
	Document ID:	TDS-RLL-001-100ML	Version:	009
	Date of Issue:	15-DEC-2025	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2027	Signature:	
	Title:	TECHNICAL DATASHEET		



Secoll™ Lymphocyte Separation Solution

Filtration, Treatment	0.1µm sterile filtered
Product Code	RLL-001-100ML
Shelf Life	36 months from DOM
Storage Temperature	2-25°C (in darkness)
Shipping Temperature	2-25°C (in darkness)

QC Specifications

Physical and Chemical Analysis	Method	Specifications	Units
Appearance	Visual	Clear colorless solution free from particulate matter	n/a
pH at RT	Eur. Ph. 2.2.3	6.0 - 9.0	n/a
Osmolality	Eur. Ph. 2.2.35	260 - 340	mOsm/kg
Endotoxin	Eur. Ph. 2.6.14 (LAL Kinetic)	< 1.0	EU/ml
Density	Mass Balance	1.076 - 1.078	g/ml at 20°C
Sterility			
Aerobic Bacteria	Eur. Ph. 2.6.1	Not detected	n/a
Anaerobic Bacteria	Eur. Ph. 2.6.1	Not detected	n/a
Fungi (yeast & Mold)	Eur. Ph. 2.6.1	Not detected	n/a

General Information

Secoll™ Lymphocyte Separation Solution is a sterile, ready-to-use density gradient medium designed for the efficient isolation of viable lymphocytes from whole blood and bone marrow samples. This solution exploits the principle of density gradient centrifugation to selectively separate lymphocytes from erythrocytes and polymorphonuclear leukocytes (granulocytes).

Secoll™ Lymphocyte separation solution is made with Polysucrose 400 (PS400). PS400 is a hydrophilic polymer with a molecular weight of approximately 400000 Dalton. It is used for the production of density gradients for the separation of cells and sub-cellular components, which sediment during centrifugation due to gravity.

Intended Purpose

Secoll™ Lymphocyte Separation Solution is a general laboratory sterile solution to be used for research and development and as an in vitro diagnostic device intended for the separation and isolation of human lymphocytes from whole blood or bone marrow by density gradient centrifugation. The separated cells are used for in vitro diagnostic examinations of specimens derived from the human body. THIS PRODUCT IS NOT INTENDED FOR USE IN HUMAN OR VETERINARY THERAPEUTIC APPLICATIONS.

Intended Users



THIS PRODUCT IS INTENDED FOR USE BY TRAINED LABORATORY PROFESSIONALS AND TECHNICIANS IN CLINICAL OR RESEARCH SETTINGS. IT IS NOT FOR SELF-TESTING OR OVER-THE-COUNTER USE.

Instruction For Use

Specimen Type & Requirements

This product is intended for the isolation of mononuclear cells (e.g., lymphocytes and monocytes) from the following human specimens:

- **Peripheral (Whole) Blood:** Collected via venipuncture.
- **Bone Marrow Aspirate:** Obtained through standard aspiration procedures.

	Document ID:	TDS-RLL-001-100ML	Version:	009
	Date of Issue:	15-DEC-2025	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2027	Signature:	
	Title:	TECHNICAL DATASHEET		

Anticoagulants:

Specimens should be collected into tubes containing appropriate anticoagulants, such as **heparin** (preferred) or **EDTA**. Samples containing clots or collected without anticoagulants are **not suitable** and may lead to poor cell recovery and reduced viability.

Specimen Storage and Handling:

Blood samples should be processed as soon as possible after collection to achieve the best harvesting and lymphocyte viability. If it is needed to process later, keep the blood samples fridge. Storing the blood samples at room temperature for more than 12 h would cause a significant reduction in yield.

- **Peripheral Blood:** Process as soon as possible, preferably within **6 hours** of collection. If immediate processing is not feasible, store at **2–8°C** and process within **24 hours**. Delays beyond 48 hours may significantly compromise cell integrity and result in reduced yield and viability.
- **Bone Marrow Aspirate:** Process promptly, ideally within **24 hours** of collection. If necessary, store at **2–8°C** and process within **24 hours** to maintain cell viability.
- **Do not freeze** specimens, as this will result in cellular damage and render the sample unsuitable for lymphocyte isolation.

