

**GLOBAL FIRST**

*Next Generation*

*Rapid 25-OH Vitamin D CLIA*

**CHEMI-D™**

*Fastest 25-OH Vitamin D CLIA Kit*

**20 Minutes**

**DEQAS**

CERTIFIED

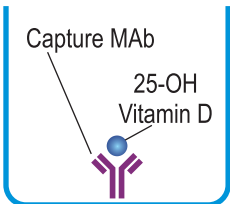
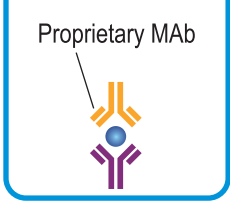
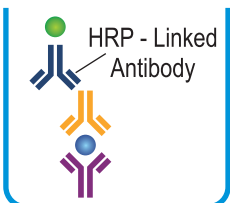
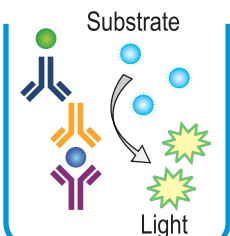


**Affimedix**  
Discovering Health Diagnostics for Life®

# CHEMi-D™

## Next Generation 25-OH Vitamin D CLIA

### EZ Assay Procedure Summary

- 
  - Add 10µl of Samples, Controls and Standards
- 
  - Add 200µl of Sample Diluent
  - Incubate : 10 mins @ RT
  - Wash
- 
  - Add 200µl of Enzyme Conjugate Reagent
  - Incubate : 10 mins @ RT
  - Wash
- 
  - Add 100µl of Luminol Substrate
  - Read within 1 to 20 Minutes

### Exceptional Benefits:

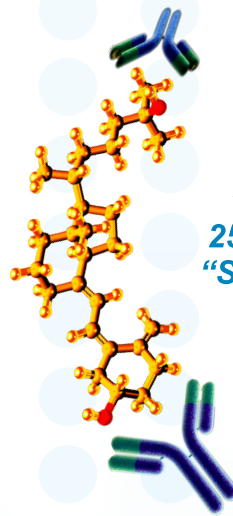
- **Just 20 Minutes CLIA!! – Potential for High-Throughput Protocol**
- **No Biotin-Streptavidin Technology**
- **Higher Specificity vs. Competitive Test**
- **Broader Dynamic Range: 2ng/ml – 150ng/ml**
- **User-friendly Procedure**
- **Direct D Detection: No off-well sample Pre-treatment or Pre-dilution steps required**
- **Detects Total 25-OH Vitamin D**
- **Superior Sensitivity**
- **Superb Correlation with LC-MS/MS ( $R^2 = 0.981$ )**
- **Greater Accuracy: 99%**
- **Excellent Precision: <5%**
- **Robust, Reliable and Automation-friendly Assay**
- **Ready to use Six Calibrators Set**
- **Longer Shelf Life: 18 Months**
- **Traceability: NIST and DEQAS**

# CHEMI-D™

## Comparison of CHEMI - D™ with CDC Target Value Samples (LC-MS/MS)

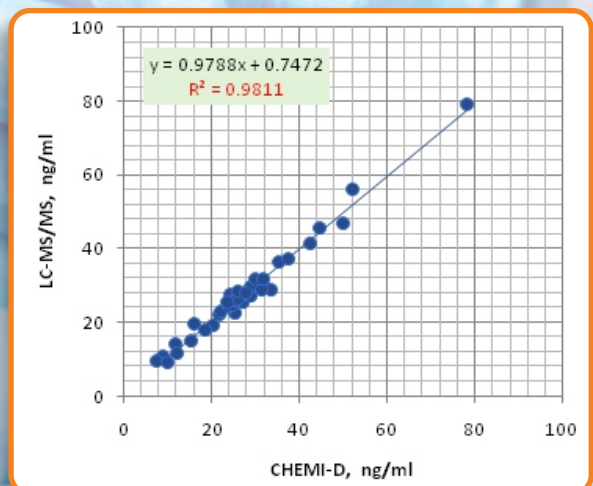
Comparison of CHEMI-D™ with 35 Reference Samples with Target Values (LC-MS/MS) from US Centers for Disease Control and Prevention (CDC) Vitamin D Standardization Certification Program (VDSCP) suggests that CHEMI-D™ Test results are very close to the true values generated by CDC criteria ( $R^2 = 0.981$ ;  $N = 35$ ).

