



IVD REF BL-215-283

## CyLyse™ LV

EN

### Identification of the IVD reagent CyLyse™ LV

#### Intended purpose

CyLyse LV is a lysing solution for flow cytometric analysis of human peripheral blood, and is used by healthcare professionals and properly trained personnel. It is intended to be used for manual sample preparation by a user or with a sample preparation system.

#### Principles of the examination method

Leukocyte analysis and detection in peripheral blood requires elimination of red blood cells. CyLyse LV provides lysis of red blood cells after antibody staining of leukocytes. The reagent contains no fixative. It is appropriate for use when viable leukocytes are required after red blood cell lysis.

#### Components

Ammonium chloride	8 %
Pyridine-2-thiol 1-oxide, sodium salt (PTO)	< 0.5 %
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CMIT/MIT)	< 0.01 %

#### Warnings and precautions

- Follow the warnings and precautions, as described on the product container, package box, package insert or device's instructions for use, to handle the product correctly.
- Do not use the product if it shows signs of contamination or instability, such as turbidity or discoloration.
- Human samples may contain infectious substances such as HIV, HBV and HCV. Handle samples carefully and follow your institution's biohazard policy.
- Be sure to wear adequate personal protective equipment, such as protective gloves, a protective mask, protective eyewear, and a lab coat.
- Avoid direct contact with skin, eyes and mucous membranes. Do not ingest.
- In case of skin contact, rinse immediately with plenty of water. In case of contact with eyes or mucous membranes, rinse immediately with plenty of water, and seek medical attention. In case of ingestion, seek medical attention immediately.
- Please see the safety data sheet for the country-specific classification.

#### Warning

H317	May cause an allergic skin reaction.
P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container to a facility in accordance with local and national regulations.
H317	Toxic by eye contact.
H317	Contains pyridine-2-thiol 1-oxide, sodium salt. May produce an allergic reaction.



#### Additional required equipment

- Sterile blood collection tubes
- Test tubes
- Automatic pipettes with disposable tips
- Vortex mixer
- Centrifuge
- Phosphate buffered saline (PBS)
- Deionized water
- Fluorochrome-conjugated antibodies
- Flow cytometer
- 0.8 % formaldehyde/PBS

Consult the instructions for use for the specific devices to be used with.

#### Primary sample collection, handling and storage

The primary specimen is human peripheral blood collected by venipuncture. Blood should be collected in EDTA anticoagulant. Note, that the anticoagulant EDTA-2Na may not dissolve easily in blood, thus causing fibrin formation or platelet aggregation in some samples. Follow the instructions for antibody reagents regarding sample handling and storage.

#### Reagent preparation

Dilute 10x with deionized water. Diluted solution is stable for 7 days at 18-28 °C.

#### Examination procedure

- Perform antibody staining following the instructions for use of the antibody reagent being used.
- Add 2 mL of the diluted solution per 100 µL of blood. Mix the tube gently with vortex mixer.
- Incubate 10-15 minutes at 18-28 °C in the dark, and confirm the turbid blood suspension becomes clear.
- Centrifuge tubes for 5 minutes at 300 × g and remove the supernatant.
- Resuspend pellet with 2 mL of PBS.
- Centrifuge tubes for 5 minutes at 300 × g and remove the supernatant.
- Resuspend cell pellet with a necessary amount of PBS appropriate for the flow cytometer being used.
- Analyze sample. If sample is not analyzed immediately, store it at 2-8 °C in the dark and analyze within 2 hours.
- Fix the cells with fixation solution such as 0.8 % formaldehyde/PBS if sample is required to be stored for more than 2 hours. Store the fixed sample at 2-8 °C in the dark and analyze within 24 hours.

#### Storage and shelf life of unopened product

Store CyLyse LV at 2-8 °C. Keep away from humidity, direct sunlight and heat. When the product is properly stored in its sealed container, it is stable until the expiration date printed on the label.

#### Storage and shelf life after first opening

Once opened the product is stable for 3 months at 2-8 °C. After opening the product container, store in the box and avoid direct contact with sunlight.

