

УТВЕРЖДАЮ

Генеральный директор
ООО «Компания «БиВи»

Т.А. Носова

2023 г.



ПО ДОВЕРЕННОСТИ
77 АД 1754197
КУСАЙЛО Р. В.

Фотографические изображения изделия:

**Реагент лизирующий для анализаторов автоматических гематологических 5-Diff для
диагностики in vitro (Hematology analyzer lyse (LYC-1/LYD-1))**

**Shenzhen Dymind Biotechnology Co., Ltd., («Шэньчжэнь Дайминд Биотекнолоджи Ко., Лтд.»),
Китай**



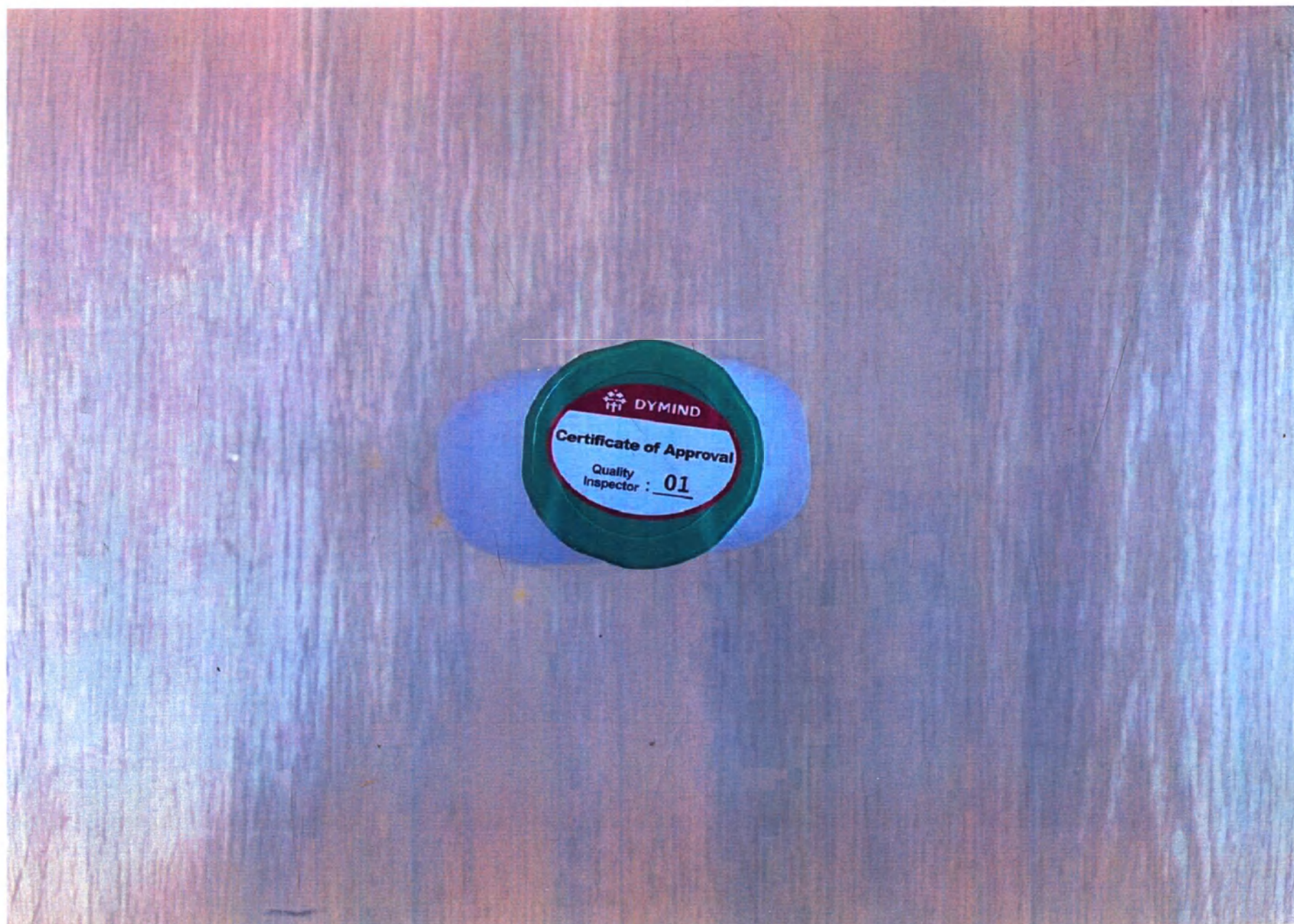
Реагент лизирующий LYC-1, 100 мл



Реагент лизирующий LYC-1, 100 мл



Реагент лизирующий LYC-1, 100 мл



Реагент лизирующий LYC-1, 100 мл



Instructions for Hematology Analyzer Reagents



Preface

Thank you for purchasing the Hematology Analyzer Reagents manufactured by Dymind Biotech.
Read and understand the entire instructions before use.
Store the instructions properly for future reference.
E-mail: info@dymind.com Tel: +86 755 26036015
Fax: +86 755 26746152
Website: <http://www.dymind.com>



Curier GmbH
Kernedamm 5, 40476 Düsseldorf, Germany
Shenzhen Dymind Biotechnology Co., Ltd.
19th Floor, Building B, High-tech Park, Guangjiao
Road, Tianlan Community, Yutong Street,
Guangning District, Shenzhen 518167 P.R. China

Release date: 2022-05-24
Date of manufacture: see product label

LYC-1 Lyse

Product Name
Hematology Analyzer Lyse

Model
LYC-1

Specification

Specification	REF
50mL	12.01.1411A
100mL	12.01.1355A
200mL	12.01.1354A
500mL	12.01.1412A
1L	12.01.1413A
4L	12.01.1414A

Intended Use

It is used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

Principle

The reagent is added to lyse the red blood cells (RBC) and react with the released hemoglobin (HGB) for the measurement of HGB, white blood cell count (WBC) and Basophils (BAS).

Active Ingredients

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

A List of Materials Provided

- RF card
- Instructions for Use
- Reagent

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56 hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Performance Characteristics

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$, HGB $\leq 1g/L$.

LYC-2 Lyse

Product Name
Hematology Analyzer Lyse

Model
LYC-2

Specification

Specification	REF
100mL	12.01.1415A

Specification	REF
200mL	12.01.1356A
500mL	12.01.1357A
1L	12.01.1416A
4L	12.01.1417A

Intended Use

It is used to lyse (destroy) red blood cells and maintain the morphology of cells before blood cell analysis, so as to facilitate the counting of white blood cells.

Principle

The product is added to lyse the red blood cells (RBC) and maintain the morphology of cells for white blood cell (WBC) differential.

Active Ingredients

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

A List of Materials Provided

- RF card
- Instructions for Use
- Reagent

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56 hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Performance Characteristics

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$.

