**Operations Testing Department**

The Operations Testing Department performs routine screening for Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Serum Ferritin and syphilis as well as the blood grouping (including ABO, Rh, Irregular antibody screen and allo-agglutinin titer test) on all units of donated blood. The WHO regulations only recommend performing serological screening using 4th generation assays whereas Food and Drug Administration (FDA) regulations stipulate mini-pool (16) nucleic acid testing whereby 16 donations are pooled together and tested. SANBS, however decided to be more stringent in its screening approach due to the high prevalence of disease in South Africa, and has implemented Individual Donation Nucleic Acid Testing (ID-NAT) in parallel to serological screening. South Africa was the first country in the world to implement ID-NAT to screen all blood donations on a large scale in October 2005. This screening has reduced the infectious window periods for HIV, HBV and HCV to 5, 15 and 3 days respectively.

The Operations Testing department of SANBS consists of two state of the art ISO 15189 accredited testing laboratories, one in Johannesburg, Gauteng and the other in Mount Edgecombe, Kwa-Zulu Natal, a Quality and Projects Section, a Virology Reference Laboratory and a National Bio-Repository.

The Donation Testing laboratories test approximately 1 022 000 donations per annum; 685 000 in Johannesburg and 337 000 in Mount Edgecombe. The Mount Edgecombe laboratory tests donations from Kwa-Zulu Natal, the Eastern Cape and the Free State / Northern Cape while the Johannesburg laboratory tests donations from all other areas excluding the Western Cape. The testing performed in each laboratory is identical.

The **Donation Testing laboratory** is broken into three sections with specific testing and functions performed in each:

 Blood Grouping

 Virology

 Nucleic Acid Amplification Technology (NAT)

**Blood Grouping**

This includes performing an ABO blood group and Rh type, an allo-agglutinin titre test for high titre antibodies, an antibody screen for irregular antibodies and a serological test for syphilis. This testing is currently performed on high throughput automated instruments. Any tests found to be inconclusive are confirmed manually or sent to the SANBS Red Cell Serology laboratory for further testing and confirmation.

**Virology**

Serological screening for HIV, HBV and HCV is performed on every unit of donated blood. Anti-HIV I and II, Hepatitis B Surface antigen (HBsAg) and Anti-HCV testing is currently performed on a fully automated virology screening system which uses chemiluminescent microparticle technology. Any unit found to be initial reactive is repeated in duplicate and confirmatory testing is performed to confirm viral positives.

Serum Ferritin testing was introduced in 2021. Serum Ferritin screening is performed to assess the donors iron stores. If they are depleted this could be an indication that the donor has iron deficiency and should not be donating until the iron stores are the acceptable normal range. All donors will be screened once to determine a base line and thereafter every forth donation unless the levels are low in which case a serum ferritin test will be performed at the donors next donation to confirm the low levels.

**Nucleic Acid Amplification Technology (NAT)**

In 2005 ID-NAT was introduced in South Africa. Every donation is tested using molecular techniques to detect Hepatitis B virus Deoxyribonucleic Acid (HBV DNA), Human Immunodeficiency virus Ribonucleic Acid (HIV RNA) and Hepatitis C virus Ribonucleic Acid (HCV RNA) on a fully automated NAT Screening system. Units found to be positive are repeated in duplicate and additional testing is performed to identify the viral marker.

The virology and NAT results are usually both positive. This is known as a concordant positive. Units where the NAT result is positive but the virology result is negative are known as NAT yields. Units in which the virology result is positive but the NAT result is negative are known as serology yields. Further testing is performed on these units to confirm the results. The donor is also contacted to obtain follow-up specimens for further testing and confirmation of results.

All donors who are confirmed concordant positive for a viral marker or who are found to be a NAT or serology yield are contacted and counselled by the SANBS Medical division. The 95% and 50% level of detection of the NAT assay for HIV, HBV and HCV is 6.9 and 5.0 copies/mL, 43.1 and 4.5 copies/mL and 21.4 and 3.3 copies/mL respectively.

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Manager KZN: Wendy Sykes

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Donation Testing operating times:

Johannesburg:

* 06:00 – 18:00 Monday to Friday
* 06:00 – 14:00 Weekends and Public holidays

Mount Edgecombe:

* 05:00 – 16:00 Monday to Friday
* O5:00 – 14:00 Weekends and Public holidays

**The Quality and Projects**  department is responsible for ensuring the quality of the testing performed in the laboratory. Quality assurance (QA) specimens, both internal and external are tested on a daily basis on each of the systems used. These are checked and must be within specified ranges prior to releasing any results. Standard Operating Procedures (SOPs) exist for all processes performed and all staff are trained and found competent to these procedures.

All instrumentation, kits and reagents used for testing are evaluated prior to implementation and routine use. Each new batch of kits or reagents received is validated upon receipt and must meet specific requirements for use.

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Quality and Projects operating times:

* 07:00 – 15:00 Monday to Friday

The **Virology Reference Laboratory** is responsible for all follow-up investigations on viral discordant test results by means of extensive repeat plasma bag testing as well as tests on these donors after they have been recalled. The laboratory utilise resources from the virology and NAT section, but additional to this also perform specialized testing for confirmation and research purposes. Data management and validation of viral positives leading to information for risk and trend analysis, is done by this section. Evaluations and research form an integral part the laboratory function.

Contact details:

Manager: Genevieve Jacobs

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Virology Reference Laboratory operating times:

* 08:00 – 16:00 Monday to Friday

The **National Biorepository** stores and aliquots plasma from donations which are found to be viral positive. This plasma is available to assay developers, quality control (QC) manufacturers, external QA programmes and research institutions worldwide and is also used in international collaborations.

Contact details:

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National Biorepository operating times:

Johannesburg:

* 07:00 – 15:00 Monday to Friday

Mount Edgecombe:

* 07:00 – 15:00 Monday to Friday

**Residual Risk**

We currently estimate the residual risk of infection via a blood product (using a worst case scenario of one virion in a red blood cell (RBC) unit as being infectious) at 1:80,000, 1:40,000 and 1:21,000,000 for HIV, HBV and HCV respectively. However in reality, since the implementation of ID-NAT in 2005 SANBS has had two reported case of HBV transmission through a blood transfusion, one reported transmission case of HIV and no cases of transfusion transmitted HCV in over 7 million donations.