

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. 25-OH Vitamin D levels are expressed in ng/ml. Results obtained with the **Rapi-D™** Quantitative Vitamin D Test are interpreted with following Messages:

25-OH Vitamin D Level (ng/ml)	Result Message
< 10.0 ng/ml	DEFICIENT
≥ 10.0 – < 30.0 ng/ml	INSUFFICIENT
≥ 30.0 – < 100.0 ng/ml	SUFFICIENT
≥ 100.0 ng/ml	

PERFORMANCE CHARACTERISTICS:

Sensitivity:

The sensitivity of **Rapi-D™** Quantitative Vitamin D Test is 3ng/ml (7.5nmol/l). The sensitivity was determined by calculating the mean plus 3.3 times of standard deviation of twenty Vitamin D-free serum tests.

Detection Range:

The Detection Range of **Rapi-D™** Quantitative Vitamin D Test with **RapiRead™** CUBE Reader is from 3ng/ml (7.5nmol/l) to 100ng/ml (250nmol/l).

Accuracy:

The accuracy of **Rapi-D™** Quantitative Vitamin D Test was evaluated using human finger-prick blood samples in comparison with a reference 25-OH Vitamin D ELISA assay using corresponding serum samples. The comparison result showed a linear regression with slope of 1.02 and Correlation Coefficient of 92%. In conclusion, **Rapi-D™** test results of human blood samples showed good agreement with the ELISA results of corresponding serum samples.

The accuracy of **Rapi-D™** Quantitative Vitamin D Test was also evaluated using 20 serum samples in comparison with LC-MS/MS Assay ("Gold Standard" for 25-OH Vitamin D measurement). The comparison result showed a linear regression with the slope of 0.98 and Correlation Coefficient of 98%. In conclusion, **Rapi-D™** Quantitative Vitamin D Test results agree closely to the true values generated from LC-MS/MS assay.

Precision:

Intra Lot

Sample	No. of Replicates	Mean ng/ml	Standard Deviation	Coefficient Variation (CV)
Serum	20	40.4	3.1	7.6%
Blood -1	10	33.0	2.5	7.6%
Blood - 2	10	38.7	3.9	10.1%

Inter Lot

Sample	No. of Lot	No. of Replicates	Mean ng/ml	Standard Deviation	Coefficient Variation
Serum # 1	3	60	33.0	4.7	14.3%
Serum # 2	3	60	55.9	6.1	11.0%
Blood - 1	3	15	38.8	4.3	11.8%

Specificity:

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

EXPECTED RESULTS

Rapi-D™ Quantitative Vitamin D Test is a Rapid Quantitative assay. The test is intended to use for screening individuals to identify Vitamin D 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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- Jenkinson C et al. High throughput LC-MS/MS method for the simultaneous analysis of multiple vitamin D analytes in serum. Chromatogr B Analyt Technol Biomed Life Sci 2016 Mar 1; 1014:56-63.

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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