Serum Samples	LC-MS/MS ng/ml	CHEMI-D™ ng/ml
1	11.0	8.8
2	29.8	31.5
3	27.6	24.3
4	41.6	42.5
5	14.1	11.7
6	22.2	21.7
7	22.4	25.2
8	23.1	22.2
9	24.3	24.0
10	24.5	24.7
11	25.6	27.3
12	26.1	25.0
13	26.6	26.2
14	56.0	52.4
15	28.3	26.2
16	19.4	20.2
17	29.5	29.1
18	30.2	31.8
19	31.7	30.2
20	27.4	29.0
21	36.4	35.3
22	15.2	15.5
23	37.4	37.7
24	25.4	23.6
25	46.8	50.0
26	45.6	44.8
27	79.2	78.4
28	9.5	7.3
29	19.7	16.1
30	28.9	33.6
31	9.3	9.9
32	29.0	31.3
33	11.6	12.2
34	31.9	31.7
35	18.0	18.5
<b>Mean</b>	<b>28.1</b>	<b>28.0</b>



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

Range from (ng/ml)	9.3 - 79.2
Number of Samples	35
Correlation Coefficient ( $R^2$ )	0.981
Slope	0.9788
Intercept	0.7472
Mean (LC-MS/MS)	28.1
Mean (CHEMI-D™)	28.0



**Benchmarked against Gold Standard**

# Game-Changer Technology!

# CHEMI-D™

Proprietary 25-OH Vitamin D **“Sandwich”** CLIA

**NO Biotin-Streptavidin Technology**

**NO Interference with high Biotin levels in patient samples**

## SAFETY WARNING!

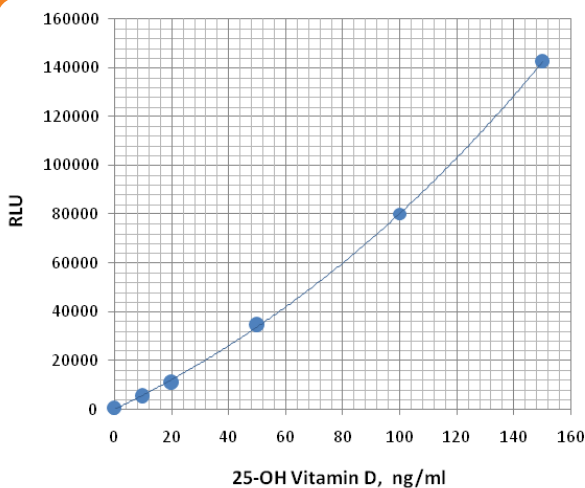
### Lab Tests using Biotin-Streptavidin Technology

- 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”. **CHEMI-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:	<4%
Inter-Assay Variation:	<5%
Limit of Blank:	1.19 ng/ml
Limit of Detection:	1.22 ng/ml
Limit of Quantitation:	2.00 ng/ml
Average Recovery:	100.6%
Dilution Linearity Study:	101.4%
Hook Effect:	No Hook effect up to 800 ng/ml
Cross-reactivity:	
25-OH Vitamin D3	100%
25-OH Vitamin D2	100%



Corporate Office:  
**Affimedix Inc.**  
3556 Investment Boulevard  
Hayward, California 94545, USA



Tel: +1-510-398-8111  
Fax: +1-510-398-8132  
Email: [info@affimedix.com](mailto:info@affimedix.com)  
[www.affimedix.com](http://www.affimedix.com)

UK

Marketed By: