

GLOBAL FIRST

Next Generation
25-OH Vitamin D Sandwich ELISA

MicrO-D™

Fastest ELISA Test for Vitamin D

40 Minutes

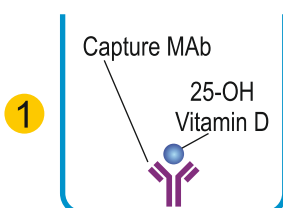


Affimedix
Discovering Health Diagnostics for Life®

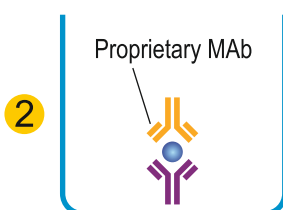
MicrO-DTM

Next Generation 25-OH Vitamin D ELISA

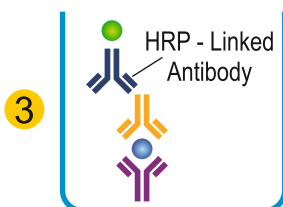
Assay Procedure Summary



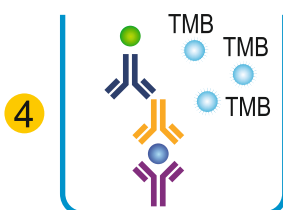
- Add 10µl of Samples, Controls and Standards



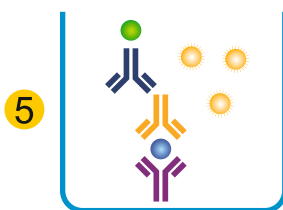
- Add 200µl of Sample Diluent
- Incubate : 20 mins @ RT
- Wash



- Add 200µl of Enzyme Conjugate Reagent
- Incubate : 10 mins @ RT
- Wash



- Add 100µl of TMB
- Incubate : 10 mins @ RT



- Add 100µl of Stop Solution
- Read @ 450nm

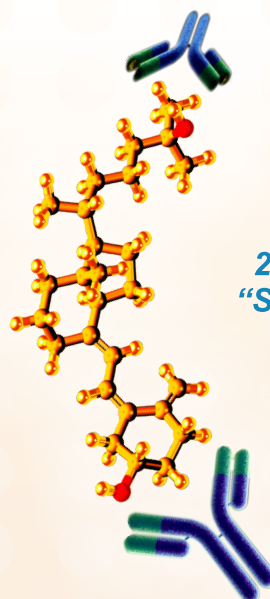
Unprecedented Advantages:

- **“Sandwich” Technology offers Higher Specificity vs. Competitive Test**
- **Fastest Test Results (40 Mins.) for Rapid Turnaround**
- **No Biotin-Streptavidin Technology**
- **Direct D Detection: No off-well sample Pre-treatment or Pre-dilution steps required**
- **Detects both Vitamin D2 and D3 equally**
- **Linear Curve with Wide Detection Range: 2.3 ng/ml – 150 ng/ml**
- **Higher Sensitivity**
- **Superb Correlation with Reference LC-MS/MS Assay (Gold Standard) ($R^2 = 0.981$)**
- **Greater Accuracy: 99%**
- **Excellent Precision: <6%**
- **Consistent Quality**
- **Robust, Reliable and Automation-friendly Assay**
- **Ready to use Six Calibrator Set**
- **Traceability: NIST and DEQAS**
- **Longer Shelf Life: 18 Months**

Benchmarked against Gold Standard

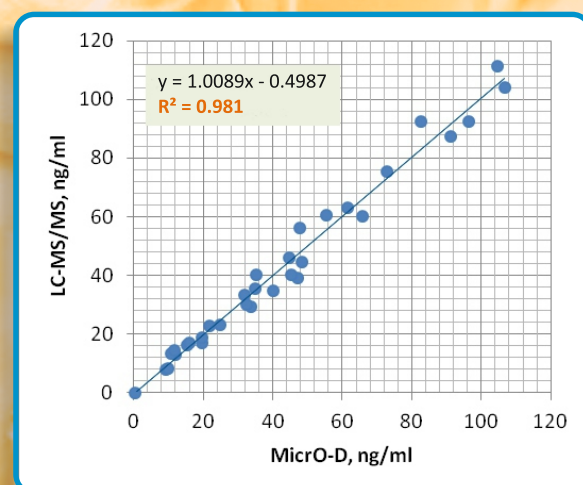
Comparison of **MicrO-D™** with a Reference LC-MS/MS Assay (Gold Standard Test) suggests that results from **MicrO-D™** Test are very close to the true values generated from LC-MS/MS test ($R^2=0.981$; $N=32$).

