
SANBS
Registration No.2000/026390/08
CLINICAL
APHERESIS SERVICES
THERAPEUTIC SERVICES FOR SOUTH AFRICA
INF-STS-043
1099779 Rev 0
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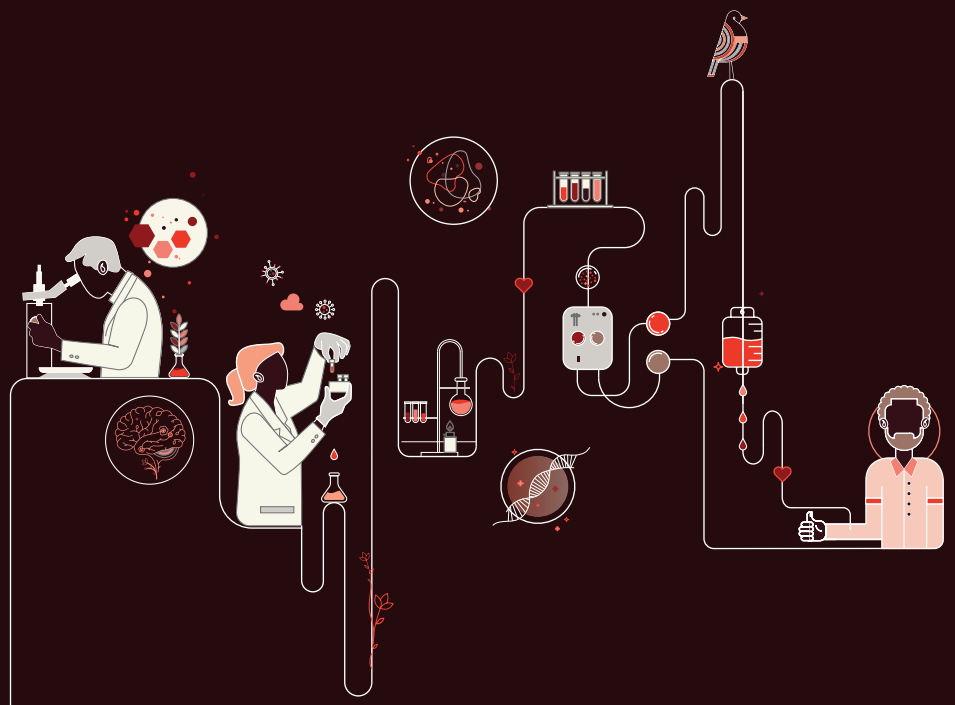
Contact us : 082- 555- 9294



SPECIALISED THERAPEUTIC SERVICES

MOBILE CLINICAL APHERESIS SERVICES FOR SOUTH AFRICA

SANBS

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At SANBS, it is our mission to reliably provide trusted blood products to all patients at a level of cost, efficiency and quality that meets the needs of our stakeholders while innovating to improve patient outcomes. We look forward to assisting you with all your clinical apheresis requirements. We can be reached on 082 555 9294 or therapeutics2@sanbs.org.za for any queries or to make a booking

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SPECIALISED THERAPEUTIC SERVICES

MOBILE CLINICAL APHERESIS SERVICES FOR SOUTH AFRICA

This document provides information on the clinical apheresis services offered by the South African National Blood Service.

OVERVIEW

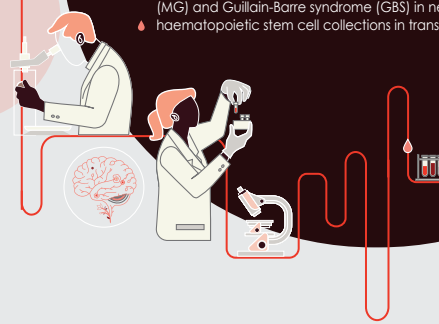
SANBS Specialised Therapeutic Services (STS) department provides life-saving clinical apheresis services for a range of clinical specialities including haematology, neurology, oncology, transplant and nephrology, to adult and paediatric patients across South Africa. Our team comprises more than 25 staff including therapeutic nursing specialists, a quality team, administrative staff and specialist doctors. Patients are treated by our internationally certified therapeutic specialists at the hospital bedside. SANBS performs over 2000 clinical apheresis procedures annually.

WHAT DOES CLINICAL APHERESIS INVOLVE?

