



# FERRITIN CALIBRATOR

#### **BEF**1478-0275 Packaging: 5 x 1 mL

# INTENDED USE

Material for the preparation of reference curves for the quantitative determination of Ferritin using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro Diagnostic use only by trained laboratory professionals.

### COMPOSITION

Liquid, non-hemolyzed, filtered human plasma with stabilizers and preservative.

### M WARNINGS – PRECAUTIONS

- For in vitro use only
- The material contains sodium azide (NaN3) <0.1%. Avoid swallowing and contact with skin and mucous membranes. •
- Biological materials of human origin contained in this product were tested for Anti-HCV. HbsAg and Anti-HIV 1 and 2 using FDA approved ٠ methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents 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!

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Material ready to use. 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 REQUIRED BUT NOT PROVIDED WITH THE KIT

- Ferritin reagent kit
- Automated biochemistry analyzer
- · Common laboratory equipment.

#### **STORAGE - STABILITY** $\triangle$

Unopened, the material remains stable at 2-8°C until the expiry date stated on the label. Once opened, the material remains stable for 1 month when stored tightly capped at 2-8°C.

### ▲ DETERIORATION

### The material should not be used:

• After prolonged exposure to direct sunlight or high temperature

- After the expiry date
- When microbial growth is evident

### ▲ WASTE DISPOSAL

This product contains sodium azide (NaN<sub>3</sub>), 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.

# PROCEDURE

Refer to the appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for serum/plasma application.

If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within acceptable intervals. Results outside the specified values even after recalibration could be due to reagent/calibrator/control deterioration, unsuitable storage conditions, instrument malfunction, or error during test procedure. Every laboratory should establish its own corrective measures in case control recovery lies outside acceptable intervals.

Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

## ASSIGNED VALUES - Lot specific

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

### SYMBOLS



In vitro diagnostic medical device IVD



REF

PICTUS® Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com MEDICON HELLAS S.A. reserves the right to change the information contained in the insert without prior notice. Version 2 - Last updated 2020.06.30





Catalogue Number

