

Cylyse™ LV

Product Name

Cylyse™ LV

Intended use

For Research Use Only. Not for use in diagnostic procedures. Cylyse LV is a lysing solution for red blood cell lysis in the preparation of biological samples from human peripheral blood after staining leukocytes with fluorochrome-conjugated antibodies prior to the flow cytometry analysis.

Principle of the procedure

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 %
 Potassium hydrogen carbonate 0.9 %
 Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CMT/MT) < 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 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.



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

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 x g and remove the supernatant.
- Resuspend pellet with 2 mL of PBS.
- Centrifuge tubes for 5 minutes at 300 x 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 10x concentrated 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.

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 expiry 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 $6 \times 10^7/\mu\text{L}$, it is recommended that the blood sample be diluted with PBS to obtain a red blood cell concentration of approximately $5 \times 10^7/\mu\text{L}$.

- 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

The requirements of applicable local regulations should be followed.

Manufacturer

 Sysmex Corporation
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 Chuo-ku, Kobe 651-0073, Japan

Authorized representatives

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Product information

Cylyse LV (CLN-200A) 50 mL x 1

Example data

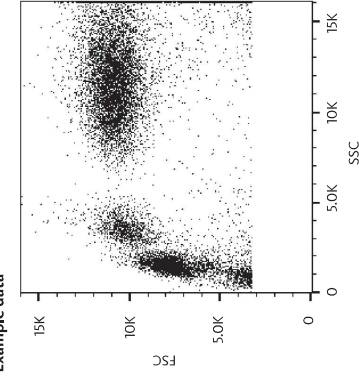


Fig. Dot plot of peripheral blood treated with Cylyse LV

Date of issue or revision

05/2018

Printed in Japan

REF

Catalogue number

LOT

Batch code



Manufacturer



Keep away from sunlight



Temperature limitation



Concentrated reagent



Use by