

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

| Product | Lot Number | Expiration Date |
|-------------------------------------------------------------------|------------|-----------------|
| NOD [®] 13111-100 HbA1c Control, (1) L1 & (1) L2 = (2)mL | 5286A21002 | September 2023 |
| NOD [®] 13122-100 HbA1c Control, (2) L1 & (2) L2 = (4)mL | 5286A21002 | September 2023 |

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 in individual laboratories.

SUMMARY AND PRINCIPLE

Laboratories should run both quality control materials 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 and is ready to use as is. **No further dilution of each control solution is needed for A1cNow and DCA instrument methods.**

STORAGE AND STABILITY

Kits may be received thawed but should be stored refrigerated (2 °C to 8 °C) or frozen immediately upon receipt. Refrigerated **OPEN or CLOSED** vials are stable for 180 days for use with most **immunoassay methods**, (i.e. DCA or A1cNOW). **The date refrigerated storage starts or “outdates” should be noted on the kit box.**

For the users convenience, a **refrigerated** 6 month “outdate guideline” is stamped on the front side of the kit box in case the site fails to note the date received on the kit box.

Refrigerated **OPEN or CLOSED** vials are stable for 30 days when used with **HPLC methods**, (i.e. Tosoh G8 or Primus Ultra 2)

For long term storage, when not in monthly or weekly use, the control material can be stored frozen (- 15°C to - 25°C) immediately upon receipt . The Controls are stable until the frozen expiration date printed on the container when stored frozen. Please Note: Commercial Mini refrigerator freezers do not freeze control materials to the temperature specified. If the control is stored in one of these warmer refrigeration / freezer units your controls should be treated as refrigerated immediately upon receipt and the date noted.

Aliquots made immediately from freshly open vials which have been stored frozen may be frozen one time and stored until expiration date printed on the container. Thawed aliquots cannot be refrozen.

PROCEDURE

NOD[®] A1c Control should be treated in the same manner as patient samples in accordance with instructions for the A1c assay method being used. No further dilution of each control solution is needed for A1cNow and DCA test methods.

- (A) Frozen controls should be thawed to 2-8°C and mixed by gentle inversion several times prior to use.
- (B) Refrigerated controls should be mixed by gentle inversion prior to use. Do not shake vigorously.

Do not warm up refrigerated control material to room temperature before using. NOD control vials should be used, recapped and back in the refrigerator in approximately 5 minutes or less to preserve refrigerated stability.

If used with an assay “collector device” (i.e. A1cNow or DCA) use a pipette to apply a drop of control to a clean dry disposable surface (i.e. a slide cover or paper cup bottom) touch the collector tip to the control sample drop until the collector is full, see illustration on reverse side of this insert.

(1) For operators convenience the kit contains 100 disposable pipettes and 100 disposable slide covers. Remove two (2) of the NOD[®] disposable pipettes and if used with a collector device two (2) NOD[®] disposable slide covers.

(2) Obtain the L1 & L2 NOD[®] control vials from the refrigerator and have two HbA1c testing devices or two sets of HbA1c analyzer sample cuvettes ready for testing.

(3) Use one of disposable pipettes to withdraw (aspirate) a drop of L1 control sample. Depress the disposable pipette shaft – then insert the tip into the L1 vial – relax the pressure on the pipette shaft to draw a small amount - place the L1 control sample on one of the disposable slide covers (as shown) or into the analyzer sample cuvette..

(4) Recap the NOD[®] L1 control vial and return it to the refrigerator. Properly dispose of the disposable pipette and slide cover used with the L1 control sample according to Good Laboratory Practice as shown. **DO NOT REUSE THESE DISPOSABLE ITEMS WITH THE NOD L2 control sample.**

Repeat steps 1 Thru 4 with the L2 NOD[®] A1c control 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.

ANALYTE VALUES

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

NOVA-ONE[®] DIAGNOSTICS

A1C CONTROL LEVELS 1 & 2

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.

WARNING

Biological source material, treat as potentially infectious. All individual donor units used in manufacturing this product have been tested 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.

If using with collector device (i.e. A1cNow or DCA) apply a drop of control to a clean dry disposable surface (i.e. a slide cover or paper cup bottom or a piece of tin foil) touch the collector tip to the control sample drop until the collector is full. Dispose of the “clean dry surface” according to good laboratory practices. SEE BELOW

 **Complete test within 15 minutes.**



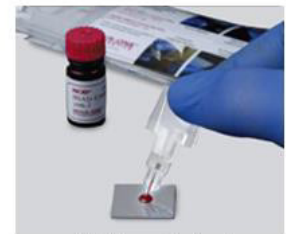
Kit Contents



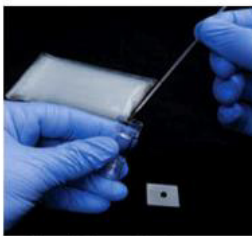
Using Pipette



A1CNow Collector



A1CNow+ Collector



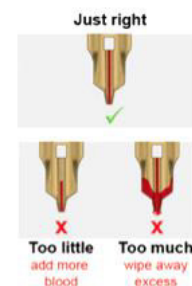
Tosoh Sample Cuvette



Proper GLP¹ disposal of pipette



Proper GLP¹ disposal of slide



¹GLP = Good Laboratory Practice

NOD[®] 13111-100 & NOD[®] 13122-100 HbA1c Control, L1 & L2
Assigned Values and Ranges Lot # 5286A21002 EXP DATE September 2023
(Containing Vial Lots L1 #5257A21002 & L2 #5258A21003 Representative Values)

| For In Vitro Diagnostic Use | | LEVEL 1 – 5257A21002 | | | LEVEL 2 – 5258A21003 | | |
|-----------------------------|-------|----------------------|----------------|-----|----------------------|----------------|------|
| INSTRUMENT METHOD | UNITS | MEAN | Expected Range | | MEAN | Expected Range | |
| A1CNow+ | % | 5.1 | 4.1 | 6.1 | 9.4 | 7.5 | 11.3 |
| Siemens DCA Vantage | % | 5.7 | 4.6 | 6.8 | 11.4 | 9.1 | 13.7 |
| Tosoh G8 | % | 5.5 | 4.4 | 6.6 | 10.2 | 8.2 | 12.2 |
| Trinity Premier | % | 5.5 | 4.4 | 6.6 | 10.0 | 8.0 | 12.0 |
| Sebia Capillars2 | % | 5.4 | 4.3 | 6.5 | 9.8 | 7.8 | 11.8 |
| * | | | | | | | |

*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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