Apheresis is a procedure in which whole blood is removed from a patient and separated into different components via centrifugation using a cell separator device. The blood component of interest is removed, and the rest of the blood is returned to the patient. The services are performed by highly trained nurses using using apheresis technology. There are over 80 different diagnostic indications with many patients requiring critical care.

In SA the most common indications for clinical apheresis include:

- plasma exchange for Thrombotic Thrombocytopenic Purpura (TTP) in haeamatology.
- plasma exchange for neuromyelitis optica (NMO), myasthenia gravis (MG) and Guillain-Barre syndrome (GBS) in neurology.
- haematopoietic stem cell collections in transplant /oncology.



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AMERICAN SOCIETY FOR APHERESIS (ASFA) GUIDELINES

The American Society for Apheresis (ASFA) publishes evidence-based guidelines for the use of clinical apheresis which are updated every three years. The 9th edition is available at:

https://www.ammtac.org/docs/articulos/Guias%20ASFA%202023_compressed.pdf

These guidelines provide recommendations on the level of evidence, frequency and number of treatments and replacement fluids to be used for each condition. All conditions are categorised as level I-IV namely:

- I - apheresis is accepted as first-line therapy, either as a primary standalone treatment or in conjunction with other modes of treatment
- II - apheresis is accepted as second-line therapy, either as a standalone treatment or in conjunction with other modes of treatment
- III - optimum role of apheresis therapy is not established and decision-making should be individualised
- IV - published evidence demonstrates or suggests apheresis to be ineffective or

SANBS uses these guidelines to prioritise patient referrals and to guide treatment plans.

THE RANGE OF CLINICAL APHERESIS SERVICES AT SANBS

HAEMATOPOIETIC STEM CELL COLLECTION SERVICES

SANBS STS department provides a range of services to transplant facilities across South Africa and neighbouring countries for autologous and allogeneic haematopoeitic stem cell transplants. Patient and donor selection is performed by the transplant facility. Once the donor/ patient is assessed to be fit and healthy, the stem cell harvest can be booked and mobilisation of the donor can begin. On the day of collection, the donor is reassessed and if in good health then venous access is obtained. Good venous access is essential for all apheresis procedures to ensure continuous blood flow to and from the cell separator machine. Peripheral vein access may be used where appropriate, however, when peripheral veins cannot support the required blood flow rates, central venous access will be required. Our team is available to perform a vein assessment and guide you on the appropriate venous access for your patient. The stem cell harvest entails removing whole blood from the donor and separating it into its various components. The circulating stem cells are removed and directed to the collection bag by the cell separator and the red cells, white cells, and platelets are returned to the patient. Citrate, an anticoagulant, is added to the extracorporeal circulation to prevent clotting. On completion of the stem cell harvest, the stem cell product is transported to the Cellular Therapy Laboratory at SANBS for testing, processing, and storage.
SANBS is extremely proud to be a JACIE-accredited haematopoietic stem cell transplant service provider. This international accreditation is awarded to centres that show ongoing excellence in patient outcomes and stringent commitment to quality standards.

THERAPEUTIC PLASMA EXCHANGE

During a therapeutic plasma exchange (TPE) procedure, whole blood is removed from the patient. The plasma is separated from the rest of the blood using a cell separator machine and the red cells, white cells, and platelets are returned to the patient. In this way, any disease-causing substances in the plasma are removed. A plasma replacement fluid is given to the patient too, to compensate for the plasma that has been removed. Citrate, an anticoagulant, is added to the extracorporeal circulation to prevent clotting.
The fluid used to replace the removed plasma is usually 4% human albumin or Gelofusine for neurological/ renal conditions and fresh frozen plasma (FFPs) for haematological conditions. TPE removes coagulation factors with the plasma, therefore when albumin/Gelofusine are used as a replacement fluid, monitoring of coagulation factors is required. American Society for Apheresis (ASFA) guidelines recommend INR, PTT, and fibrinogen testing before the first TPE procedure and on alternate days thereafter. When coagulation abnormalities are present, FFP, cryo-poor plasma, and/or cryoprecipitate may be added to the fluid replacement.
Good venous access is essential for all TPE procedures to ensure continuous blood flow to and from the cell separator machine. Peripheral vein access may be used where appropriate, however, when peripheral veins cannot support the required blood flow rates (especially when multiple procedures are necessary), central venous access will be required. Our team are available to perform a vein assessment and guide you on the appropriate venous access for your patient.