Sample Volume:

- **Peripheral Blood:** A minimum of **3 mL** is recommended per separation, depending on the protocol and desired cell yield.
- **Bone Marrow Aspirate:** A minimum of **5 mL** is recommended per separation, depending on the protocol and desired cell yield.



Preparation:

1. Bring Secoll™ separation solution to room temperature in the dark.
2. Check the expiry date on bottle label to verify that the shelf life is still valid.
3. Open the sterile package under a qualified clean bench if aliquoting or keeping the sterility for the next steps are require.
4. Fill a centrifuge tube with Secoll™ separation solution as follows using proper pipets:

Centrifuge Tube Volume	Secoll™ Volume
15ml	3ml
25ml	10ml
50ml	20ml

The centrifuge tubes are then ready for filling with whole blood or bone marrow aspirate.

5. Diluting the sample material with balanced salt solution is not required, however, it can help with separation in certain circumstances. We recommend a whole blood dilution of 1:2, and bone marrow dilution of 1:4.

	Document ID:	TDS-RLL-001-100ML	Version:	009
	Date of Issue:	15-DEC-2025	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2027	Signature:	
	Title:	TECHNICAL DATASHEET		

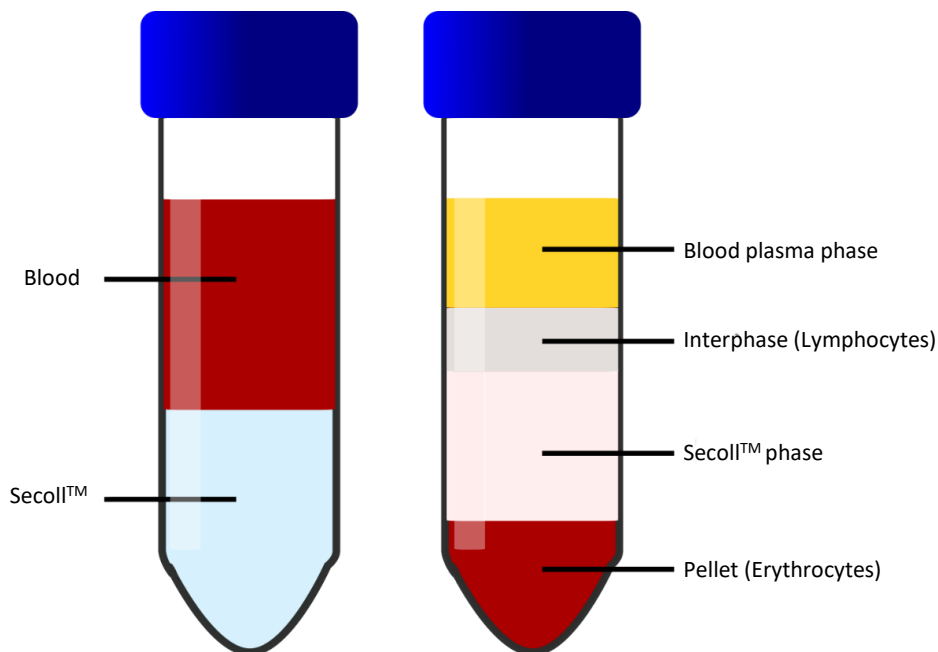


Figure. 1: Blood Separation Tube before (left) and after centrifugation (right).

- Procedure:



- Carefully load the prepared sample directly from the sampling tube onto the prepared Secoll™ tube in equal volume to the Secoll™ volume. (e.g. Sample Volume = 7ml when Secoll™ Volume = 7ml). Perform this step slowly and constantly so as to not mix the two phases and a sharp border is present.
- Centrifuge @ RT for 10 minutes at 1000 x g in a swinging bucket rotor. No braking function should be enabled on the centrifuge.
- After centrifugation, the layering should look as follows in Figure 1.
- Carefully extract the lymphocytes/peripheral blood mononuclear cells (PBMCs) using a Pasteur pipette.
- Wash the lymphocytes/PBMCs with 10 ml of Phosphate Buffer Saline (PBS), then centrifuge for a further 10 minutes at 250 x g.
- If required, repeat steps 4 & 5 and resuspend the lymphocytes/PBMCs with 10 ml of PBS.

Storage and Handling

- Store at room temperature (2 – 25°C) in the dark. The product is also stable in fridge temperature, but it is not required.
- Protect from light and moisture. Keep the container tightly closed in a dry and well-ventilated place.
- Do not use the product if you see damage on the bottle or cap that may cause risk of losing sterility. Discard the product if sterility is lost.

