

NOVA-ONE[®]
DIAGNOSTICS
A1C CONTROL LEVELS 1 & 2

P/N: NOD13122-100 (4 Vial) & NOD13111-100 (2 Vial)

Product	Lot Number	Expiration Date
NOD[®] A1c Control, Level 1 & 2	3220N003	October 2012

INTENDED USE

NOD[®] A1c Control is intended for use as quality control material to monitor the performance and precision of Hemoglobin A1c (HbA1c %) Immunoassay and HPLC test methods using protocols established by the FDA and State laboratory inspection agencies for individual laboratories.

SUMMARY AND PRINCIPLE

Laboratories should run both quality control materials monthly – weekly – or daily, according to FDA prescribed intervals, before any patient samples to ensure proper performance of instruments and reagents. NOD[®] A1c Control is provided at two levels – normal (L1) and abnormal (L2).

REAGENT

NOD[®] A1c Control is prepared from human whole blood to which stabilizers are added. The product is provided in liquid form for user convenience. No further dilution of the control solution is needed.

STORAGE AND STABILITY

Kits may be received thawed but should be stored frozen (- 15°C to - 25°C) immediately upon receipt. Unopened NOD[®] A1c Control is stable until the expiration date printed on the container when stored frozen. Refrigerated vials are stable for 180 days for use with immunoassay methods; and 30 days when used with HPLC methods, when stored properly and tightly capped.

(Please Note: Commercial refrigerator freezers do not freeze control materials to the temperature specified. Your controls should be treated as refrigerated immediately upon receipt. The control will expire 180 days from the date received when stored properly and tightly capped.)

Upon receiving the kit, mark the specific date refrigerated storage began on the vials; product is stable for 180 days when stored at 2-8°C in **tightly** closed containers. Aliquots made immediately from freshly open vials may be frozen one time and stored until expiration date printed on the container. Thawed aliquots cannot be refrozen. Dried red control residue in top of cap means vials are not being recapped properly. (Please Note) Refrigerated Stability for HPLC methods is 30 days.

PROCEDURE

NOD[®] A1c Control should be treated in the same manner as patient samples in accordance with instructions for testing determination method being used. No further dilution of the control solution is needed. Frozen control should be thawed at 2-8°C and mixed by gentle inversion several times prior to use. Refrigerated control should be mixed by gentle inversion prior to use. Do not shake vigorously. **Do not warm up refrigerated control material before using and always clean any excess control material from dropper tip before tightly recapping a vial.**

LIMITATIONS

Different values from those obtained with reagents available at the time of assay may be obtained as a result of changes in manufacturer's reagents or lot-to-lot reagent variability. NOD[®] A1c Control should not be used past its expiration date or after improper handling. Microbial contamination will affect performance of this product.

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(REV 07-21-2010)

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ANALYTE VALUES

In accordance with good laboratory practices, each laboratory should establish its own analyte means and acceptable performance ranges.

SPECIFIC PERFORMANCE CHARACTERISTICS

NOD[®] A1c Control is manufactured in accordance with industry guidelines and standards. To perform as intended, the control requires proper storage and handling as described in this package insert. Over time and repeated use the dropper tip can collect dried control debris if not wiped clean immediately after each use and recapped quickly. If this debris is allowed to collect it can block your test assays collector channel and cause a low reading for the control material. **If you are recording out of range low control values and a dropper vial cap shows evidence of dried red colored control material on the inside of the cap – Order a fresh control kit.**

WARNING

Biological source material, treat as potentially infectious. All human plasma units used in manufacturing this product have been tested according to by FDA accepted methods and found non-reactive or negative for Hepatitis B Surface Antigen (HbsAg), HCV antibodies, and HIV-1/2 antibodies. This product may contain other human or animal source materials for which there are no approved tests and should be considered as potentially infectious for Hepatitis B (HBV), Hepatitis C (HCV), HIV-1, HIV-2, HTLV-I, HTLV-II, as well as any other infectious agents, and handled with the same precautions used in handling patient specimens.

Assigned Values and Ranges Lot #3220N003 (Representative Values)
(Containing Vial Lots L1 #3222N012 & L2 #3224N006)

For In Vitro Diagnostic Use INSTRUMENT METHOD	UNITS	LEVEL 1 – 3222N012			LEVEL 2 – 3224N006		
		MEAN	Expected RANGE		MEAN	Expected RANGE	
BAYER A1cNOW Plus+	%	5.2	4.2	6.2	10.6	8.5	12.7
Tosoh 2.2 Plus	%	5.5	4.4	6.6	11.0	8.8	13.2
Siemens DCA 2000 “Vantage”	%	+			+		
Tosoh G7	%	+			+		
Tosoh G8	%	+			+		
Variant II	%	+			+		
Primus Ultra2	%	+			+		
Cobas Integra 400	%	+			+		
*							

+Data not available at time of printing. Contact NOD for updated package insert values.

*Add your analyzers values by establishing your own internal value assignment if not already listed

Complementary NOD Liquid HbA1c Linearity is also available:
DIABETES A1c LINEARITY 4 LEVEL **Part No: HbL-G04041-100**

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