Serum Samples	LC-MS/MS ng/ml	MicrO-D™ ng/ml
1	0.7	0.5
2	7.9	9.2
3	8.3	9.8
4	13.1	12.0
5	13.2	10.8
6	14.3	11.8
7	16.2	15.5
8	16.8	16.0
9	16.8	19.7
10	18.9	19.8
11	22.8	21.7
12	23.1	24.8
13	29.3	33.8
14	30.0	32.5
15	33.1	31.8
16	34.6	40.3
17	35.3	34.9
18	39.1	47.2
19	40.1	45.3
20	40.3	35.3
21	44.7	48.4
22	45.9	44.6
23	56.3	47.7
24	60.3	65.9
25	60.4	55.5
26	63.1	61.6
27	75.4	72.9
28	87.4	91.1
29	92.3	82.5
30	92.4	96.3
31	103.9	106.7
32	111.3	104.7
Mean	42.1	42.2



*“Proprietary”
25-OH Vitamin D
“Sandwich” ELISA
Technology*

Range From (ng/ml)	0~111.3
Number of Samples	32
Correlation Coefficient (R^2)	0.981
Slope	1.0089
Intercept	-0.4987
Mean (MicrO-D™)	42.2
Mean (LC-MS/MS)	42.1



Game-Changer Technology!

MicrO-D™

Proprietary 25-OH Vitamin D “Sandwich” ELISA
NO Biotin-Streptavidin Technology
NO Interference with high Biotin levels in patient samples

SAFETY WARNING!

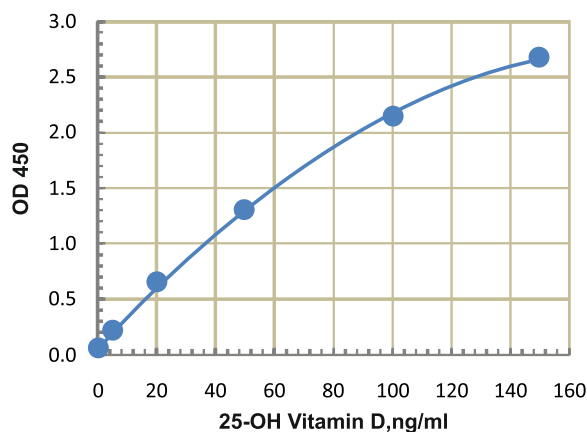
Lab Tests using Biotin-Streptavidin Technology

- The US FDA is alerting the public, health care providers, lab personnel, and lab test developers that Biotin (Vitamin B7) can significantly interfere with certain lab tests and cause incorrect test results which may go undetected. Biotin in blood or other samples taken from patients who are ingesting high levels of biotin in dietary supplements or drugs can cause clinically significant incorrect lab test results. The US FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests.*
- Recently, the German MOH published a notification on safety concerns about Biotin interferences in Lab Assays using a “Biotin-Streptavidin” Technology leading to false results in patients having elevated biotin levels (e.g. from some food supplements or drugs).±
- DEQAS (Vitamin D External Quality Assessment Scheme), UK also published data on “Biotin Interference Study” on commercially available Vitamin D Assays”. **MicrO-D™** showed NO interference with high level of exogenous Biotin added. ±

* <https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication>

± Please request Affimedix, Inc., USA for evidence.

Standard Curve



Assay Characteristics

Intra-Assay Variation:	<5%
Inter-Assay Variation:	<6%
Limit of Detection:	0.93 ng/ml
Limit of Quantitation:	1.67 ng/ml
Average Recovery:	102.1 %
Dilution Studies:	99.5%
Hook Effect:	No Hook effect up to 800 ng/ml
Cross-reactivity	
25-OH Vitamin D3	100%
25-OH Vitamin D2	100%



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