

Instructions For Use

Cleaning Solution Exclusively for the iSED[®] PRO ESR Analyzer

REF	112-12-022	deepCLEAN [®] PRO 3 x 3.0 mL	CE	IVD
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INTENDED USE

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

SUMMARY AND PRINCIPLE

deepCLEAN PRO is exclusively for the iSED PRO Automated ESR Analyzer. The deepCLEAN PRO Cleaning Solution is a sodium hypochlorite solution used for removing blood residue and proteins from within the iSED PRO analyzer after intervals of routine use or during other maintenance/troubleshooting procedures. The use of deepCLEAN PRO removes accumulated blood residuals from the fluidics path and is important for proper functioning of the iSED PRO analyzer. The iSED PRO deep cleaning process uses 500 µl of deepCLEAN PRO solution and takes approximately three (3) minutes. The deepCLEAN PRO tubes can be used up to four (4) times and are designed to be stored onboard iSED PRO when in use. The analyzer automatically performs a deep cleaning procedure with deepCLEAN PRO every 7 days or 1000 samples (whichever comes first). Once cleaning with deepCLEAN PRO is complete, testing can resume as normal. The deepCLEAN PRO 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

This product is stable until the expiration date. The deepCLEAN PRO tubes **must remain capped and upright at all times** in order to maintain product integrity and reduce the risk of exposure to sodium hypochlorite. Product should be stored protected from light until loaded onto the iSED PRO analyzer. Once onboard the analyzer, the deepCLEAN PRO tube can be used up to four (4) times.

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

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 PRO, see the iSED PRO Instructions for Use (120-09-007). This product should only be used with the iSED PRO analyzer.

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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