diatron

2°C 8°C

CLINICAL CHEMISTRY CONTROL LEV.2

REF 1578-0902-12 **Packaging:** 12 x 5 mL

INTENDED USE

Material for internal quality control of the following analytes: Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Albumin, Amylase, Inorganic Phosphorus, Calcium, Creatinine, Lactate Dehydrogenase, Lactate, G-Glutamate Dehydrogenase, Magnesium, Total Protein, Acid and Prostatic Phosphatase, Urea, Uric Acid, Glucose, Iron, Triglycerides, UIBC, Direct and Total Bilirubin, Cholesterol, HDL, LDL, Potassium, Sodium and Chloride using the related Medicon reagents with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Lyophilized human serum with biological additives in concentrations inside the reference ranges. The analyte concentrations / activities are LOT dependent. Contains preservative.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only.
- Contains sodium azide (NaN3) <0.1%. Avoid contact with eyes, skin and mucous membranes.
- Every donor used for the preparation of this material was tested and found negative for HbsAg, anti-HCV, anti-HIV 1 and 2 by FDA approved methods. However, since no test method can offer complete assurance that infectious agents are absent, this product should be handled as any potentially infectious material.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!

⚠ **PREPARATION**

Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial. Reconstitute by adding exactly 5ml of cold (2°-8°C) deionized or distilled water.
Place the rubber stopper back on the vial, swirl gently 2-3 times and let it stand for 10 minutes. Mix gently to obtain a homogeneous mixture. Ideally use a hematology tubes mixer for 20 minutes. Avoid foaming. Use 30 minutes after water addition.
Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.
For the quality control process refer to the user's manual of the analyzer.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls should be tested each day patient samples are tested and each time calibration is performed. T
he 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.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Automated biochemical analyzer
- Redistilled water
- Clinical chemistry reagents
- Common laboratory equipment

⚠ **STORAGE - STABILITY**

Unopened, the content of vials is stable at 2-8ºC up to the expiration date stated on the label. Reconstituted serum is stable for 8 hours at 25°C, 7 days at 4°C and 1 month when frozen once at -20 °C.
Exceptions:
Bilirubin: (if stored protected from light): 4 days at 4°C. Do not store at 15-25°C. Do not freeze
Acid Phosphatase: For Total and Prostatic-Acid Phosphatase, the material should be stabilized by adding 20 µL of Medicon's ACP stabilizer to 1 mL of the serum exactly 30 minutes after reconstitution. After stabilization Total and Prostatic Acid Phosphatase are stable for: 2 hours at 25°C, 2 days at 4°C and 1 month at -20°C when frozen once
Alkaline phosphatase: Levels in the reconstituted serum will rise during storage. It is recommended that the reconstituted serum be allowed to stand for 1 hour at 25°C before measurement.
HDL- cholesterol / LDL- cholesterol: Do not freeze. It is recommended to dispense the remaining reconstituted material in aliquots and store at –20 ºC for future use taking into consideration the above limitations.

⚠ **DETERIORATION**

The material should not be used:

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

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), 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

Please refer to the value sheet for the specific lot available at https://medicondoc.com.

SYMBOLS

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