DIL-C Diluent

Product Name
Hematology Analyzer Diluent

Model
DIL-C

Specification

Specification	REF
10L	12.01.1384A
20L	12.01.1320A

Intended Use

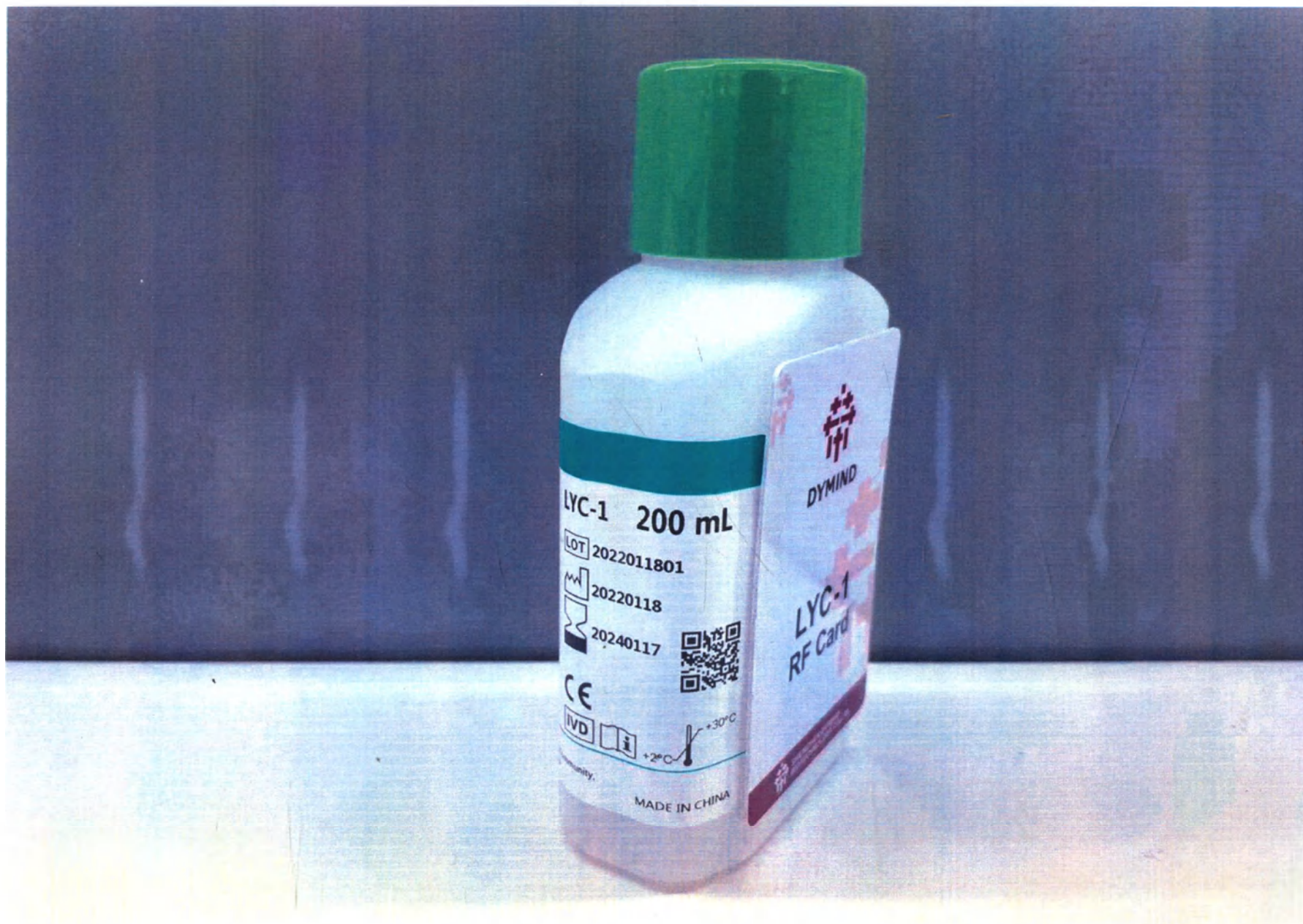
It is used for blood cell analysis, sample dilution and cell suspension preparation.

Principle

This diluent is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell counting.

Реагент лизирующий LYC-1, 100 мл, в составе:

- Реагент лизирующий LYC-1- 100 мл.
- Инструкция по применению – 1 шт.



Реагент лизирующий LYC-1, 200 мл



Реагент лизирующий LYC-1, 200 мл



Реагент лизирующий LYC-1, 200 мл



Instructions for Hematology Analyzer Reagents

IVD CE

Preface

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E-mail: info@dymind.com Tel: +86 755 25008015
Fax: +86 755 20740102
Website: <http://www.dymind.com>

EC REP

Eunitor GmbH
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Shenzhen Dymind Biotechnology Co., Ltd.
10th Floor, Building B, High-tech Park, Guangqiao
Road, Tianliu Community, Yutang Street,
Guangming District, Shenzhen 518107, P.R. China

Release date: 2022-05-24
Date of manufacture: see product label

LYC-1 Lyse

Product Name
Hematology Analyzer Lyse
Model
LYC-1

Specification	REF
50mL	12.01.1411A
100mL	12.01.1355A
200mL	12.01.1354A
500mL	12.01.1412A
1L	12.01.1413A
4L	12.01.1414A

Intended Use

It is used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

Principle

The reagent is added to lyse the red blood cells (RBC) and react with the released hemoglobin (HGB) for the measurement of HGB, white blood cell count (WBC) and Reticulocyte (RAS).

Active Ingredients

Surface active agent, Buffering agent, Antifungal and antibacterial agents.

A List of Materials Provided

- RF card
- Instructions for Use
- Reagent

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56 hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Performance Characteristics

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$, HGB $\leq 1g/L$.

LYC-2 Lyse

Product Name
Hematology Analyzer Lyse
Model
LYC-2

Specification	REF
100mL	12.01.1415A

Specification	REF
200mL	12.01.1356A
500mL	12.01.1357A
1L	12.01.1416A
4L	12.01.1417A

Intended Use

It is used to lyse (destroy) red blood cells and maintain the morphology of cells before blood cell analysis, so as to facilitate the counting of white blood cells.

