



Upgrade
your Vitamin
B12 testing

Active-B12 Assay

Atellica IM Analyzer and ADVIA Centaur Systems

The Siemens Healthineers Active-B12 (AB12) assay offered on the Atellica® IM Analyzer and ADVIA Centaur® Immunoassay Systems measures holoTC in the blood—the only form of vitamin B12 that is taken up and used by cells of the body.

Active-B12 Clinical Utility

Vitamin B12 (cobalamin) plays an important role in DNA synthesis and neurologic function. Deficiency can lead to a wide spectrum of hematologic and neuropsychiatric disorders that can often be reversed by early diagnosis and prompt treatment.¹

The primary analysis of vitamin B12 deficiency is the measurement of serum cobalamin (vitamin B12).² These commonly used tests measure total vitamin B12, which is found in blood bound to two carrier proteins: haptocorrin and transcobalamin. When vitamin B12 is bound to transcobalamin it is referred to as holotranscobalamin (holoTC). HoloTC contains the biologically available cobalamin as only holoTC promotes the uptake of cobalamin by all cells via specific receptors. In comparison, approximately 80% of the circulating cobalamin that is carried by haptocorrin is considered metabolically inert because no cellular receptors exist (with the exception of receptors found in the liver).³

Active-B12 Benefits

- Identify anemia sooner by using a better indicator of vitamin B12 status.^{4,5}
- Measure the biologically active form of vitamin B12, delivering confidence in patient results with improved sensitivity and specificity.
- Minimize lot-to-lot variability with an Active-B12 assay that uses kitted calibrators and is traceable to WHO International Standard for holotranscobalamin; NIBSC code 03/178.

Assay Characteristics^{3,6,7}

System	Sample Type	Sample Volume	Assay Range	Detection Capability XP/XPT	Calibration Interval	Onboard Stability	Time to First Result
Atellica IM	Serum	50 µL	4.25–146.00 pmol/L	LoB: 0.46 pmol/L LoD: 0.83 pmol/L LoQ: 4.25 pmol/L	Lot: 28 days Pack: 28 days	28 days	38 min
ADVIA Centaur	Serum	50 µL	5.00–146.00 pmol/L	XP/XPT: LoB: 0.52 pmol/L LoD: 1.19 pmol/L LoQ: 5.00 pmol/L CP: LoB: 2.73 pmol/L LoD: 2.99 pmol/L LoQ: 5.00 pmol/L	XP/XPT: 44 days CP: 30 days	XP/XPT: 44 days CP: 38 days	XP/XPT: 47 min CP: 42 min

Method Comparison Data^{3,7}

System	Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N	r
Atellica IM	Serum	ADVIA Centaur AB12	Y=1.05x–1.21 pmol/L	6.77 – 137.67 pmol/L	113	0.98
ADVIA Centaur	Serum	Abbott ARCHITECT Active-B12	y = 1.31x–7.85 pmol/L	11.39 – 116.96 pmol/L	111	1.00

Standardization^{3,7}

Atellica IM and ADVIA Centaur Systems AB12 assay is traceable to World Health Organization (WHO) International Standard for holotranscobalamin (HoloTC); NIBSC code 03/178. Assigned values for calibrators are traceable to this standard.

Ordering Information

System	SMN No.	Contents
Atellica IM	10733001	1 ReadyPack primary reagent pack containing Atellica IM AB12 Lite Reagent and Solid Phase: 1 vial Atellica IM AB12 CAL low calibrator 1 vial Atellica IM AB12 CAL high calibrator
	10733002	Atellica IM AB12 quality control material: 1 x 7.0 mL quality control level 1 1 x 7.0 mL quality control level 2
	10733003	Atellica IM AB12 MCM (master curve material): 5 x 2.0 mL levels of master curve material
ADVIA Centaur XP/XPT/CT	10995088	1 ReadyPack(r) primary reagent pack containing ADVIA Centaur AB12 Lite REagent and Solid Phase: 1 vial ADVIA Centaur AB12 low calibrator 1 vial ADVIA Centaur AB12 high calibrator
	10995091	ADVIA Centaur AB12 quality control material: 1 x 7.0 mL control 1 1 x 7.0 mL control 2
	10995090	ADVIA Centaur AB12 master curve material: 5 x 2.0 mL

References:

- <https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/>
- Yetley EA, Pfeiffer CM, Phinney KW, et al. Biomarkers of vitamin B-12 status in NHANES: a roundtable summary. *Am J Clin Nutr* 2011;94:313S–21S.
- Siemens Healthineers ADVIA Centaur AB12 Instructions for use: RPBL116OR3_EN Rev. C, 2017-09.
- Valente E, Scott JM, Ueland PM, et al. Diagnostic accuracy of holotranscobalamin, methylmalonic acid, serum cobalamin, and other indicators of tissue vitamin B12 status in the elderly. *Clin Chem* 2011; 57(6):856–863.
- Nexo E, Hoffmann-Lucke E. Holotranscobalamin, a marker of vitamin B12 status: analytical aspects and clinical utility. *Am J Clin Nutr* 2011;94(1):359S–365S.
- Siemens Healthineers ADVIA Centaur AB12 Instructions for use: RPBL1169R1_EN Rev. A, 2018-04
- Siemens Healthineers Atellica IM AB12 Instructions for use: RPBL1359R1_ENG Rev.01, 2018-09

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