

A Complete Mass Spectrometry Assay Kit for Vitamin D



SCIEX Vitamin D 200M Assay for the Topaz™ System

Innovation That Delivers Accuracy, Without the Complexity

Mass spectrometry provides the specificity and sensitivity that other technologies lack, enabling labs to deliver reliable results to clinicians to support quality patient care. With the pre-developed Vitamin D 200M Assay Kit for the Topaz™ System, you will be up and running faster than ever.

Benefits

- **CDC certified (VDSCP):** meeting stringent accuracy requirements (<5% bias)
- **FDA-cleared: Proven performance:** an *in vitro* (IVD) mass spectrometry method for total 25-hydroxyvitamin D
- **Excellent sensitivity:** Lower Limit of Measuring Interval (LLMI) = 4.0 ng/mL
- **High specificity:** confirmed by extensive interference testing (58 compounds)
- **Consistent and reproducible:** traceable to NIST international standards
- **Wide linear dynamic range:** minimizes re-testing and sample dilution
- **Simple adoption:** locked IVD method for simplified implementation

The Pinnacle of Diagnostic Accuracy

Unlike standard Vitamin D testing methods that are subject to cross-reactivity and interferences, liquid chromatography with tandem mass spectrometry (LC-MS/MS) provides a direct measurement of the analytes of interest to deliver extremely accurate quantitation. The Vitamin D 200M Assay Kit for the Topaz system individually quantitates both the 25-hydroxyvitamin D2 and D3 to generate a precise determination of Vitamin D status. The assay also separates potential interferences, such as the D3 epimer, which minimizes the risk of assay bias and inaccurate results.

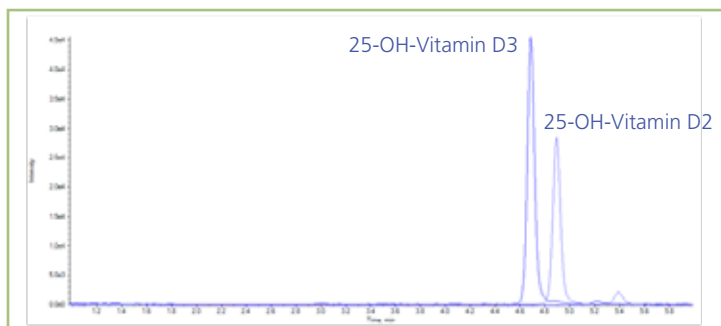


Fig 1. The Vitamin D Assay directly measures both 25-OH-Vitamin D2 and D3 forms individually, to ensure accurate quantitation of total Vitamin D.

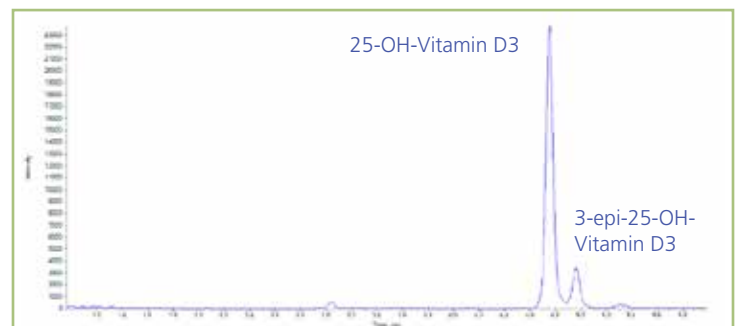


Fig 2. The Vitamin D Assay removes interference from the 3-epi-25-OH-Vitamin D3 and D2 epimers, preventing overestimation of total Vitamin D levels.

Certified Gold Standard

The Vitamin D 200M assay underwent a rigorous method comparison study against the CDC Reference Measurement Procedure standard method. The assay exhibited excellent correlation, showing <5% bias versus this method. It has been certified within the CDC Vitamin D Standardization Certification Program.

A Complete Solution

With the Vitamin D 200M Assay Kit, you get everything you need to run the assay from the start. The kit eliminates any concerns regarding component sourcing and compatibility. All components required, from calibrators and controls, columns, mobile phases and even test tubes for sample preparation are included within the kit. All individual components were validated and verified to ensure seamless and highly accurate quantitation of total Vitamin D levels.

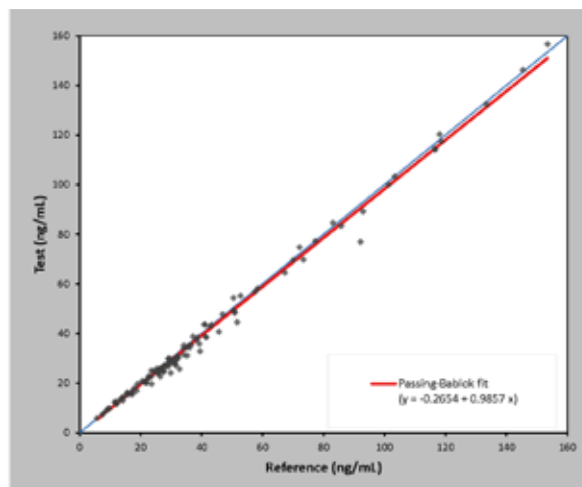


Fig 3. Passing Bablock showing method comparison data between the Vitamin D 200M Assay and the CDC reference method

Eliminate method development to start running your own Vitamin D test in weeks, not months.

Included in the Vitamin D 200M Assay Kit

- Calibrator Set (7 Points)
- Controls (3 Levels)
- Internal Standard
- PBS Solution
- Sample Prep Reaction Vials
- System Suitability Mix
- Precipitation Reagent
- Mobile Phase A and B, and Rinsing Solution
- Analytical Column and Trap Column

Key Specifications

Sample Material/Volume	Human Serum; 100 µL
LC-MS/MS Testing Time	6.2 minutes (injection to injection)
Calibration	6 points (D2); 7 points (D3)
Sample Preparation Method	Protein Precipitation
Lower Limit of Measuring Interval (LLMI)	25-OH-Vitamin D2: 2.0 ng/mL 25-OH-Vitamin D3: 2.0 ng/mL Total 25-OH-Vitamin D: 4.0 ng/mL
Measuring Range	25-OH-Vitamin D2: 2.0 to 165 ng/mL 25-OH-Vitamin D3: 2.0 to 160 ng/mL Total 25-OH-Vitamin D: 4.0 to 325 ng/mL
Precision	For Total 25-OH-Vitamin D over the entire range: Repeatability: 2.9% to 3.8% Reproducibility: 4.2% to 6.1%

Ordering Information

Vitamin D 200M Assay for the Topaz System; 1000 tests	5044484
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SCIEX Diagnostics products are for *in vitro* diagnostic use. Product(s) may not be available in all countries.

For information on availability, please contact your local representative. All other SCIEX products are for research use only. Not for use in diagnostic procedures.

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