

Instructions For Use

Cleaning Solution for the iSED®, iSED ELITE, and miniiSED® ESR Analyzers

REF

112-12-020

deepCLEAN® 3 x 2.0 mL

CE

IVD

INTENDED USE

deepCLEAN is an alkaline cleaning solution intended for use with the iSED, iSED ELITE, and miniiSED Automated Erythrocyte Sedimentation Rate (ESR) Analyzers and is used to remove residue and proteins built up within the analyzers during routine testing.

SUMMARY AND PRINCIPLE

The deepCLEAN Cleaning Solution is a sodium hypochlorite solution used for removing blood residue and proteins from within the iSED, iSED ELITE, and miniiSED analyzers after intervals of routine use or during other maintenance/troubleshooting procedures. The use of deepCLEAN removes accumulated blood residuals from the fluidics path and is important for proper functioning of the iSED, iSED ELITE, and miniiSED analyzers. The pre-filled deepCLEAN tubes are ready-to-use to facilitate analyzer maintenance. Each deepCLEAN tube is designed to be used up to three (3) times over 30 days. The deep cleaning process uses 200 µl of deepCLEAN solution and takes approximately three (3) minutes. The iSED, iSED ELITE, and miniiSED analyzers require a deep cleaning procedure monthly or 1000 samples (whichever comes first). Once cleaning with deepCLEAN is complete, testing can resume as normal. The deepCLEAN tubes are designed to be used with the caps on and should remain capped at all times.

MATERIAL

Contents: Sodium hypochlorite solution
Tube: High Density Polyethylene (HDPE)

STORAGE & STABILITY

Each deepCLEAN tube can be used up to three (3) times. Once pierced, the deepCLEAN tube must be used within 30 days. The unused product is stable until the expiration date. Product must be stored protected from light. The deepCLEAN tubes **must remain capped and upright at all times** in order to maintain product integrity and reduce the risk of exposure to sodium hypochlorite.

Storage temperature is 4°C to 22°C. It is important to adhere to these storage conditions as warmer temperatures are known to reduce the effectiveness of sodium hypochlorite solutions.

WARNINGS AND PRECAUTIONS

This solution contains sodium hypochlorite. Tubes should remain capped and upright to reduce the risk of exposure to sodium hypochlorite. Wear appropriate personal protective equipment (PPE) when using this product.

Avoid contact with skin and eyes. If the solution comes into contact with the eyes, immediately flush with water and get emergency medical help. If the solution comes into contact with the skin, immediately rinse the affected area.

This product contains substances classified as **very toxic to aquatic organisms**. Accidental release into the environment may lead to significant ecological damage. Take appropriate precautions to prevent environmental exposure. Disposal must comply with applicable hazardous waste regulations.



WARNINGS AND PRECAUTIONS (cont'd)

H314	Causes severe skin burns and eye damage.
H400	Very toxic to aquatic life
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303 + P361 + P353	IF ON SKIN (OR HAIR): Immediately take off all contaminated clothing. Rinse skin with water/shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P501	Dispose of contents/container in accordance with local and national regulations.
EUH031	Contact with acids liberates toxic gas.

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

PROCEDURE

For a detailed procedure for cleaning with deepCLEAN, see the iSED Operator's Manual (112-09-043), iSED/iSED ELITE Operator's Manual (222-09-007), or miniSED Operator's Manual (1017-09-001).

For additional information or questions regarding the information above, please contact ALCOR® Scientific Technical Support at techservice@alcorscientific.com or 1.800.495.5270 (US only) / + 1.401.737.3774.



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