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NEUROLOGICAL CONDITIONS TREATED WITH PLASMA EXCHANGE

Over 25 neurological conditions are managed with plasma exchange. In South Africa, the most common conditions include:

- Neuromyelitis Optica
- Myasthenia Gravis
- Acute Inflammatory Demyelinating Polyradiculopathy/ Guillain-Barre syndrome (GBS)
- Chronic Inflammatory Demyelinating Polyradiculopathy (CIDP)

HAEMATOLOGY AND ONCOLOGY CONDITIONS TREATED WITH PLASMA EXCHANGE

The most common haematology/oncology conditions treated with plasma exchange include:

- Thrombotic Thrombocytopenic Purpura (TTP)
- Thrombotic Microangiopathy
- Atypical Haemolytic Uraemic Syndrome
- Hyperviscosity in Monoclonal Gammopathies
- Cryoglobulinaemia
- Hyperleukocytosis
- ABO Incompatible Transplants

NEPHROLOGY CONDITIONS TREATED WITH PLASMA EXCHANGE

Renal conditions managed with plasma exchange include:

- ANCA-associated Rapidly Progressive Glomerulonephritis
- Anti-Glomerular Basement Membrane Disease
- Recurrent FSGS after Transplant
- Renal Transplant Rejection /Desensitisation

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CLINICAL APHERESIS SERVICES

FOR ONCOLOGY/ HAEMATOLOGY PATIENTS

DISEASE	INDICATION	PROCEDURE	NOTES
Thrombotic Microangiopathy: Thrombotic Thrombocytopenic Purpura (TTP)	ASFA category I	TPE	ASFA 2023 categorises TPE for TTP as a category I criteria (first-line therapy) with the working hypothesis that it removes anti-ADAMTS13 antibodies and replaces ADAMTS13 protease activity. TPE has decreased the overall mortality of immune-mediated TTP from nearly uniformly fatal to <10-20%. Plasma or plasma (50%)/albumin (50%) are used as replacement fluid. Recommendations include 1-1.5 total plasma volume (TPV), performed daily until the platelet count is >150 × 10^9/L, and LDH is near normal for 2-3 consecutive days. Tapering of procedures has been documented to lower recurrence rates.
Thrombotic Microangiopathy: Drug Associated	Ticlopidine ASFA category I Clopidogrel ASFA category III	TPE TPE	ASFA 2023 categorises TPE for Ticlopidine and Clopidogrel-associated thrombotic microangiopathy as category I and III respectively. Ticlopidine: Most patients develop TMA >2 weeks after initial drug exposure with most cases responding to TPE. Clopidogrel: Patients usually present ≤2 weeks after starting therapy, the majority are unresponsive to TPE. Recommendations include 1-1.5 TPV exchange with plasma replacement performed daily until recovery of haematologic parameters and then either discontinued or tapered off, similar to treatment for idiopathic TTP.
Sickle Cell Anaemia: Acute	Acute stroke ASFA category I Acute chest syndrome ASFA category II Other complications* ASFA category III	RBC Exchange RBC Exchange RBC Exchange	ASFA 2023 categorises red cell exchange for sickle cell disease acute stroke and chest syndrome indications as categories I and II respectively. Replacement fluid is RBC units to achieve target HbS levels, which can generally be achieved in one procedure. Leucoreduced and phenotyped red cell units are the recommended replacement fluid. All patients with sickle cell anaemia should have baseline extended phenotyping performed to prevent/reduce alloimmunisation and reduce the time needed to find appropriately matched blood. This includes: ABO blood group, RhD, C/E/c/e/Kell, irregular red cell antibody screen and identification (if screen positive).*Including priapism, multiorgan failure, splenic/hepatic sequestration, and intrahepatic cholestasis.
Sickle Cell Anaemia: Non-Acute	Stroke prophylaxis ASFA category I Pregnancy ASFA category II Recurrent vaso- occlusive pain crisis ASFA category II Pre-operative management ASFA category III	RBC Exchange RBC Exchange RBC Exchange RBC Exchange	ASFA 2023 categorises red cell exchange for sickle cell disease non-acute stroke prophylaxis as category I and pregnancy and vaso-occlusive pain crisis as category II. RBC exchange has been shown to reduce iron overload and improve rheology. Replacement fluid is RBC units to achieve target HbS levels. Duration of treatment varies depending on the patient's HbS levels.
Hyperviscosity in hypergamma-globulinaemia	Symptomatic ASFA category I Prophylaxis for rituximab ASFA category I	TPE TPE	ASFA 2023 categorises TPE for hyperviscosity in hypergammaglobulinemia as category I, first-line therapy. TPE reduces viscosity by 20-30% by removing the paraprotein. Recommendations include daily/ alternate day TPE procedures with 1-1.5 TPV exchange and albumin replacement fluid. As 80% of IgM is located in the intravascular space, serum viscosity rises steeply with increasing IgM levels. A transient increase in IgM level after rituximab therapy has been reported in 30-70% of patients within 4 weeks of treatment initiation. TPE should be considered before giving rituximab if the IgM level is >4 g/dL.
Hyperleukocytosis	Symptomatic ASFA category III	Leukapheresis	ASFA 2023 categorises leukapheresis for hyperleukocytosis as category III. Definitive treatment of hyperleukocytosis involves induction chemotherapy with aggressive supportive care. A single leukapheresis can reduce the WBC by 30-60%, however leukapheresis is a supportive measure only and definitive treatment should not be delayed. Replacement fluids include crystalloids, plasma or albumin. Recommendations include daily TPE with a 1.5-2 TBV exchange as needed.
Thrombocytosis	Symptomatic ASFA category I Prophylactic or secondary ASFA category III	Thrombocytapheresis	ASFA 2023 categorises Thrombocytapheresis for symptomatic thrombocytosis as category I. Thrombocytosis is defined as a circulating platelet count ≥450 × 10^9/L. Thrombocytapheresis has been utilised to prevent recurrence or treat acute thromboembolism or hemorrhage in selected patients with myeloproliferative neoplasms and uncontrolled thrombocytosis. It is performed daily using replacement saline and/or albumin as necessary to maintain the blood pressure.
Neutropenic Sepsis	Acceptable criteria to consider a granulocyte transfusion include: • Absolute Neutrophil Count <500 cells/µl • Evidence of bacterial or fungal infection • Unresponsiveness to antimicrobial treatment for at least 48 hours	Granulocyte Collection	In a procedure similar to a stem cell collection, granulocytes are collected from a healthy ABO-matched donor by apheresis. Donor selection entails a series of laboratory and clinical tests. The product is transported for irradiation and delivered to the patient's bedside within 24 hours of collection.

