

MEDI-CAL

REF 1578-0891 Packaging: 12 x 5 mL



INTENDED USE

Material for the preparation of reference curves for the quantitative determination of the listed analytes 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 that contains adjusted quantities of the following analytes: Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Albumin, Amylase, Inorganic Phosphorus, Calcium, Creatinine, Lactate Dehydrogenase, G-Glutamate Transpeptidase, Creatine Kinase, Lactate, Magnesium, Total Protein, Acid Phosphatase, Urea, Uric Acid, Glucose, Iron, Triglycerides, Direct and Total Bilirubin, Cholesterol, HDL-Cholesterol, LDL-Cholesterol, and Unsaturated Iron Binding Capacity (UIBC), Cholinesterase.

⚠ WARNINGS – PRECAUTIONS

- For in vitro use only.
- Contains sodium azide (NaN₃) <0.1%. Avoid contact with eyes, skin and mucous membranes.
- Different lot numbers of this material should not be interchanged as the values assigned to the materials vary from lot to lot.
- Every donor used for the preparation of this control 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 a 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

Material must only be reconstituted using the following procedure:

1. Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial.
2. Reconstitute by adding exactly 5 ml of cold (2°-8°C) deionized or distilled water.
3. Place the rubber stopper back on the vial, swirl gently 2-3 times and let it stand for **30 minutes, keep the vial away from light.**
4. Swirl gently several times during the reconstitution period to ensure that the contents are completely dissolved, and keep the vial away from light. Ideally use a hematology tubes mixer for 20 minutes.
5. Prior to use, mix the contents by inverting the vial. Do not shake the vial as the formation of foam should be avoided. Ensure that no lyophilized material remains un-reconstituted.
6. The calibrator material is then ready for use (**use the material 30 min after reconstitution**).
7. Prepare and place aliquot samples on the analyzer.
8. Replace the cap immediately after preparing the aliquots and store at 2-8°C, store away from light. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

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

⚠ STORAGE - STABILITY

Unopened, the content of vials is stable at 2-8°C up to the expiration date stated on the label. Reconstituted material 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): 1 day 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 for the reconstituted material to be allowed to stand for 1 hour at 25°C before measurement.

HDL- cholesterol / LDL- cholesterol: Do not freeze

⚠ 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.

PROCEDURE

Refer to the user's manual of the analyzer. The concentrations / activities of the components are LOT dependent. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ WASTE DISPOSAL

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



Manufacturer



Temperature Limit



Caution

