

Deproteinizer

REF	CONTENT	SYSTEM
03110435180	125 mL	9180 Electrolyte Analyzer cobas b 221 <2> system cobas b 221 <4> system cobas b 221 <6> system cobas ISE neo

English

Intended use

The Deproteinizer (Mat. No. 03110435180) is intended to be used by professional users in near-patient testing and laboratory environment with the **cobas b 221** system, the 9180 Electrolyte Analyzer and the **cobas ISE neo** Analyzer for the periodic external cleaning or decontamination of the measuring system in manual or automatic workflows.

For the 9180 Electrolyte Analyzer, the Deproteinizer is used for the regular decontamination of surfaces of the analyzer, including the front door and the areas around the measuring chamber window.

Additionally, it is used for the **cobas b 221** system for the decontamination of the waste separator, T&D disk, tubing paths and after emptying the W Waste Container to wipe the exterior, as well as for decontamination of the measuring chamber when this is contaminated (protein deposits) or when sample path components have to be exchanged.

Furthermore, the Deproteinizer is intended to be used with the **cobas ISE neo** Analyzer for cleaning the ISE flow path.

Summary

The Deproteinizer is used in critical professional near-patient environments such as e.g. intensive care areas, emergency departments and operating rooms as well as the hospital laboratories.

For more information on the handling of the reagent, refer to the latest 9180 Electrolyte Analyzer Instructions for Use or the **cobas b 221** system Instructions for Use or the **cobas ISE neo** User Guide.

Test principle

Following laboratory-specific regulations, regularly decontaminate the surfaces of the analyzer according to the latest 9180 Electrolyte Analyzer Instructions for Use or the **cobas b 221** system Instructions for Use.

Regularly clean the ISE reagent flow path according to the **cobas ISE neo** User Guide. For maintenance on **cobas ISE neo** the Deproteinizer needs to be prepared freshly.

Reagents

The Deproteinizer is an aqueous sodium hypochlorite solution.

User training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Precautions and warnings

For in vitro diagnostic use for health care professionals.

Do not use Deproteinizer or other disinfectants on electrical contacts. The surfaces of the analyzer should remain untouched for at least 15 minutes after its disinfection.

⚠ CAUTION! To avoid destroying the MSS cassette, do not use Deproteinizer in or around the MSS measuring chamber of the **cobas b 221** system.

⚠ WARNING! Do not use the Deproteinizer after the expiry date.

⚠ CAUTION! Follow good laboratory practice rules when handling the Deproteinizer.

Exercise the normal precautions required for handling all laboratory reagents.

⚠ WARNING! Direct exposure to Deproteinizer, such as inhalation, swallowing or skin contact, may lead to serious skin burns, eye damage and other serious health risks.

While handling Deproteinizer wear appropriate personal protective equipment, such as eye protection with side shields, fluid-resistant laboratory coat, approved lab gloves and face shield.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Read the Material Safety Data Sheet for Deproteinizer before handling. Safety data sheet available for professional user on request.

For more information on the handling of the reagent, refer to the latest 9180 Electrolyte Analyzer Instructions for Use or the **cobas b 221** system Instructions for Use or the **cobas ISE neo** User Guide.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning:

H314 Causes severe skin burns and eye damage.

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P273 Avoid release to the environment.

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

Response:

P301 + P330 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
+ P331

P303 + P361 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
+ P310 Immediately call a POISON CENTER/ doctor.

P305 + P351 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
+ P338 Continue rinsing. Immediately call a POISON CENTER/ doctor.

Hazardous components: 7681-52-9 sodium hypochlorite

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Storage and stability

Storage and In-Use time:

- up to the stated expiration date at +15 °C to +30 °C (+59 °F to +86 °F)

Materials required (but not provided)

Please refer to the appropriate Instructions for Use for the instrument concerned.

For further information, please refer to the appropriate Instructions for Use for the instrument concerned.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Deproteinizer

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):



Device for near-patient testing



Device not for self-testing



Analyzers/Instruments on which reagents can be used



Content of kit



Global Trade Item Number



Corrosive

Rx only

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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