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NEUROLOGICAL INDICATIONS

THERAPEUTIC PLASMA EXCHANGE

NOTE

ASFA 2023 has added TPE as a treatment option for Alzheimer's disease (category III, grade 2A - decision making should be individualised)

NOTE

Autologous stem cell transplant (aHSCT) is indicated in highly active relapsing remitting Multiple Sclerosis (MS) failing to respond to disease modifying therapies. aHSCT may have a potential role in the treatment of the progressive forms of MS with a significant inflammatory component and other immune-mediated neurological diseases, including chronic inflammatory demyelinating polyneuropathy, neuromyelitis optica, myasthenia gravis and stiff person syndrome. Currently in Europle MS is the fastest growing indication for aHSCT.

DISEASE	INDICATION	NOTES
Acute inflammatory demyelinating polyradiculo neuropathy (Guillain Barré syndrome)	ASFA category I (first line therapy)	ASFA 2023 categorises TPE for GBS as a category I criteria (first line therapy) as it removes circulating autoimmune antibodies which are damaging to the peripheral nerve myelin. Several randomised controlled trials comparing plasma exchange to supportive care alone have shown that TPE can accelerate motor recovery, decrease time on the ventilator, and speed attainment of other clinical milestones. TPE has a beneficial effect in severely and mildly affected individuals, with a significantly increased proportion of patients able to walk after four weeks. Studies have shown equal efficacy of TPE and IVIG as treatment options in severe disease however TPE was found to be more cost-effective in certain settings. An average of 5-6 TPE procedures over 10-14 days are usually required. SANBS performs almost 100 TPE procedures per year for GBS patients.
Myasthenia Gravis (MG)	Acute short-term treatment: ASFA category I (first line therapy) Long term treatment in chronic disease: ASFA category II (second line therapy)	In MG, ASFA 2023 categorises TPE for acute short-term treatment (moderate-severe disease including myasthenic crisis, unstable or refractory disease, unstable disease activity pre-thymectomy) as a category I criteria (first line therapy) and as a category II criteria (second line therapy) for long-term treatment in chronic disease. There are three major mechanisms of action for TPE in MG: immediate intravascular reduction of autoantibody concentration, pulsed induction of antibody redistribution, and subsequent immunomodulatory changes. TPE works rapidly and clinical effects can be apparent within 24 hours but may take up to a week. In therapy refractory patients TPE may represent an option for long-term management of MG. IVIG and TPE are regarded as equally effective in treating severe MG. The number of TPE procedures depends on the clinical scenario. In acute attack, relapse or unstable disease, 3-6 treatments over 10-14 days are usually required. For chronic treatment, weekly to bi-weekly individually adjusted procedures may be performed. SANBS performs in excess of 80 TPE procedures a year for patients with MG.
Chronic Inflammatory Demyelinating Polyradicul'o'neuropathy (CIDP)	ASFA category I (first line therapy)	ASFA 2023 categorises TPE for CIDP as a category I criteria (first line therapy). There are 3 first-line treatment options: intravenous/ oral corticosteroids, which are commonly used; IVIG; or TPE with evidence from randomised controlled trials in favour of IVIG or TPE. TPE is used to remove circulating auto antibodies but therapies need to be initiated early to stop the inflammatory demyelination and prevent secondary axonal degeneration and therefore permanent disability. TPE provides short-term benefit, but rapid deterioration may occur afterwards. This may necessitate maintenance treatment with repeated TPE and/or other immunomodulation therapies, with frequency tailored to symptoms and tolerability of the individual patient. TPE is usually performed 2-3 times per week until clinical improvement is achieved and then tapered to weekly or monthly. SANBS performs over 50 TPE procedures per year for patients with CIPD.
