

AUTION EYE Sheath Solution

Read this package insert carefully before use.

If you have had or could have had any serious incident related to the device, please report it directly to the manufacturer or through the authorised representative and to your local regulatory authority.

Intended Purpose

AUTION EYE Sheath Solution is a sheath solution for use with AI-4510, which is intended for the quantitative and semi-quantitative measurement of several physiological markers in urine. For *in vitro* diagnostic use and professional use only.

Methodology

AUTION EYE Sheath Solution is a solution for regulating refractive index and pH level.

Composition

AUTION EYE Sheath Solution
Buffer and preservative

Warnings and Precautions

1. Never use it on a human body.
2. Performance cannot be guaranteed if it is used for purposes or in methods other than those specified in this package insert.
3. Read the AI-4510 operating manual of the dedicated instrument carefully before use.

<Handling Precautions>

1. For professional use only.
2. Always wear personal protective equipment when carrying out work on or with AUTION EYE Sheath Solution. Avoid direct bodily contact with the reagent. It may cause irritation of the eyes, skin and mucous membranes.
3. Be careful not to splash the solution when opening.
4. Should you inadvertently come into contact with reagent, rinse the skin immediately with plenty of water.
5. If the solution gets into the eye, rinse at once with plenty of water. Consult a doctor without delay.
6. If swallowed, seek medical advice immediately.

<Precautions for Use>

1. Do not use AUTION EYE Sheath Solution after the expiration date has passed.
2. Evaporation of moisture may increase the concentration of the reagent. Seal the cap securely for storage. Incorrect storage may deteriorate the specific performance.
3. Avoid the ingress of microbes or dust after opening.
4. Use up the reagent in the container. Do not mix solution with the reagent from another container even when they have the same lot number.

Procedure

1. Refer to the operating manual of AI-4510 for instructions for analyzing urine using AUTION EYE Sheath Solution.
2. Discard the container after using up the reagent. Do not reuse the container.

Storage and Stability

1. Storage
Do not expose to direct sunlight. Store the product in the box at temperatures between 2 and 35°C. (Do not freeze.)
2. Expiration date
The expiration date is printed on the box label.
3. Validity period after opening
Use the reagent within 30 days of opening.

Performance characteristics and limitations of the method

1. AUTION EYE Sheath Solution is intended solely for use with specific instrument and reagents. Do not use with other systems.
2. Do not use for purposes other than specimen analysis in accordance with the specifications of AI-4510.

Disposal Procedure

AUTION EYE Sheath Solution does not contain any biohazardous substances. Dispose of the container in accordance with applicable local regulations.

Product Information

Materials provided

AUTION EYE Sheath Solution
10 L / box

Materials required but not provided

Refer to the operating manual of AUTION EYE AI-4510.



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This product conforms
to the Medical Devices
Regulations 2002.