CYSTATIN C CALIBRATOR

For use with discrete analyzers
Product code: 1478-0592
Package: **Level 1: 1 x 1ml**
Level 2: 1 x 1ml
Level 3: 1 x 1ml
Level 4: 1 x 1ml
Level 5: 1 x 1ml
Level 6: 1 x 1ml
Store at 2-8°C
For *in vitro* use only

diatron

INTENDED USE

Material for the preparation of calibration curves for the quantitative determination of Cystatin C in human serum or plasma using MEDICON and other types of reagents, on MEDILYZER®, Diatron Pictus series, BECKMAN COULTER AU400/600/600-IVD/640/2700/5400, or ADVIA 1200/1800/2400, DIMENSION® RxL /RxL HM /RxL Max/RxL Max HM/ Xpand/ Xpand HM/Xpand Plus/Xpand Plus HM/ EXL/EXL LOCI Module automated analyzers, or any other type of discrete analyzer. For in vitro use only.

COMPOSITION

Human cystatin C in buffer. Stabilizers and preservatives.

WARNINGS – PRECAUTIONS

- For in vitro use only
- The material contains sodium azide (NaN_3) <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 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.

MATERIAL PREPARATION

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 SUPPLIED WITH THE KIT

Cystatin C reagent kit.
Automated biochemistry analyzer
Common laboratory equipment.

STORAGE-STABILITY

The materials unopened are stable at 2-8°C up to the expiry date stated on the label. After opening the materials are stable for 1 month when stored tightly capped after use 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

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.

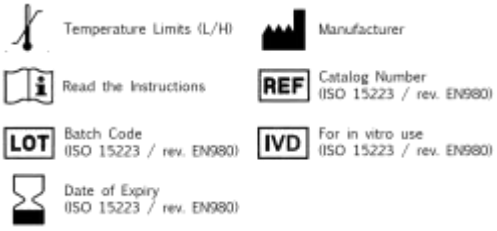
ASSIGNED VALUES – Lot specific

Refer to the table of assigned values. The range represents the maximum acceptable deviation for one measurement only.

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 pipes. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

SYMBOLS



CE IVD