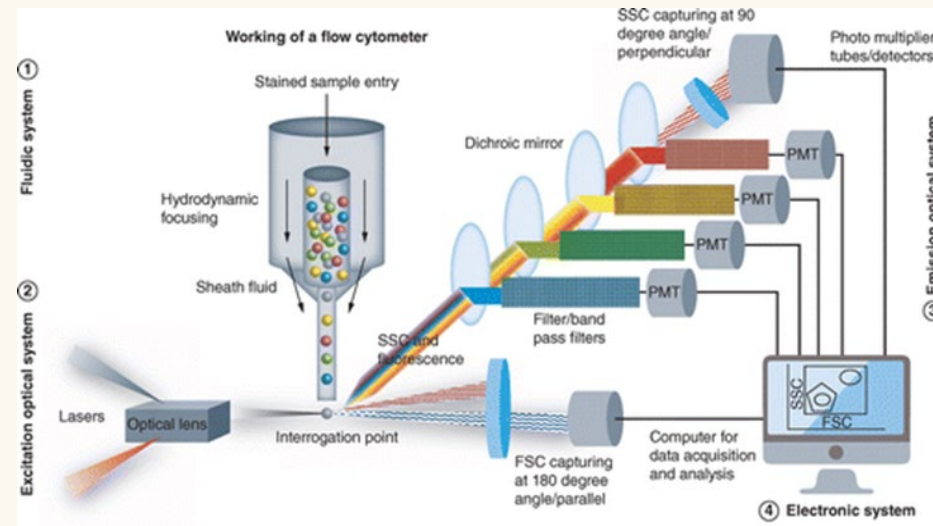
- WCC scatter graph



Method



- Beckman Coulter, FC500 Flow Cytometer, this instrument can simultaneously measure forward scatter, side scatter, and five fluorescent dyes using one or two lasers at 488 nm and either 635 nm (Solid-state laser) or 633 nm (HeNe laser). Therefore, the instrument can perform correlated multiparameter analyses of individual cells .

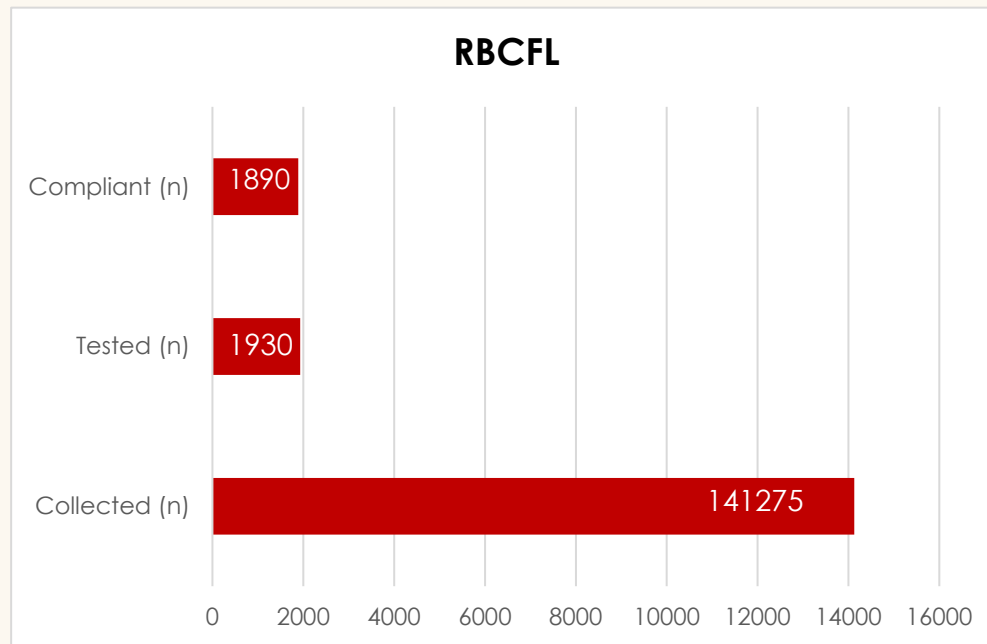


- Laser - Flow Cytometry Hydrodynamic Focusing Cell Diagram



Results

- 141 275 RBCFL units were produced in 2021, 1 930 samples were tested and 1 890 (98%) were QC compliant.
- 1 930 samples were tested on both methods and results were compared.
- The average WCC per product was $0.01 \times 10^6 \text{ul}$ for the RBCFL on both methods.

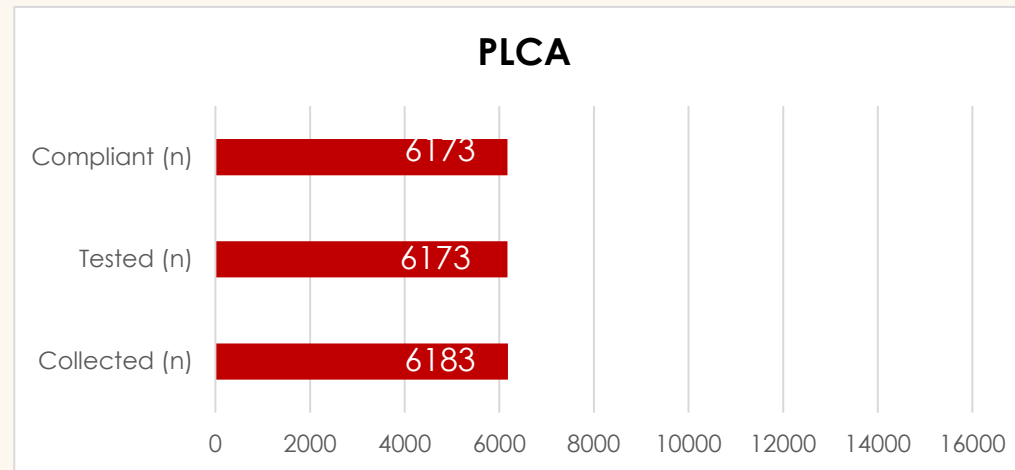


- 1% of the production is tested for product QC



Results

- Of the 6 183 Apheresis platelets (PLCA) produced in 2021, 6 173 were tested and 6 173 (100%) were QC compliant.
- 6 173 samples were tested on both methods and results were compared.
- An average WCC per product was $0.01 \times 10^6/\text{ul}$ for the Apheresis platelets for both methods.



- A 100% correlation and a p value of <0.05 was obtained between the two methods for both RBCFL and PLCA showing no significant difference.





Conclusion

- The leucodepletion methods used in SANBS to reduce white cells in blood and platelet products are effective in removal of leucocytes below the set threshold.
- The two testing methods used in QC department,
 - Haematology Advia 2120i and the
 - Flow Cytometry FC500,are able to detect leukocytes of $<5 \times 10^6$ ul cells per unit on leukodepleted units
- We can therefore be confident that we achieve the international benchmark of $<5 \times 10^6$ ul and that we provide products that will limit the risk of alloimmunization and associated risks in transfused patients.



Acknowledgments

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- Thank you to the QC team for their support and dedication.





Thank you