Principle

The product is added to lyse the red blood cells (RBC) and maintain the morphology of cells for white blood cell (WBC), differential.

Active Ingredients

Surface active agent, Buffering agent, Antifungal and antibacterial agents.

A List of Materials Provided

- RF card
- Instructions for Use
- Reagent

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56 hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Performance Characteristics

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$.

DIL-C Diluent

Product Name
Hematology Analyzer Diluent
Model
DIL-C

Specification	REF
10L	12.01.1334A
20L	12.01.1335A

Intended Use

It is used for blood cell analysis, sample dilution and cell suspension preparation.

Principle

The diluent is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell counting.

Реагент лизирующий LYC-1, 200 мл, в составе:

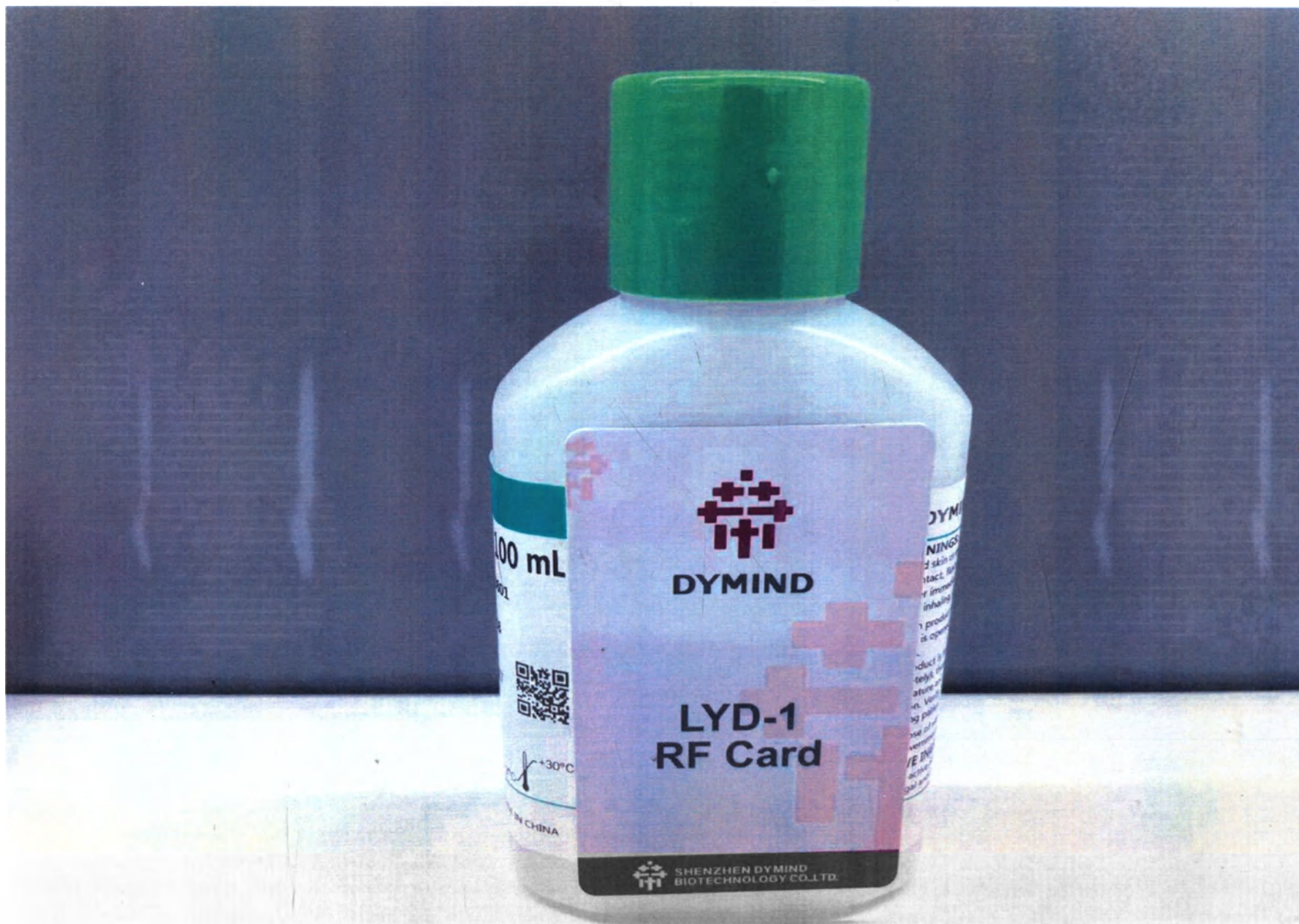
- Реагент лизирующий LYC-1- 200 мл.
- Инструкция по применению – 1 шт.