Handling after opening: The product is intended for single opening and single-use only. After first opening, any remaining solution shall be discarded.

Exception: If reuse or aliquoting is required, opening and subsequent handling shall only be performed under a validated Class A clean bench (laminar airflow cabinet) using qualified sterile containers and sterile tools, and by trained

	Document ID:	TDS-RLL-001-100ML	Version:	009
	Date of Issue:	15-DEC-2025	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2027	Signature:	
	Title:	TECHNICAL DATASHEET		



personnel. Even under these conditions, the risk of contamination increases with repeated opening, and the manufacturer does not guarantee sterility beyond the initial use.

Reactivity and Stability












The reactivity and stability of Secoll™ are based on its hydroxyl groups and on the glycoside bonds within the sucrose residues. It is stable in alkaline and neutral solutions. At pH values lower than 3, it is rapidly hydrolyzed, especially at elevated temperatures. In neutral solutions Secoll™ can be sterilized by autoclaving at 110°C for 30 minutes, without affecting the reactivity. Avoid heavily oxidizing or reducing substances.

Troubleshooting/Changes in analytical Performance

Issue	Possible Cause	Solution
Poor lymphocyte yield but they are viable	<ul style="list-style-type: none"> Improper blood dilution or mixing Abnormally high haematocrit in blood 	<ul style="list-style-type: none"> Ensure proper dilution and gentle mixing before layering on Secoll™. Dilute the blood sample Avoid excessive agitation.
Poor yield and viability of the lymphocytes	<ul style="list-style-type: none"> Temperature too high Improper blood dilution or mixing 	<ul style="list-style-type: none"> Secoll™ has a lower density at higher temperatures and lymphocytes can penetrate to the Secoll™ phase. Adjust Secoll™ to 20°C. Ensure proper dilution and gentle mixing before layering on Secoll™. Avoid excessive agitation.
Contaminated lymphocyte with other cell types	<ul style="list-style-type: none"> Inadequate separation or centrifugation 	<ul style="list-style-type: none"> Carefully aspirate the lymphocyte layer without disturbing the Secoll™ interface. Use precise centrifugation settings.
Erythrocyte contamination	<ul style="list-style-type: none"> Insufficient centrifugation speed or time Temperature too low 	<ul style="list-style-type: none"> Increase centrifugation speed or time as per the recommended protocol. Ensure no sudden stops. Secoll™ has a higher density at lower temperatures and erythrocytes aggregate less. Adjust Secoll™ to 20°C.
Cell clumping	<ul style="list-style-type: none"> Improper sample handling or Secoll™ gradient disruption 	<ul style="list-style-type: none"> Avoid vortexing the sample. Use fresh reagents and ensure gentle layering of blood onto Secoll™.
Low cell viability	<ul style="list-style-type: none"> Overexposure to high temperatures or delays in processing 	<ul style="list-style-type: none"> Process samples immediately. Maintain proper temperature conditions during separation.
Inconsistent separation	<ul style="list-style-type: none"> Incorrect pipetting technique 	<ul style="list-style-type: none"> Ensure proper pipetting to prevent mixing.

	Document ID:	TDS-RLL-001-100ML	Version:	009
	Date of Issue:	15-DEC-2025	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2027	Signature:	
	Title:	TECHNICAL DATASHEET		

Symbols and Definitions

Symbol	Definition
	Sterile, Aseptic filling
	Batch Number
	Catalogue Code
	Expiration Date
	Storage conditions: temperature limit
	CE Marking
	In vitro diagnostics
	See instructions for the user manual
	Do not use if the packaging is damaged
	Protect from sunlight
	Manufacturer

10. Precautions and Disclaimer

- This product is not intended for any human or animal therapeutic use.
- The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008. For further information see the product Material Safety Data Sheet.
- Do not use the product if the primary packaging is damaged or opened.
- Do not use the product if any particles/sedimentation is observed.
- Dispose of used materials as per local regulations.

CE marked

Secoll™ is a CE marked medium for IVD which fulfils the requirements of the Directive 98/79/CE.

DMIDS registration Nr: DE/CA76/IVD0017/001

DO NOT USE IT IN HUMAN OR VETERINARY THERAPEUTIC APPLICATIONS.