

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Erba Lachema s.r.o.
Karásek 2219/1d
62100 Brno
Czech Republic

Holds Certificate Number:

MD 745529

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, production and sales of in vitro diagnostics medical devices according to own and customer requirements.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-08-03

Latest Revision Date: 2022-05-23

Effective Date: 2021-12-02

Expiry Date: 2024-12-01

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...making excellence a habit.™

Erba Diluent-Diff



Diluent for automated analyzers

IVD

Name	Cat. No.	Package volume
Erba Diluent-Diff	HEM00004	20 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Diluent-Diff is a buffered, stabilized and micro-filtered electrolyte solution for automated dilution of human blood samples, quantitative and qualitative determination of erythrocytes (RBC), leucocytes (WBC) and the leucocyte subpopulations, thrombocytes (PLT) and measurement of hemoglobin (HGB) concentration on hematology analyzers.

Erba Diluent-Diff should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.

Please refer to the instrument's User Manual for further information.

INGREDIENTS

Sodium chloride	< 1.5 %
Buffers	< 1.0 %
Preservative	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Diluent-Diff is environmental friendly, azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Diluent-Diff is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) °C or up to 24 hours after collection when refrigerated (+2 to +8) °C.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Diluent-Diff diluent between +15 and +30°C.
- The shelf life of the Erba Diluent-Diff diluent is 36 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF	Catalogue Number	Manufacturer	See Instruction for Use	LOT	Lot Number
Storage Temperature	Expiry date	IVD	In vitro Diagnostics	CONT	Content

CE Mark - Device comply with the Directive 98/79/EC

Erba Cleaner



Cleaning solution for automated analyzers

IVD

Name	Cat. No.	Package volume
Erba Cleaner	HEM00001	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Cleaner is a stabilized and micro-filtered detergent solution for regular automated cleaning, rinsing and washing of hematology analyzers' capillaries, tubing and chambers, removing blood component precipitates and lipoprotein deposits on Erba Lachema hematology analyzers.

Erba Cleaner should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.

Please refer to the instrument's User Manual for further information.

INGREDIENTS

Detergents	< 1.0 %
Buffers	< 1.0 %
Preservative	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Cleaner is environmental friendly, azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Cleaner reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) °C or up to 24 hours after collection when refrigerated (+2 to +8) °C.

Please refer to the instrument's User Manual for further details.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Cleaner reagent between +15 and +30°C.
- The shelf life of the Erba Cleaner is 48 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

Catalogue Number

Manufacturer

See Instruction for Use

Lot Number

CE Mark - Device comply with the Directive 98/79/EC

Storage Temperature

Expiry date

In vitro Diagnostics

Content

50003767

Erba Lyse-Diff



EN

Lysing reagent for automated analyzers

IVD

Name	Cat. No.	Package volume
Erba Lyse-Diff	HEM00007 (opened)	1 L
Erba Lyse-Diff	HEM00008 (closed)	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Lyse-Diff lysing reagent is a stabilized and micro-filtered lysing agent for stromatolysis of erythrocytes (RBC), for quantitative determination of leukocytes (WBC), leukocyte three-part differentiation (LYM, MID, GRAN) and hemoglobin (HGB) concentration measurement in human blood on hematology analyzer.

Erba Lyse-Diff lysing reagent should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.

Please refer to the instrument's User Manual for further information.

INGREDIENTS

Surfactants	< 3.5 %
Buffers	< 1.0 %
Preservative	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Lyse-Diff lysing reagent is environmental friendly, cyanide-free and azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

- Erba Lyse-Diff lysing reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) °C or up to 24 hours after collection when refrigerated (+2 to +8) °C.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.


REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Lyse-Diff lysing reagent between 15 and 30°C.
- The shelf life of the Erba Lyse-Diff lysing agent is 48 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

 Catalogue Number

 Manufacturer

 See Instruction for Use

 Lot Number

 Storage Temperature

 Expiry date

 In vitro Diagnostics

 Content

 CE Mark - Device comply with the Directive 98/79/EC

50003764
50004171

Каталожный номер	Название реагента	Фасовка
50003763	Раствор дилуента Erba Diluent- Diff	20 литров
50003764	Лизирующий раствор Erba Lyse-Diff	1 литр
50003767	Очищающий раствор Erba Cleaner	1 литр
50003832	Гематологический контроль Erba низкий уровень	4,5 мл
50003833	Гематологический контроль Erba нормальный уровень	4,5 мл
50003834	Гематологический контроль Erba высокий уровень	4,5 мл

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ELite 3

Современный гематологический анализатор с дифференцировкой лейкоцитов на 3 популяции



Почувствуйте комфорт в гематологии



Контакт / Mapa



Преимущества

- Работа с тремя реагентами для полного анализа (Раствор дилуента Erba Diluent-Diff, Лизирующий раствор Erba Lyse-Diff, Очищающий раствор Erba Cleaner)
- Встроенный принтер, ширина термобумаги 58 мм, распечатка полных отчетов с гистограммами
- USB интерфейс с поддержкой подключения: компьютера, клавиатуры, внешнего принтера, ручного считывателя штрих-кода, внешнего устройства памяти
- Возможность обновления программного обеспечения и резервного копирования данных с использованием внешних устройств памяти
- Использование стандартных комплектующих высокой степени надёжности
- Долговечная апертура из технического рубина

Удобство в работе

- Защита оператора от контакта с кровью – забор пробы внутри прибора
- Использование 3 типов адаптеров пробирок для работы с венозной, капиллярной и контрольной кровью
- Компактный размер прибора, не требуется частого технического обслуживания
- Полноцветный сенсорный ЖК дисплей с высокой контрастностью
- Дружелюбный русифицированный интерфейс пользователя

Принципы измерения

- Импедансометрический метод дифференцировки клеток крови
- Фотометрический метод для определения уровня гемоглобина

Определяемые параметры

- 20 параметров, полный подсчет клеток, включая дифференцировку лейкоцитов на 3 популяции
- WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM, MID, GRA, LYM%, MID%, GRA%, RDW-SD, RDW-CV, PDW-SD, PDW-CV, MPV, PCT
- 3 гистограммы: WBC-3 части, RBC, PLT

Контроль и калибровка

- 3 уровня контрольной крови для правильного и тщательного контроля качества с построением диаграмм Леви-Дженнигса
- 2 вида калибровки: по фактору или с помощью контрольной крови
- Хранение результатов калибровки и контроля качества в базе данных пользователя

Вывод результатов

- Прямая печать результатов на бумаге (встроенный термопринтер)
- Подключение и вывод данных в ЛИС (лабораторную информационную систему)
- Запись данных на внешнее запоминающее устройство через USB порт

Очистка и предотвращение образования сгустка

Применение 3 типов очистки в анализаторе:

- Прожиг высоким напряжением в апертуре
- Химическая очистка
- Метод обратного потока в апертуре

Техническая спецификация

Тип дозирования образца:

открытая пробирка с автоматическим ротором подачи

Производительность:

80 тестов в час

Объем образца:

25 мкл цельной крови, 50 мкл в режиме предварительного разведения

Получение результата:

через 45 секунд

Индикатор статуса прибора:

Информирование пользователя о статусе прибора изменением цветовой индикации LED полосы состояния (красный/жёлтый/зелёный)

Емкость памяти:

1000 результатов, с гистограммами по RBC, PLT и трём популяциям WBC

Питание:

Внешний источник питания, 200-240 Вт, 50-60 Гц.

Размеры:

320x260x365 (Д x Ш x В)

Вес:

12 кг