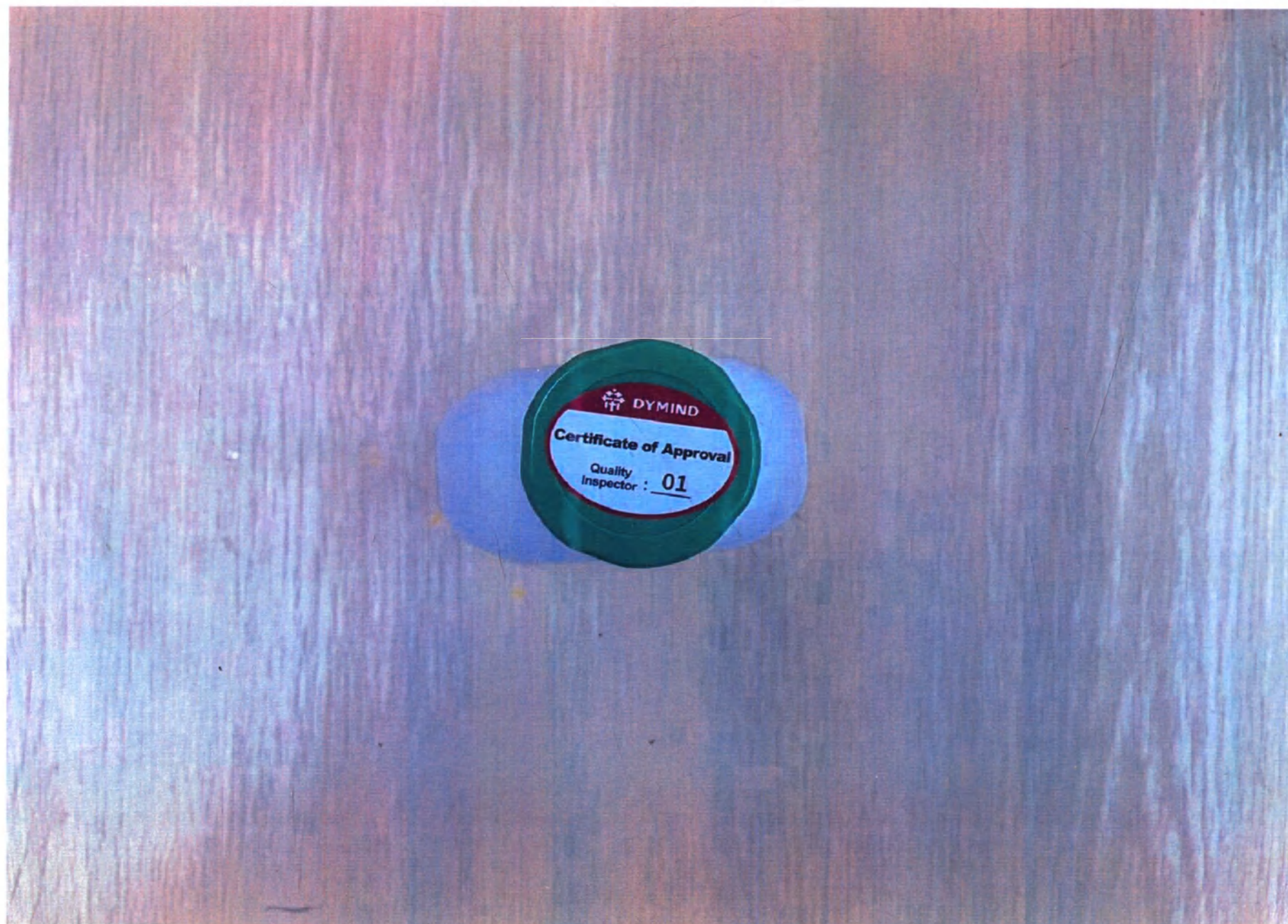
Реагент лизирующий LYD-1, 100 мл



Реагент лизирующий LYD-1, 100 мл



Реагент лизирующий LYD-1, 100 мл



Реагент лизирующий LYD-1, 100 мл



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Fax: +86 755 26746162 Website: <http://www.dymind.com>



