

INTERPRETATION OF RESULTS:

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

PERFORMANCE CHARACTERISTICS:

Sensitivity:

The sensitivity of **TestNOW® - Testosterone** Quantitative Test device is 0.07 ng/ml (LOD).

Detection Range:

The Detection Range of **TestNOW® - Testosterone** Quantitative Test with **RapiRead™** CUBE Reader is from 0.07 ng/ml to 25 ng/ml.

Accuracy:

The accuracy of **TestNOW® - Testosterone** Quantitative Test was also evaluated using 20 serum samples in comparison with LC-MS/MS Assay ("Gold Standard" for Testosterone measurement). The comparison result showed a linear regression with the slope of 1.02 and Correlation Coefficient of 98%. In conclusion, **TestNOW® - Testosterone** Quantitative Test results agree closely to the true values generated from LC-MS/MS assay.

The accuracy of **TestNOW® - Testosterone** Quantitative Test was evaluated using human finger-prick blood samples in comparison with a reference Testosterone ELISA assay using corresponding serum samples. The comparison result showed a linear regression with slope of 0.98 and Correlation Coefficient of 92%. In conclusion, **TestNOW® - Testosterone** Quantitative Test results of human blood samples showed good agreement with the ELISA results of corresponding serum samples.

Precision:

Intra Lot

Sample	No. of Lot	No. of Replicates	Mean ng/ml	Coefficient Variation (CV)
Serum -1	3	20	6.31	7.9%
Serum -2	3	20	0.30	12.0%
Blood -1	3	10	3.50	9.7%

Inter Lot

Sample	No. of Lot	No. of Replicates	Mean ng/ml	Coefficient Variation (CV)
Serum -1	3	60	6.25	8.2%
Serum -2	3	60	0.29	12.8%
Blood -1	3	15	3.45	10.7%

Specificity:

30 Testosterone 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® - Testosterone Quantitative Test is a Rapid Quantitative assay. The test is intended to use for screening individuals to identify Testosterone 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

1. Total Testosterone: Health Encyclopedia: https://www.urmc.rochester.edu/encyclopedia/content.aspx?contentTypeid=167&contentid=testosterone_total.
2. Testosterone Levels by Age: <https://www.healthline.com/health/low-testosterone/testosterone-levels-by-age>.
3. High Testosterone Levels in Women: <https://www.healthline.com/health/high-testosterone-in-women>.
4. Testosterone, Serum testosterone: <https://www.mountsinai.org/health-library/tests/testosterone>
5. Chen, A., Bookstein, J.J., Meldrum, D.R., Diagnosis of a testosterone-secreting adrenal adenoma by selective venous catheterization. Fertil. Steril., 1991; 55: 1202-1203.
6. Granoff, A.B. and Abraham, G.E., Peripheral and adrenal venous levels of steroids in a patient with virilizing adrenal adenoma. Obstet. Gynecol., 1979; 53:111-115.

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SHELF LIFE: 18 Months

INDEX OF CE SYMBOLS

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

