diagnotix•••

Cortisol & Cortisone in urine/saliva

Value Data Sheet 1041 CON M CORT

Controls for LCMSMS Assay in urine and saliva

REF 1041 CON M CORT

LOT K01K20/01

2023/05

IVD For in vitro diagnostic use

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Replaces:

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Intended use:

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

Reconstitution:

Add exactly 2 ml of deionized water to the vial and let stand for 15 minutes. Mix 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 Control Set 3 x 3 x 2 ml, Control I - III

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:

1041 CON M CORT	LOT	Cortisol (nmol/l)		Cortisone (nmol/l)	
		Mean	Range	Mean	Range
Control I 1054	17G19/07 2023/05	6.9	5.1 – 8.7	6.6	5.0 – 8.2
Control II 1055	17G19/08 2023/05	147.6	110.7 – 184.5	140.7	105.5 – 175.9
Control III 1056	17G19/09 2023/05	394.4	295.8 – 493.0	384.8	288.6 – 481.0