[tech] guide

Vitamin D Testing

	Abbott	DiaSorin Inc	DiaSorin Inc
	Abbott Park, Ill (847) 937-6100 www.abbott.com	Stillwater, Minn (651) 351-5721 www.diasorin.com	Stillwater, Minn (651) 351-5721 www.diasorin.com
1) What is the name of your company's Vitamin D testing product?	Abbott ARCHITECT 25-OH Vitamin D Assay	25-Hydroxyvitamin D 125I RIA kit	LIAISON® 25 OH Vitamin D TOTAL Assay
2) Does the assay help clinicians distinguish between patients who have deficiency/insufficiency/sufficiency of total vitamin D?	The most accurate way to measure vitamin D blood levels is the 25-hydroxy vitamin D test. The assay is used for the quantitative determination of 25-hydroxyvitamin D in human serum and plasma to aid in the assessment of vitamin D sufficiency.	Yes	Yes
3) 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
4) If not, please briefly note what the test detects.	N/A	N/A	N/A
5) What is the specimen type (ie, serum or plasma) and sample volume?	A minimum of 150 µL of serum is required. Serum gel tubes are acceptable, and so is plasma collected in lithium heparin tubes.	Human serum or EDTA plasma/50 µL	Human serum/250 µL
6) What type of platform is used for the assay?	The assay is performed on the fully automated Abbott ARCHITECT immunochemistry system, which employs chemiluminescent microparticle immunoassay technology (CMIA).	Gamma counter/radioimmunoassay	LIAISON® and LIAISON® XL (both chemiluminescence)
7) Does the platform connect to scalable stand-alone or track-based automation systems?	Both	No	LIAISON®: no, LIAISON® XL: yes
8) Does the assay use monoclonal antibodies?	No	No	No
9) Is the assay traceable to LC-MS/MS?	The assay has shown excellent precision (<10% CV), as well as good correlation versus the reference method, LC-MS/MS.	Yes	Yes
10) What is the turnaround time for test results, and how much tech time is required per assay setup?	Application time to first result is 36 minutes.	5 hours/1hour	35 minutes/5 minutes
11) Is the product FDA-cleared/ approved/pending?	The assay is FDA-cleared	FDA-cleared	FDA-cleared
12) What differentiates this assay from others on the market?	The Abbott ARCHITECT 25-OH Vitamin D assay is fully automated and helps laboratories manage increasing vitamin D testing volumes. The Abbott vitamin D test satisfies the need for an automated, reliable and cost-effective vitamin D test to help laboratories provide rapid and highly accurate results.	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.

Diazyme Laboratories Poway, Calif (860) 729-0121 www.diazyme.com	Quantimetrix Redondo Beach, Calif (310) 536-0006 www.quantimetrix.com	Siemens Healthcare Diagnostics Tarrytown, NY (888) 588-3916 www.usa.siemens.com/diagnostics
Diazyme 25-OH Vitamin D EIA	Complete D 25-OH Vitamin D Control	ADVIA Centaur® Vitamin D Total assay
Yes	This is a control product designed to be compatible with assays measuring total 25-OH Vitamin D	The ADVIA Centaur Vitamin D Total assay is intended as an aid in the determination of vitamin D sufficiency.
Yes	The control contains an equimolar mixture of 25-OH D2 and D3	Yes. The ADVIA Centaur Vitamin D Total assay measures a patient's total 25(OH) vitamin D level – ~100% of 25 (OH) vitamin D2 and D3, metabolites of the two major forms of vitamin D.
N/A	N/A	N/A
Both serum and plasma can be used as specimen. Sample volume = 90 µL.	The control is in a human serum matrix.	Specimen type: Serum/Plasma (EDTA, lithium-heparin, sodium heparin) Sample volume: 20 µL
Automated Enzyme-Immuno-Assay (EIA)	The control can be used for both chromatography and immunoassay methods	ADVIA Centaur and ADVIA Centaur XP systems
Yes	It is handled as a patient sample.	Yes. The ADVIA Centaur and ADVIA Centaur XP systems connect to Siemens automation systems.
Yes	The control is compatible with immunoassay methods, which use monoclonal antibodies.	Yes. The proprietary ADVIA Centaur Vitamin D Total assay monoclonal antibody was selected specifically for equimolar 25(OH) vitamin D2 and D3 recognition.
The assay is traceable to NIST controls, which are LC-MS/MS assigned.	Yes, it traceable to JCTLM LC-MS-MS Isotope Dilution Methods #C8RMP4 and C8RMP3.	Yes
Turnaround time for results: ~2 hours. Tech time per assay setup: 30 minutes	The control is handled as per a patient sample.	The ADVIA Centaur Vitamin D Total assay delivers results in as little as 18 minutes. Tech time required per assay setup is negligible.
FDA approval is pending.	The product is FDA-approved.	The ADVIA Centaur Vitamin D Total assay was cleared by the FDA in October 2011.
1) The assay is shorter than conventional EIA assays (2 hours instead of 4). 2) The Vitamin D analyte is organic-solvent-extracted from serum before assaying. This step eliminates most of the interference problems observed with other commercially available Vitamin D assays. 3) The assay is fully automated (including the organic extraction step).	The Complete D 25-OH Vitamin D control is liquid ready to use with separate 25-OH Vitamin D2 and D3 values for the chromatography laboratories. It is traceable to the JCTLM methods and to NIST standard SRM 972. It has a 1-year open-vial shelf life when the control is stored at 2^0C to 8^0C.	The Siemens assay provides results in less than 18 minutes with a throughput of 240 tests per hour without impacting other routine, stat, or specialty assays. Lack of 3-epi cross reactivity and equimolar 25 (OH) vitamin D2 and D3 recognition