diagnotix•••

Cortisol & Cortisone in urine/saliva

Value Data Sheet 1042 CAL M CORT

Calibrators for LCMSMS Assay in urine and saliva

REF 1042 CAL M CORT

LOT 04B22/S

2024/07

IVD For in vitro diagnostic use

Diagnotix BV
De Plassen 4
9902 SE Appingedam
The Netherlands

+31 (0)596 - 20 10 62 info@diagnotix.com order@diagnotix.com Document version: 1.0

Replaces:

Date of release: 10-02-2022



Intended use:

This product is to be used as a means of calibrating the Cortisol and Cortisone assay. These lyophilized Cortisol and Cortisone calibrators are prepared in a urine matrix. Stabilizers are added to stabilize the analytes for accurate calibration of the Cortisol and Cortisone procedure. After reconstitution these lyophilized calibrators should be treated as a patient sample.

Reconstitution:

Add exactly 1 ml of deionized water to the vial, re-place the plug and let stand for 15 minutes. Swirl gently and let stand for another 15 minutes. Swirl one last time. When all material is dissolved the solution is ready for use.

Storage and Stability

This product will be stable until the expiration date when stored unopened at 2 - 8 °C. After reconstitution the stability of the analytes is: 1 week at 2 - 8 °C 1 month at - 20 °C

The stated stabilities are only valid in case of no bacterial contamination. Avoid repeated freezing and thawing.

Caution

The raw biological material is tested for contaminants. However, because no test method can offer complete assurance that products derived from biological sources will not transmit infectious agents, it is recommended that this product be handled with the same precautions as patient samples.

Pack size:

Cortisol and Cortisone Calibrator Set 6 x 2 x 1 ml, Calibrator 1 - 6

Notes:

The concentrations of the analytes are chosen in ranges where valid results can be obtained. The variation of the filling volume (CV) is < 1 %.

Concentrations:

1042 CAL M CORT	LOT \(\sigma\)	Cortisol (nmol/l)	Cortisone (nmol/l)
Calibrator 1 1043	04B22/12 2024/07	1.5 nmol/l	0 nmol/l
Calibrator 2 1044	04B22/03 2024/07	10.6 nmol/l	12.0 nmol/l
Calibrator 3 1045	04B22/04 2024/07	19.7 nmol/l	24.3 nmol/l
Calibrator 4 1046	04B22/05 2024/07	94.1 nmol/l	105 nmol/l
Calibrator 5 1047	04B22/06 2024/07	280 nmol/l	335 nmol/l
Calibrator 6 1048	04B22/07 2024/07	603 nmol/l	720 nmol/l