STFR CONTROL

2°C – 8°C

REF 1478-0748 **Packaging:** (3+3) x 1 mL

INTENDED USE
Material for internal quality control of soluble Transferrin receptor (sTfR) assays using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION
Freeze dried, human sTfR in buffer, containing stabilizers and preservative.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only.
- 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 observing the same precautions employed when handling 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 1 ml 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.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- sTfR assay reagent.
- Automated biochemistry analyzer.
- Usual laboratory equipment.

⚠ **STORAGE - STABILITY**

The contents of vials are stable at 2-8°C until the expiry date stated on the label. Once reconstituted, contents remain stable for 1 week when stored tightly capped at 2-8°C after each use.

TEST PROCESS
Refer to the appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for calibration.
If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within the 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.

⚠ **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


In vitro diagnostic medical device


Temperature Limit


Catalogue Number


Caution


Biological Risks

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 2 - Last updated 2020.06.30

CE IVD