#### Performance characteristics

##### Lymphocyte purity

To evaluate Lymphocyte purity ten peripheral blood samples from healthy volunteers were treated with the diluted solution following anti-CD45 antibody staining. The ratio of CD45 positive cells to lymphocytes gated in the dot plot (Side Scatter vs Forward Scatter) was evaluated. The data of the lymphocyte purity is shown below.

Mean	Max	Min
97.4 %	99.0 %	94.9 %

#### Limitations of the examination procedure

- Accurate analysis results will be obtained with the procedure in accordance with the package insert or device's instructions for use. It is the responsibility of the user to validate modifications to these instructions.
- Results may be inaccurate due to interfering substances such as dust, dirt or bacteria growth in the sample or product.
- The reliability of the analysis values cannot be guaranteed if the product is used outside the prescribed intended use.
- The product must not be used after its expiration date.
- Do not refill and reuse product containers.
- Handle the product with care to prevent bubble formation.
- Avoid contamination with dust or bacteria after the container is opened. If the product displays any signs of contamination or instability, as indicated by cloudiness or color change, it should be replaced.
- Do not use a product that is suspected to have been frozen.
- Use of reagent other than as directed may cause erroneous results.
- The flow cytometer may produce erroneous results if the device has not been aligned, calibrated and maintained appropriately.
- Red blood cells from abnormal specimens may be resistant to lysis.
- If the red blood cell concentration in the specimen is more than  $6 \times 10^6/\mu\text{L}$ , it is recommended that the blood sample be diluted with PBS to obtain a red blood cell concentration of approximately  $5 \times 10^6/\mu\text{L}$ .
- In some specimens, neutrophils are separated into two populations with different Forward Scatter characteristics. In that case, set the gate to include both populations.
- CyLyse LV must be diluted referring to "Reagent preparation". The temperature of the diluted solution for red blood cell lysis must be between 18-28 °C.

#### Disposal procedures

- Make sure that any remaining liquid has been removed from the container before disposing of the container.
- Disposal procedures for emptied containers, remaining liquids and waste effluents from the device should meet the requirements of applicable local regulations.

#### Manufacturer



**Sysmex Corporation**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

#### Authorized representatives

Europe, Middle East and Africa:



**Sysmex Europe SE**  
Bornbarch 1, 22848 Norderstedt, Germany  
Tel +49-40-52726-0 Fax +49-40-52726-100

Americas:

**Sysmex America, Inc.**  
577 Aptakasic Road, Lincolnshire, IL 60069, U.S.A.

Asia-Pacific:

**Sysmex Asia Pacific Pte Ltd.**  
9 Tampines Grande #06-18, Singapore 528735

#### Product information

CyLyse LV (CLN-200B) 50 mL × 1

#### Notice to the user

For a patient or user or third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative in the European Union and to your national competent authority. Reports to the authorized representative in the European Union, Sysmex Europe SE, must be sent by email to: [vigilance@sysmex-europe.com](mailto:vigilance@sysmex-europe.com), or by post to Sysmex Europe SE, Bornbarch 1, 22848 Norderstedt, Germany.

#### Example data

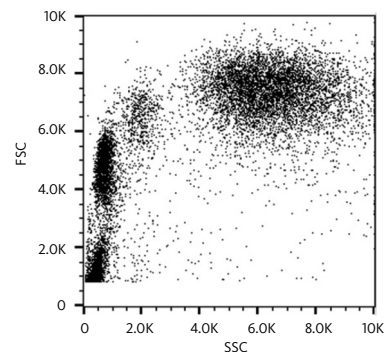


Fig. Dot plot of peripheral blood treated with CyLyse LV

#### Date of issue or revision

06/2023

Revised parts in this version

## Revision history

Date of issue or revision	Revised section
04/2022	<ul style="list-style-type: none"><li>• Added: <b>IVD</b> <b>Notice to the user</b></li><li>• Updated: <b>Intended purpose</b> <b>Components</b> <b>Warnings and precautions</b> <b>Additional required equipment</b> <b>Authorized representatives</b> <b>Example data</b></li></ul>
11/2022	<ul style="list-style-type: none"><li>• Updated: <b>Authorized representatives</b></li></ul>
06/2023	<ul style="list-style-type: none"><li>• Updated: <b>Components</b> <b>Warnings and precautions</b></li></ul>