N-METHYL-D ASPARTATE RECEPTOR (NMDAR) Encephalitis	ASFA category I (first line therapy)	ASFA 2023 categorises TPE for NMDAR-encephalitis as a category I criteria (first line therapy). First-line therapy includes high dose corticosteroids, IVIG or TPE, and a search for potential underlying tumour (with teratoma excision if present). TPE removes the pathophysiologically relevant antibody and acts an adjunct to immunotherapy by suppressing active inflammation and antibody production. There is a substantial percentage of patients with NMDAR encephalitis who do not respond to TPE, however TPE remains among the treatment options and is included in the treatment recommendations from the German Network for Research on Autoimmune Encephalitis. An average of 5-12 TPE treatments over 1-3 weeks with individually adjusted number of and intervals between treatments is usually performed. SANBS performs ~30 TPE procedures per year for patients with NMDAR encephalitis
Neuro Myelitis Optica Spectrum Disorders (NMOSD)	Acute attack/relapse: ASFA category II (second line therapy) Maintenance: ASFA category III (optimum role of apheresis therapy is not established and decision-making should be individualised)	ASFA 2023 categorises TPE for acute/ relapsing NMOSD as a category II criteria (TPE is a second line therapy). Several case reports have shown TPE benefits in corticosteroid-refractory NMOSD exacerbation, with 50–70% of patients showing improvement (in conjunction with steroids). Prompt initiation of TPE is a strong predictor of beneficial outcome in severe attacks of NMOSD - for every day delay in therapy initiation, the odds of achieving complete remission are reduced by 6.3%. TPE should begin within 5 days of symptom onset and be performed daily or on alternate days for an average of 5 procedures (range 2-20 procedures), depending on clinical response. TPE may be beneficial as a chronic treatment for the prevention of NMOSD relapse in select patients (category III criteria). SANBS performs almost 300 TPE procedures per year for patients with NMOSD.
Multiple Sclerosis	Acute/ relapsing: ASFA category II (second line therapy) Chronic: ASFA category III (optimum role of apheresis therapy is not established and decision-making should be individualised)	ASFA 2023 categorises TPE for MS as a category II criteria (second line therapy) for acute / relapsing MS and category III (optimum role of apheresis therapy is not established and decision-making should be individualized) for chronic MS. TPE may benefit MS patients through the immediate removal of plasma antibodies and immune complexes, induction of a redistribution of antibodies from the extravascular space, and subsequent immunomodulatory changes. An increasing number of disease-modifying medications have become available in recent years which reduce the likelihood of the development of new white-matter lesions, clinical relapses, and stepwise accumulation of disability. Standard treatment for clinically isolated syndrome (CIS) or acute MS attacks or relapses in adult and paediatric patients without change is intravenous administration of high dose steroids. If patients are unresponsive, which occurs in 20-25%, a second steroid pulse in combination with TPE is recommended after an interval of 10-14 days. TPE is regarded as ineffective for the chronic phase of PPMS/SPMS (Primary progressive multiple sclerosis / Secondary progressive multiple sclerosis) based upon results of several RCTs. TPE has been used for drug removal in MS patients treated with natalizumab who developed progressive multifocal leukoencephalopathy. In acute attack/relapse cases unresponsive to steroids, 5-7 TPE procedures over 10-14 days are recommended with a response rate of >50%. Early initiation of therapy, within 14-20 days of symptom onset, is a predictor of response. However, response has still been shown in patients treated 60 days after the onset of symptoms.
Acute Transverse Myelitis	Unclassified	TPE has emerged as a possible intervention in patients with transverse myelitis unresponsive to high-dose corticosteroids.

