BD FACS™ Lysing Solution

Catalog No. 349202

23-1358(13)
2021-11
English

CE IVD

1. INTENDED USE

BD FACS™ Lysing Solution is intended for lysing red blood cells for flow cytometric applications. It can be used in both lyse/wash and lyse/no-wash procedures.

2. SUMMARY OF THE TEST

Efficient detection of leucocytes in specimens depends on the elimination of interfering cells. Whole blood lysis has been shown to be as effective as density gradient centrifugation in the preparation of peripheral blood mononuclear cells (PBMCs) for lymphocyte subset analysis.[1,2,3,4] In clinical laboratories, whole blood lysis methods have essentially replaced Ficoll-Paque™ density gradient separation because of shorter sample preparation time and less handling of whole blood.[5] Studies have also shown that the lysed whole blood method is less likely to show loss of leucocyte subsets and may help improve assay reproducibility when compared to earlier methods.[5,6,7]

BD FACS™ Lysing Solution is intended for use by laboratory professionals.

Principle of Operation

When the specimen is added to the antibody reagent, the fluorochrome-labeled antibodies in the reagent bind specifically to leucocyte surface antigens. The stained samples are then treated with BD FACS™ Lysing Solution, which lyses red blood cells (RBCs) under gentle hypotonic conditions while preserving the leucocytes.

3. REAGENT

Reagent Composition

BD FACS™ Lysing Solution is a proprietary buffered solution containing <10% formaldehyde and <50% diethylene glycol.

Precautions

BD FACS™ Lysing Solution contains 25 – <50% 2,2´-oxybisethanol (diethylene glycol) (CAS number 111-46-6, EC number 203-872-2), 5 – <10% formaldehyde (CAS number 50-00-0, EC number 200-001-8), and 3 – <5% methanol (CAS number 67-56-1, EC number 200-659-6). The lysing solution is classified as hazardous according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and Regulation (EC) No 1272/2008. Go to regdocs.bd.com/regdocs/sdsSearch to download the Safety Data Sheet.

	Danger
	H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H341: Suspected of causing genetic defects. H350: May cause cancer. H371: May cause damage to organs. H335: May cause respiratory irritation. H373: May cause damage to organs through prolonged or repeated exposure.
Prevention	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust/fume/gas/mist/vapors/spray. P264: Wash thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor if you feel unwell. P337+P313: If eye irritation persists: Get medical advice/attention. P308+P313: If exposed or concerned: Get medical advice/attention.

For the US, the following warnings apply in addition to the ones shown previously:

Hazard	H402: Harmful to aquatic life.
Prevention	P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P270: Do not eat, drink or smoke when using this product. P281: Use personal protective equipment as required.
Response	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352: IF ON SKIN: Wash with plenty of water. P301+P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P330: Rinse mouth. P321: Specific treatment (see Safety Data Sheet). P363: Wash contaminated clothing before reuse.
Storage	P405: Store locked up. P403: Store in a well-ventilated place. P233: Keep container tightly closed.
Disposal	P501: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Storage and Handling

- BD FACS™ Lysing Solution (10X) is stable until the expiration date shown on the bottle label when stored as directed.
- The storage temperature is 2°C–25°C.
- Do not use this reagent if discoloration occurs or a precipitate forms.

4. INSTRUMENT

BD FACS™ Lysing Solution is designed for flow cytometers equipped with appropriate computer hardware and software. The flow cytometer must be equipped to detect forward scatter (FSC) and side scatter (SSC).

5. SPECIMEN COLLECTION AND PREPARATION

See the instructions for use (IFU) for the reagent you are using for information about specimens supported.

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[8,9] and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves.

6. PROCEDURE

Reagents and Materials

Reagents and materials provided

BD FACS™ Lysing Solution is provided as 100 mL of a 10X concentrate. After dilution, this volume is sufficient for 2,000 tests when used in lyse/no-wash procedures or for 500 tests when used in lyse/wash procedures.

