diatron

AMMONIA CONTROL

For discret analysers Product code: 1478-1045 Package: 2 x 5 ml Level 1 2 x 5 ml Level 2 Store at 2-8°C

For *in vitro* use

INTENDED USE

Material for the quality control of the determination of Ammonia using MEDICON reagents on MEDILYZER®, Diatron Pictus series, BECKMAN COULTER AU400/600/600-IVD/640/2700/5400, or ADVIA 1200/1800/2400, DIMENSION® RxL /RxL HM /RxL Max/RxL Max HM/ Xpand/ Xpand HM/Xpand Plus/Xpand Plus HM/ EXL/EXL LOCI Module automated analyzers or any other type of discrete analyzer. For in vitro use only.

COMPOSITION

Ammonium chloride in aqueous buffer, stabilizer, preservative.

WARNINGS - PRECAUTIONS

- For in vitro use only.
- Contains sodium azide (NaN3) ≤0.1%. Avoid contact with eyes, skin and mucous membranes.

PREPARATION

The material is ready to use. Allow the material to reach room temperature. Swirl the vials gently before use. Avoid foaming. Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS NEEDED BUT NOT PROVIDED WITH THE KIT

- Ammonia reagent
- Automated biochemical analyzer
- Common laboratory equipment

STORAGE – STABILITY

The unopened material is stable up to the expiry date stated on the label when stored at 2-8°C. After opening the material is stable for 2 weeks when stored tightly capped immediately after use at 2-8°C.

DETERIORATION

The material should not be used:

- · After the expiration date.
- After prolonged exposure to direct sunlight or high temperature
- · When microbial growth is evident

TEST PROCEDURE

Refer to the user's manual of the analyzer for the quality control process.

Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed. The results obtained by any individual laboratory may vary from the given mean value but should fall within the corresponding acceptable ranges given in the enclosed table. If any trends or sudden shifts in values are detected, review all operating parameters. Each laboratory should establish guidelines for corrective actions to be taken if controls do not recover within the specified limits. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

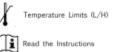
WASTE DISPOSAL

This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

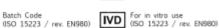
ASSIGNED VALUES – Lot specific

Refer to the table of assigned values. The range represents the maximum acceptable deviation for one measurement only.











Date of Expiry (ISO 15223 / rev. EN980)



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