Product is manufactured in accordance with current Good Manufacturing Practices.



REF AE238377

Technical Data Sheet

ΕN

Identification of the reagent

Name	CyLyse™ FXP
Ref. No.	AE238377
UDI-DI	04250878904399
Content	25 mL Fixation Buffer (Ref. No. BW901813)
	25 mL Permeabilization Buffer (Ref. No. BW412407)

Product description

CyLyse™ FXP is a set of two ready-to-use reagents, Fixation and Permeabilization Buffer. This includes fixing and permeabilising of the cytoplasmic membrane of leukocytes and is used 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

Human leukocytes are stained with fluorochrome-conjugated antibody reagents that specifically bind to the antigenic determinants on the cell surface. The surface-stained leukocytes are fixed with Fixation Buffer. Erythrocytes are lysed with deionized water and the remaining leukocytes are pelleted by centrifugation. The sediment is resuspended in Permeabilization Buffer and mixed with fluorochrome-conjugated antibody reagents against intracellular antigens. Antibodies enter the intracellular compartment and bind to their specific targets. The unbound antibodies are removed by washing and the cells are analyzed by a suitably equipped flow cytometer.

Storage and shelf life

Unopened product

Store CyLyse™ FXP at 2-28 °C in the dark. Do not freeze or expose to light. Do not use after the expiration date stated on the label.

After first opening

The shelf life after first opening is the same as the shelf life for unopened reagent if stored at stated storage conditions and used according to the instructions in this document.

Components

Fixation Buffer is provided in one vial containing 25 mL of a proprietary buffered clear and colourless fixative containing $\leq 5 \%$ (v/v) formaldehyde.

Permeabilization Buffer is provided in one vial containing 25 mL of a proprietary buffered clear and colourless permeabilization solution and detergents.

The reagents are sufficient for 100 staining reactions.

Evidence of deterioration

Avoid contamination of reagents. In case of components deterioration seen as a visible precipitation or discoloration of the reagent or if data obtained show any performance alteration, please contact the Technical Support of your local Sysmex representative.

Any problem that has occurred in relation to the product shall be reported by the user to the manufacturer.

Precautions and warnings

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet (SDS). SDS are available at http://www.sysmex-partec.com/services, or at https://us.sysmex-flowcytometry.com/ (U.S. customers only).

Always meet the national and international guidelines and regulatory standards for personal protective equipment.

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Warning symbols



Signal word DANGER Warnings

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.H341 Suspected of causing genetic defects.

H350 May cause cancer.

Precautions

P201 Obtain special instructions before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

Additional required equipment

Instrument Flow cytometer equipped with appropriate computer hardware and

software. The flow cytometer must be equipped to detect forward scatter

(FSC) and side scatter (SSC).

Required laboratory

equipment .

Vortex mixer,

Centrifuge,
Material necessary for the collection of whole blood,

Disposable test tubes (e.g., 12 x 75 mm) for staining of samples,

Pipettes with disposable tips for 10, 100 and 1000 µL,

Adequate personal protective equipment

Required reagents Fluorochrome-conjugated antibody reagents (e.g., Sysmex CyFlow™

antibody reagents),

Phosphate-buffered saline (PBS; pH 7.4),

Deionized water

Other materials may be required. Refer to the manufacturer's instructions for the appropriate antibody reagent for more information.

Reagent preparation

CyLyse™ FXP is ready to use. If the CyLyse™ FXP is stored at 2-8 °C, allow the reagent to warm up to room temperature before use.

Primary sample collection, handling and storage

⚠ WARNING

Consider all biological specimens and materials which come in contact with them as biohazardous. Specimens should be handled as potentially infectious and disposed in accordance with federal, state, and local regulations.

Collect whole blood in a sterile tube with K3 or K2 EDTA as anticoagulant. Follow the manufacturer's instructions for the antibody reagent for sample handling and storage.

Disposal

All disposables, which have been in contact with biohazardous material, must be decontaminated and disposed of according to local legislations and laws. Clean and disinfect contaminated surfaces immediately, use appropriate procedures of decontamination. Always dispose blood samples, assays, and accessory fluids after expiration of the maximal storage time.

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Technical Data Sheet

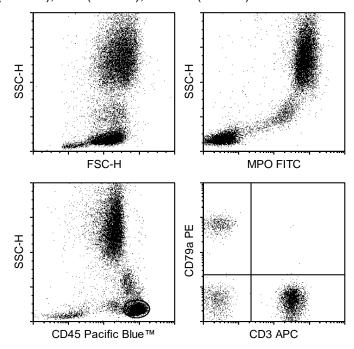
ΕN

Examination procedure

- 1. Stain 100 µL of whole blood following the manufacturer's instructions for the antibody reagent (e.g., Sysmex CyFlow™ antibody reagents).
- 2. Add 250 µL of Fixation Buffer to the tube and vortex gently.
- 3. Incubate for 10 minutes at room temperature (18-28 °C) in the dark.
- 4. For red blood cell lysis, add 3 mL of deionized water (18-28 °C) to the tube and vortex gently.
- 5. Incubate for 10 minutes at room temperature (18-28 °C) in the dark.
- 6. Centrifuge tubes for 5 minutes at 300 g and remove the supernatant by decanting.
- 7. Add 250 µL of Permeabilization Buffer.
- 8. Add antibody reagents intended for intracellular staining (e.g., Sysmex CyFlow™ antibody reagents) and vortex gently.
- 9. Incubate for 15 minutes at room temperature (18-28 °C) in the dark.
- 10. Add 2 mL of PBS to the tube and vortex gently.
- 11. Centrifuge tubes for 5 minutes at 300 g and remove the supernatant by decanting.
- 12. For subsequent analysis, resuspend the cell pellet in a sufficient volume of PBS appropriate for your flow cytometer.
- 13. For later analysis, follow the manufacturer's instructions for the antibody reagent.

Representative data

The following representative data was obtained using human peripheral whole blood stained with Sysmex CyFlow™ antibody reagents (CD3 APC, CD79a PE, Myeloperoxidase (MPO) FITC and CD45 Pacific Blue™) and treated with CyLyse™ FXP. The data was collected on a Sysmex flow cytometer equipped with violet (405 nm), blue (488 nm), and red (638 nm) lasers.



Manufacturer



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Technical Data Sheet

ΕN

Symbols

REF

Reference number



Manufacturer



Use-by date

Batch code



Temperature limit



For research use



only



Keep away from sunlight

Danger

Signal word: Danger

UDI

Unique device identifier

Consult accompanying documents

CONTENT

Content of kit

Date of issue or revision

Rev.:

Rev. date:

25-08-2023

Doc. No.:

AE238377 TDS GB EN

CN 2837

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