Reagents and materials required but not provided

- 1X BD FACS™ Lysing Solution, diluted as described
- BD fluorochrome-conjugated antibodies to human leucocyte antigens
- Vortex mixer
- Micropipettor with tips
- Other materials might be required. Refer to the appropriate reagent IFU for more information.

Diluting BD FACS™ Lysing Solution

Dilute the 10X concentrate 1:10 with room temperature (20°C–25°C) deionized water. The prepared solution is stable for 1 month when stored in a glass or high density polyethylene (HDPE) container at room temperature.

Staining the Specimen

Stain the specimen following instructions in the appropriate reagent IFU. Lyse RBCs as directed using diluted (1X) BD FACS™ Lysing Solution.

7. LIMITATIONS

- Samples with nucleated erythrocytes show incomplete lysis of RBCs because BD FACS™ Lysing Solution does not lyse nucleated erythrocytes as efficiently as enucleated RBCs. This may also occur when assaying blood samples from patients with certain hematologic disorders in which RBCs are difficult to lyse, as in myelofibrosis, sickle-cell anemia, thalassemia, and spherocytosis.[7,8]
- BD FACS™ Lysing Solution was developed for use with BD flow cytometers.
- BD FACS™ Lysing Solution was developed using EDTA as the anticoagulant. BD has limited information concerning use of other anticoagulants such as heparin.

REFERENCES

1. de Paoli P, Reitano M, Battistin S, Castiglia C, Santini G. Enumeration of human lymphocyte subsets by monoclonal antibodies and flow cytometry: a comparative study using whole blood or mononuclear cells separated by density gradient centrifugation. *J Immunol Methods*. 1984;72:349-353.
2. Ashmore LM, Shopp GM, Edwards BS. Lymphocyte subset analysis by flow cytometry. Comparison of three different staining techniques and effects of blood storage. *J Immunol Methods*. 1989;118:209-215.
3. Renzi P, Ginns LC. Analysis of T cell subsets in normal adults: comparison of whole blood lysis technique to Ficoll-Hypaque separation by flow cytometry. *J Immunol Methods*. 1987;98:53-56.
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5. Jackson A. Basic phenotyping of lymphocytes: selection and testing of reagents and interpretation of data. *Clin Immunol Newslett.* 1990;10:43-55.
6. Kidd PG, Vogt RF, Jr. Report of the workshop on the evaluation of T-cell subsets during HIV infection and AIDS. *Clin Immunol Immunopathol*. 1989;52:3-9.
7. Landay AL, Muirhead KA. Procedural guidelines for performing immunophenotyping by flow cytometry. *Clin Immunol Immunopath*. 1989;52:48-60.
8. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI document M29-A4.
9. Centers for Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html. Accessed March 12, 2019.

NOTICE

EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

WARRANTY

Unless otherwise indicated in any applicable BD general conditions of sale for non-US customers, the following warranty applies to the purchase of these products.

THE PRODUCTS SOLD HEREUNDER ARE WARRANTED ONLY TO CONFORM TO THE QUANTITY AND CONTENTS STATED ON THE LABEL OR IN THE PRODUCT LABELING AT THE TIME OF DELIVERY TO THE CUSTOMER. BD DISCLAIMS HEREBY ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE AND NONINFRINGEMENT. BD'S SOLE LIABILITY IS LIMITED TO EITHER REPLACEMENT OF THE PRODUCTS OR REFUND OF THE PURCHASE PRICE. BD IS NOT LIABLE FOR PROPERTY DAMAGE OR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING PERSONAL INJURY, OR ECONOMIC LOSS, CAUSED BY THE PRODUCT.

TRADEMARKS

HISTORY

Revision	Date	Changes made
23-1358(13)	2021-11	Updated to meet requirements of Regulation (EU) 2017/746.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.
US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
EC REP	Authorized representative in the European Community
CH REP	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	In vitro diagnostic medical device
CONTROL -	Negative control
CONTROL +	Positive control
Σ	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
#	Patient number
	This way up
	Do not stack
	Single sterile barrier system
PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
CE	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
R_x Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
FC	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier

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