

文件类型	技术文件	文件编号	S-65.02.0048A
机密等级	秘密	版本	AB
项目代码	DM3104	页码	共 6 页
项目名称： 血细胞分析用试剂			
文件名称： 3104 血细胞分析用试剂 使用说明书 (LYC-1、LYC-2、DIL-C、CLE-P) (英文)			
适用范围： DF50、DF51、DF52、DF53、DF55、DF56、DF5-CRP、 DF1-CRP、DF3-CRP、DF50CRP、DF52CRP、DF53CRP			
拟制： 日期：	审核： 日期：	批准： 日期：	
相 关 文 档			
文件编号	文件名称		版本
磁盘文件名称	字节数	复核	日期

修 订 记 录

版本	TCN/ECR/PCN 编号	修订内容概述	修订人	修订日期
1.0	-	新建。	张淑娴	2015-12-31
2.0	-	- 注册后核对更新全文。 - 增加文件模板。 - 调整全文布局，将说明书合成到一张 A4 纸。 - 增加清洁液。 - 按法规要求更改溶血剂预期用途。	张淑娴	2016-04-05
2.1	ECR2016010	更新欧代地址。	张淑娴	2016-12-24
2.2	ECR2017015	- 加工要求-装订形式（材料）添加选项。 - 添加描述 “Date of manufacture: see product label”。 - 添加制造日期标志 “”。 - 打印模式更新为“双面打印，彩色，80 克书纸”。	宋佳欣	2017-11-08
3.0	ECR2017026	- DIL-C 新增适用机型（1109 机型：DF5-CRP、DF1-CRP、DF3-CRP、DF50CRP、DF52CRP、DF53CRP）。 - LYC-1、LYC-2 适用机型“DF5X”更新为“DF50、DF51、DF52、DF53、DF55、DF56”。 - 公司网址 “http://www.dymind.com.cn” 更新为 “http://www.dymind.com”。	宋佳欣	2017-11-17
3.1	ECR2018001	“CLE-P 清洁液”更新：储存有效期由“1 年”变更为“2 年”。 “CLE-P 清洁液”更新：主要组成成分中“Naclo”更新为“NaClO”。	陈玉书	2018-01-28
4.0	ECR2018045	- 公司住址门牌号由 1183 更改为 4093。 - 欧代地址由之前的：“Dorfstrasse 2/4, Emmendingen”改为“Dorfstrasse 2/4, 79312 , Emmendingen, Germany”。	陈玉书	2018-10-09
5.0	ECR2019034	- DIL-C 主要成分中添加“防腐剂”。 - DIL-C:性能指标，将空白计数删掉。 - 添加稀释液粒子计数相关描述。 - 切换说明书新模板。 - 删除“版权、声明及服务”相关信息。 - 增加发布日期。 - 完善包装相关注意事项。	龚瑜	2019-07-17
AA	ECR2020002	“Precautions”中补充一点“Inner packing (soft bucket) and outer packing of the diluent should be used together.”。 - 技术文件封面更新为最新模板。 - 版本号切换为 AA 版本。 - 更新注册地址及欧代地址。 - 修改 Preface，统一使用“instructions”。	康梦紫	2020-10-10
AB	ECR2021021	- 切换新 VI。 - 更新欧代地址。 - 优化标识及其解释，增加运输标识。	王怡岚	2021-08-27

版本	TCN/ECR/PCN 编号	修订内容概述	修订人	修订日期
		● 技术文件封面升级。 ● 更新发布日期。		

加工要求（选择一项）**加工类型：**

☐ 外购（供应商加工） ☒ 自制

封面颜色、图案：

☐ 帝迈通用 ☐ OEM 定制 ☐ 无图案 ☒ 无封面

装订形式（材料）：

☐ 胶装

☐ 过厚塑（限简易操作指南）

☐ 骑马订（需要封面且内容少于 30 页）

☐ 订书钉（内容少于 30 页且多于 1 页）

☒ 其他：无

页面形式：

☒ A4 ☐ A5 ☐ 其他（如***mm×***mm）：

加工的起始页码和纸张要求：

封面：无 封底：无

纸张要求：无

正文：第 5 页~第 6 页

纸张要求：打印机用纸，黑白，双面打印

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.

Service Tel: 400-998-7276

Tel: +86 755 26008015

Fax: +86 755 26746162

Website: <http://www.dymind.com>



Eunitor GmbH

Kennedydamm 5, 40476 Duesseldorf, Germany

Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park,
Guangqiao Road, Tianliao Community, Yutang
Street, Guangming District, Shenzhen 518107,
P.R.China

Release date: 2021-09-15

Date of manufacture: see product label

LYC-1 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYC-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 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.

Specifications

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

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 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.

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.

LYC-2 Lyse

Product Name

Hematology Analyzer Lyse

Model

LYC-2

Packing Specification

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

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.

How to Use

Restore the diluent to the use temperature, unpack the reagent, insert the corresponding catheter to the diluent barrel 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 blank determination to make sure that the measured value is within the blank 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 should be clear liquid without particles, sediment and flocs.

Particle counting: particle volume $\geq 2.5\text{fL}$, particle counting $\leq 2.5 \times 10^5/\text{L}$.

CLE-P Cleanser**Product Name**

Cleanser

Model

CLE-P

Packing Specification

50 mL

Intended Use

It's used on hematology analyzers for regular cleaning and washing of the probe and tubing system within machines.

Principle

The product is a strong alkaline solution that effectively cleans out protein stains and other particles affecting blood cell counting.

Active Ingredients

Surface active agent, NaClO, NaOH

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 the hematology analyzers manufactured by Dymind.

How to Use

Follow the instructions on the analyzer operating screen and set the uncapped cleanser to the sample probe when required. Then press the aspirate key to start cleanser maintenance. Refer to the operator's manual of the analyzer for further information.

Specifications

The product should be light yellow transparent liquid without particles, sediment and flocs.

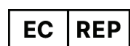
Background result: WBC $\leq 0.2 \times 10^9/\text{L}$, RBC $\leq 0.02 \times 10^{12}/\text{L}$, HGB $\leq 1\text{g/L}$, PLT $\leq 10 \times 10^9/\text{L}$.

Precautions

- Do not inhale. In case of inhaling, immediately go see a doctor. Avoid skin or eye contact. In case of skin contact, flush the affected area with plenty of water immediately. In case of eye contact, flush the affected area with plenty of water immediately and go see a doctor.
- Use product before the expiration date.
- If product is frozen (either partially or completely), thaw completely, warm to room temperature and mix thoroughly by gentle inversion. Verify background results before analyzing patient samples.
- Dispose of reagents, waste and consumables according to government regulations.
- Test result may be unreliable if: reagent expired or invalid; reagent polluted with dust from the air; sample is not processed cleanly; reagent is mixed or used with third party reagents.
- After delivery, please check the outer packing. If it's damaged and the liquid leaks out, don't use the reagent. If no leakage occurs, please perform quality control test before using the analyzer to ensure the detecting system operates well.
- Inner packing (soft bucket) and outer packing of the diluent should be used together.

Interpretation of Symbols

Consult instructions for use or consult electronic instructions for use



Authorized representative in the European Community/European Union



In Vitro diagnostic medical device



CE MARKING OF CONFORMITY



Batch code



This is the correct upright position of the distribution packages for transport and/or storage.



Use-by date



Contents of the distribution packages are fragile therefore it shall be handled with care.



Manufacturer



Keep dry



Date of manufacture



Stacking limit by number



Temperature limit