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LEUKAPHERESIS FOR CLINICAL/VACCINE TRIALS

SANBS STS offers leukapheresis for clinical trials in South Africa. We work hand in hand with the clinical trial facility to ensure the safe and adequate collection of peripheral blood mononuclear cells (PBMC). Historically PBMC collections were performed via large blood draws. Leukapheresis allows for the isolated collection of an adequate amount of PBMCs while preserving the participant's red cells and platelets. In addition, the viability of PBMC is improved when collected via leukapheresis which improves testing and analysis.

Two peripheral lines are used to draw and return blood from the participant. The procedure may take 3-5 hours and may be repeated if the trial requires it. Participants are requested to hydrate well and eat a balanced meal on the day of the procedure. Participants are monitored closely throughout the procedure. A total of 60-80mls of cellular product is collected and any symptoms of low calcium (tingling mouth, metallic taste and muscle cramping) are treated with calcium replacement.

WE OFFER

- A flexible and responsive service 365 days per year to both public and private patients.
- Experienced medical, technical and logistic teams.
- A robust quality management system.
- A comprehensive range of therapies.

- plasma exchange
- plasmapheresis
- leukapheresis
- thrombocytapheresis
- granulocyte collection
- lymphocyte collection
- peripheral blood stem cell collection
- red cell exchange
- immunoadsorption
- leukapheresis for clinical trial participants

If you wish to refer a patient for any clinical apheresis procedure please contact us on 082-555-9294.

RED CELL EXCHANGE

In a red cell exchange procedure, whole blood is removed from the patient and separated into its different components based on size. Abnormal/diseased red cells are removed and replaced with healthy donor red cells that are compatible with the patient.

Indications for red cell exchange include:

- Severe Malaria
- Sickle Cell Disease – stroke, pregnancy, recurrent vaso-occlusive crisis, pre-operative management
- Babesiosis
- Acute Toxins, Drugs, Poisons

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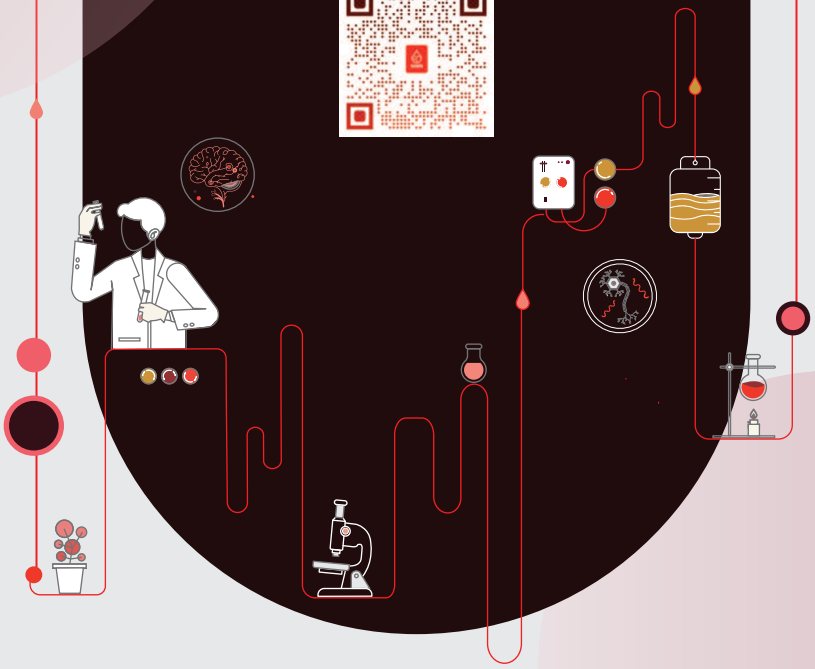

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