RF CALIBRATOR

2°C 8°C

REF 1478-1030 **Packaging:** 5 x 1 x 1 mL

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

COMPOSITION
Filtered, defibrinated, liquid human plasma base, with stabilizers and conservatives.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only.
- To avoid the possible built up of azide compounds, flush waste pipes with water after the disposal of material. Dispose of all waste materials in accordance with local guidelines.
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved 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. A Material Safety Data Sheet is available for this product by MEDICON.
- 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**
Materials are ready to use. Swirl each vial gently prior 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

- RF reagent
- Automated biochemical analyzer
- Common laboratory equipment

⚠ **CALIBRATION STORAGE - STABILITY**
The materials are stable, unopened up to the stated expiry date when stored at 2-8°C. Once opened the material is stable for 6 weeks stored at 2-8°C.

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

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.

SYMBOLS

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