[tech] guide

Vitamin D Testing

	DiaSorin Inc Stillwater, Minn (651) 351-5721; www.diasorin.com	DiaSorin Inc Stillwater, Minn (651) 351-5721; www.diasorin.com	Diazyme Laboratories Poway, Calif (858) 455-4768; www.diazyme.com
Name of Vitamin D testing product	25-Hydroxyvitamin D 125I RIA kit	Liaison 25 OH Vitamin D Total Assay	Diazyme 25-OH Vitamin D EIA
1) Does the assay help clinicians distinguish among patients who have deficiency/insufficiency/sufficiency of total vitamin D?	Yes	Yes	Yes
2) Does the test detect equimolar measurement of total 25(OH) vitamin D (the sum of 25(OH) vitamin D2 and 25(OH) vitamin D3)?	Yes	Yes	Yes
3) If not, describe briefly what the test detects.	N/A	N/A	N/A
4) What are the required specimen type (ie, serum or plasma) and sample volume?	Human serum or EDTA plasma; 50 µL.	Human serum; 250 µL.	Both serum and plasma can be used as specimen; sample volume, 90 µL.
5) What type of platform is used to perform the assay?	Gamma counter/radioimmunoassay.	Liaison and Liaison XL (both chemiluminescence).	Automated enzyme immunoassay (EIA).
6) Does the platform connect to scalable stand-alone or track-based automation systems?	No	Liaison, no; Liaison XL, yes.	Yes
7) Does the assay use monoclonal antibodies?	No	No	Yes
8) Is the assay traceable to an LC-MS/MS reference method?	Yes	Yes	The assay is traceable to NIST controls, which are LC-MS/MS assigned.
9) How much tech time is required for assay setup? What is the turnaround time for test results?	5 hours; 1hour.	35 minutes; 5 minutes.	Tech time per assay setup, 30 minutes; turnaround time for results, ~2 hours.
10) Is the product FDA-cleared/approved/pending?	FDA cleared.	FDA cleared.	FDA cleared.
11) Briefly describe what sets this product apart from others in the market.	A sensitive assay, with equimolar measurement of 25(OH) vitamin D2 and 25(OH) vitamin D3, and ready-to-use reagents.	A sensitive assay, with high throughput, quick time to first result, equimolar measurement of 25(OH) vitamin D2 and 25(OH) vitamin D3, and ready-to-use reagents.	The assay requires less time than conventional EIAs (2 hours instead of 4). The vitamin D analyte is organic solvent–extracted from serum before assaying, eliminating most of the interference problems observed with other commercially available vitamin D assays. The assay is fully automated (including the organic extraction step).

Gold Standard Diagnostics Davis, Calif (855) 268-6940; www.gsdx.us	Roche Diagnostics Indianapolis (317) 521-4443; us.diagnostics.roche.com	Siemens Healthcare Diagnostics Tarrytown, NY (888) 588-3916; www.usa.siemens.com/diagnostics	Tosoh Bisocience Inc San Francisco (800) 248-6764; www.tosohbioscience.us
GSD Vitamin D, Total 25-OH EIA	Roche Vitamin D	Advia Centaur Vitamin D Total assay	ST AIA-Pack 25-OH Vitamin D
Yes	Yes	The assay is intended as an aid in determining vitamin D sufficiency.	Yes
Yes	The assay measures total vitamin D (both 25(OH)D2 and 25(OH)D3, with cross-reactivity of 92% for D2, and 100% for D3.	The assay measures total 25(OH) vitamin D, including ~100% of 25(OH) vitamin D2 and D3, metabolites of the two major forms of vitamin D.	Yes
N/A	N/A	N/A	N/A
Serum; 50 µL.	Serum or plasma; 15 µL.	Serum or plasma (EDTA, lithium-heparin, sodium heparin); sample volume, 20 µL.	Human serum, heparinized plasma, or EDTA plasma; 60 µL.
Automated enzyme immunoassay processor (EIA); manual.	Elecsys 2010; Modular Analytics E170; cobas e 411; cobas e 601; cobas e 602.	Advia Centaur and Advia Centaur XP systems.	AIA-600II, AIA-900, AIA-1800, and AIA-2000.
Yes	Yes	Yes. The Advia Centaur and Advia Centaur XP systems connect to Siemens automation systems.	Both
Yes	Protein-binding assay.	Yes. The proprietary Advia Centaur Vitamin D Total assay monoclonal antibody was selected specifically for equimolar 25(OH) vitamin D2 and D3 recognition.	Yes
Yes	Yes. This method has been standardized against LC-MS/MS, which in turn is traceable to the NIST standard.	Yes	Yes
Setup, 30 minutes; time for results, < 4 hours.	Liquid ready-to-use reagents; no sample preparation; test duration is 27 minutes.	Tech time required for assay setup is negligible; the assay delivers results in as few as 18 minutes.	40 minutes for first result and ~1 minute for subsequent results; throughput varies based on analyzer.
FDA cleared; 510(k) number K123364.	FDA cleared.	FDA cleared, October 2011.	FDA cleared.
The assay features a unique pretreatment step that allows for easy automation on virtually any open ELISA processor. The competitive assay strongly correlates with established LC/MS, EIA, and chemiluminescence methods. It offers high sensitivity and specificity over a wide dynamic range, and is cost-effective even at low testing volumes.	The assay provides excellent low-end precision required for clinical decisions. Standardization against LC-MS/MS, traceability to the NIST standard, and lot-to-lot consistency ensure accuracy for assessment and patient follow-up. The assay provides a convenient means of integrating testing into routine workflows for increased efficiency.	The assay provides results in less than 18 minutes, with a throughput of 240 tests per hour—wihout affecting other routine, stat, or specialty assays. The assay features a lack of 3-epi crossreactivity and equimolar 25(OH) vitamin D2 and D3 recognition.	The assay correlates well with the LC-MS/MS from the University of Ghent and detects 25(OH) vitamin D2 and D3 equimolarly. With 90-day calibration stability and interchangeable reagents on multiple platforms, it offers a solution for labs with both small and large testing volumes.