

INTERPRETATION OF RESULTS:

The **RapiRead™** CUBE analyzer automatically determines the result by comparing the AU for each sample against a pre-established calibration curve. Cortisol levels are expressed in ng/ml. Please refer to Table on Page-1.

PERFORMANCE CHARACTERISTICS:

Sensitivity:

The sensitivity of **TestNOW® - Cortisol** Quantitative Test device is 30 ng/ml (LOD).

Detection Range:

The Detection Range of **TestNOW® - Cortisol** Quantitative Test with **RapiRead™** CUBE Reader is from 30 ng/ml to 1000 ng/ml.

Accuracy:

The accuracy of **TestNOW® - Cortisol** Quantitative Test was evaluated using human finger-prick blood samples in comparison with a reference Cortisol ELISA assay using corresponding serum samples. The comparison result showed a linear regression with slope of 0.91 and Correlation Coefficient of 90%. In conclusion, **TestNOW® - Cortisol** Quantitative Test results of human blood samples showed good agreement with the ELISA results of corresponding serum samples.

The accuracy of **TestNOW® - Cortisol** Quantitative Test was also evaluated using 20 serum samples in comparison with LC-MS/MS Assay ("Gold Standard" for Cortisol measurement). The comparison result showed a linear regression with the slope of 0.95 and Correlation Coefficient of 94%. In conclusion, **TestNOW® - Cortisol** Quantitative Test results agree closely to the true values generated from LC-MS/MS assay.

Precision:

Intra Lot

Sample	No. of Lot	No. of Replicates	Mean ng/ml	Coefficient Variation (CV)
Serum -1	3	20	230.0	7.9%
Serum -2	3	20	55.1	12.5%
Blood - 1	3	10	150.0	9.2%

Inter Lo

Sample	No. of Lot	No. of Replicates	Mean ng/ml	Coefficient Variation (CV)
Serum -1	3	60	231.9	8.1%
Serum -2	3	60	53.5	12.9%
Blood - 1	3	15	148.6	10.1%

Specificity:

30 Cortisol free serum samples were tested, and all showed negative results: suggesting 100% Specificity. No interference and cross reactivity were observed with Bilirubin, Triglycerides, Cholesterol, Vitamin B12 and Vitamin C.

EXPECTED RESULTS

TestNOW® - Cortisol Quantitative Test is a Rapid Quantitative assay. The test is intended to use for screening individuals to identify Cortisol level. This assay provides only a preliminary analytical test result. The liquid chromatography with tandem mass spectrometry (LC-MS/MS) assays or quantitative immunoassays are recommended to confirm the analytical result.











REFERENCES

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SHELF LIFE: 18 Months

INDEX OF CE SYMBOLS

 Consult instructions for use	 IVD For in vitro diagnostic use only	 Use by	 REF Catalog No.	 LOT Lot Number
 Tests per kit	 Store between 4-30°C	 EC REP Authorized Representative	 Do not reuse	 Manufacturer