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Shenzhen Dymind Biotechnology Co., Ltd.
10th Floor, Building B, High-tech Park,
Guangqiao Road, Tiantiao Community, Yuhang
Street, Guangning District, Shenzhen 518107,
P.R. China

Release date: 2022-08-30
Date of manufacture: see product label



LYD-1 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYD-1

Packing Specification

50mL, 100mL, 200mL, 500mL, 1L, 4L

Intended Use

It is used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

Principle

The reagent is added to lyse the red blood cells (RBC) and react with the released hemoglobin (HGB) for the measurement of HGB, white blood cell count (WBC) and Basophils (BAS).

Active Ingredients

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$, HGB $\leq 1g/L$.

LYD-2 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYD-2

Packing Specification

100mL, 200mL, 500mL, 1L, 4L

Intended Use

It is used to lyse (destroy) red blood cells and maintain the morphology of cells before blood cell analysis, so as to facilitate the counting of white blood cells.

Principle

The product is added to lyse the red blood cells (RBC) and maintain

the morphology of cells for white blood cell (WBC) differential.

Active Ingredients

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$.

DIL-C Diluent

Product Name

Hematology Analyzer Diluent

Model

DIL-C

Packing Specification

10L, 20L

Intended Use

It is used for blood cell analysis, sample dilution and cell suspension preparation.

Principle

The diluent is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell counting.

Active Ingredients

Sodium Chloride, Sodium Sulfate, Buffering Agent, Antifungal and Antibacterial Agents and Preservative.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56, DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

Реагент лизирующий LYD-1, 100 мл, в составе:

- Реагент лизирующий LYD-1- 100 мл.

- Инструкция по применению – 1 шт.



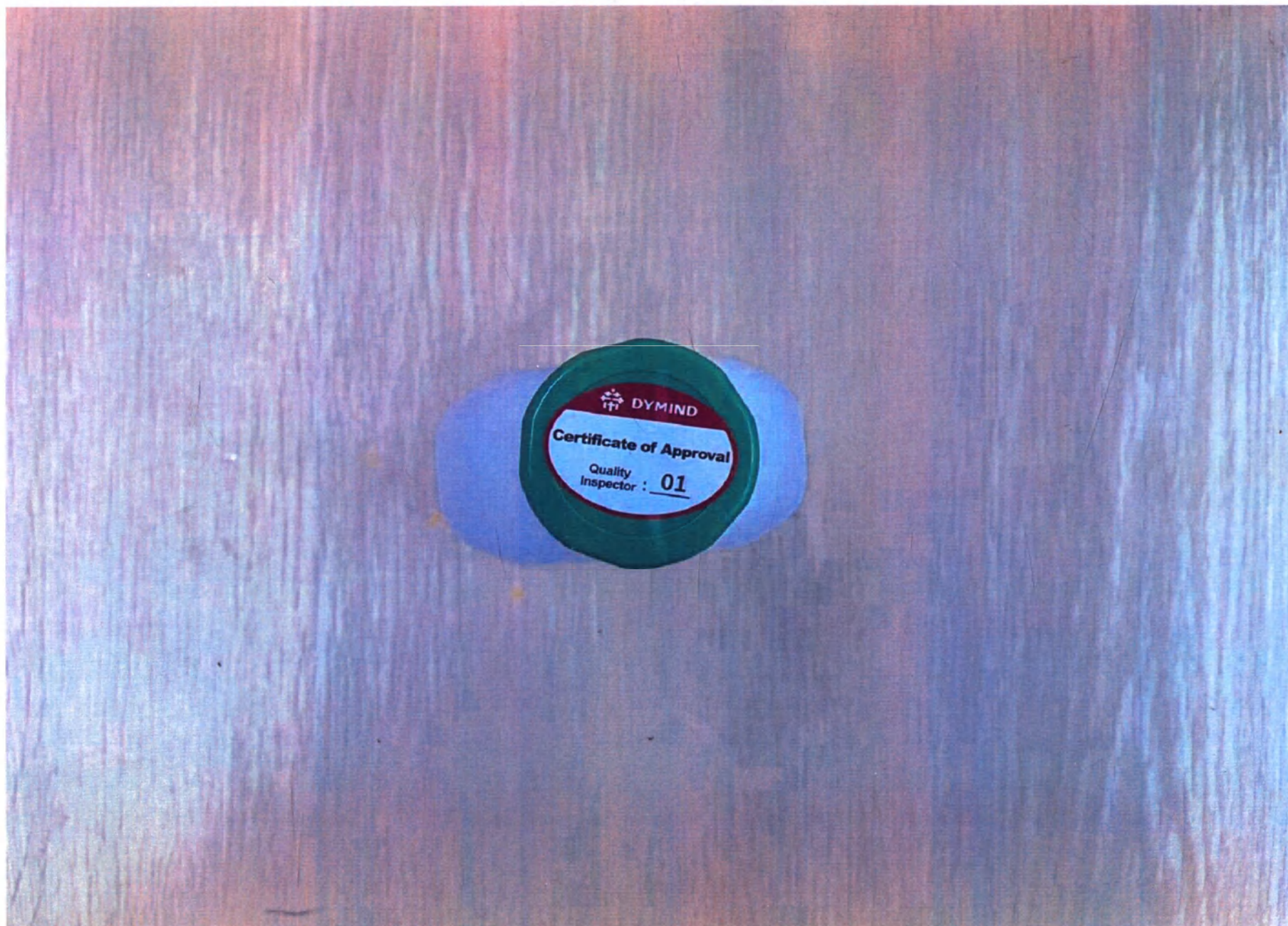
Реагент лизирующий LYD-1, 200 мл



Реагент лизирующий LYD-1, 200 мл



Реагент лизирующий LYD-1, 200 мл



Реагент лизирующий LYD-1, 200 мл



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Fax: +86 755 26740162 Website: <http://www.dymind.com>

EC REP

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Street, Guangming District, Shenzhen 518107,
P.R. China

Release date: 2022-08-30

Date of manufacture: see product label

IVD CE

LYD-1 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYD-1

Packing Specification

50mL, 100mL, 200mL, 500mL, 1L, 4L

Intended Use

It is used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

Principle

The reagent is added to lyse the red blood cells (RBC) and react with the released hemoglobin (HGB) for the measurement of HGB, white blood cell count (WBC) and Basophils (BAS).

Active Ingredients

Surface active agent, Buffering agent, Antifungal and antibacterial agents.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$, HGB $\leq 1g/L$.

LYD-2 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYD-2

Packing Specification

100mL, 200mL, 500mL, 1L, 4L

Intended Use

It is used to lyse (destroy) red blood cells and maintain the morphology of cells before blood cell analysis, so as to facilitate the counting of white blood cells.

Principle

The product is added to lyse the red blood cells (RBC) and maintain

the morphology of cells for white blood cell (WBC) differential.

Active Ingredients

Surface active agent, Buffering agent, Antifungal and antibacterial agents.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

How to Use

Restore the lysing reagent to the use temperature, unpack the reagent, insert the corresponding catheter to the reagent bottle according to the color correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the background counting to make sure that the measured value is within the background counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications

The product is a clear liquid without particle, precipitate or floccule.
Background result: WBC $\leq 0.2 \times 10^9/L$.

DIL-C Diluent

Product Name

Hematology Analyzer Diluent

Model

DIL-C

Packing Specification

10L, 20L

Intended Use

It is used for blood cell analysis, sample dilution and cell suspension preparation.

Principle

The diluent is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell counting.

Active Ingredients

Sodium Chloride, Sodium Sulfate, Buffering Agent, Antifungal and Antibacterial Agents and Preservative.

Storage and Stability

The product will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer

Applicable to DF50, DF51, DF52, DF53, DF55, DF56, DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP hematology analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd.

Реагент лизирующий LYD-1, 200 мл, в составе:

- Реагент лизирующий LYD-1- 200 мл.
- Инструкция по применению – 1 шт.

Всего прошито, пронумеровано и скреплено
печатью и подписью: 20 листа (-ов)

Генеральный директор _____ / Носова Т.А
М.П.

ПО ДОВЕРЕННОСТИ
77-АД 1754187
КУСАНОВ Р.В.

