Whole Blood Kit (HbA1c) LINEARITY 4 LEVEL
Part No: NOD HBL-G04041-100 Kit Lot # 4610A20002

Product	Lot Number	Expiration Date
NOD® DIABETES A1c LINEARITY Level 1	4586A20002	01/2023
NOD® DIABETES A1c LINEARITY Level 2	4587A20002	01/2023
NOD® DIABETES A1c LINEARITY Level 3	4588A20002	01/2023
NOD® DIABETES A1c LINEARITY Level 4	4589A20002	01/2023

INTENDED USE
NOD® DIABETES A1c LINEARITY is intended for use as quality Linearity material to monitor linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) assay methods using protocols established in individual laboratories.

SUMMARY AND PRINCIPLE
NOD® DIABETES A1c LINEARITY is provided at four levels ranging across the reportable range of HbA1c to assist in calibration linearity procedures.

REAGENT
NOD® DIABETES A1c LINEARITY is prepared from human whole blood to which stabilizers are added. The product is in liquid form for user convenience; no further reconstitution is required.

STORAGE AND STABILITY
Unopened NOD® DIABETES A1c LINEARITY is stable until the expiration date printed on the container when stored frozen at –20°C. The product is stable for 14 days when stored at 2-8°C in tightly closed containers. Aliquots made immediately from freshly open vials may be frozen at –20°C one time and stored until expiration date printed on the container. Thawed aliquots cannot be refrozen.

PROCEDURE
NOD® DIABETES A1c LINEARITY should be treated in the same manner as patient samples in accordance with instructions for assay method being used. Frozen Linearity should be thawed at room or refrigerator temperature and mixed by gentle inversion prior to use.

For operators convenience the kit contains 100 disposable pipettes (20µL) and, if used with an assay method requiring a “collector” device (i.e. DCA or A1CNow+), 100 disposable slide covers are also included. The slide covers provide a clean dry surface to mount each linearity sample for application to the collector devices as shown on the reverse side.

(1) Remove four (4) of the NOD® disposable pipettes and, if used with an assay “collector” device, four (4) NOD® disposable slide covers.

(2) Obtain the thawed L1 - L2 – L3 – L4 NOD® Linearity vials and have four sets of HbA1c analyzer sample cuvettes or four HbA1c testing devices ready for testing.

(3) Use one of the disposable pipettes to withdraw (aspirate) a drop of L1 linearity 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 Linearity sample into the first analyzer sample cuvette, or if using with a collector device, on to one of the disposable slide covers (as shown).

(4) Recap the NOD® L1 linearity vial and return it to the refrigerator. Properly dispose of the disposable pipette and slide cover used to test the L1 linearity sample according to Good Laboratory Practice (GLP) as shown. DO NOT REUSE THESE DISPOSABLE ITEMS WITH THE following NOD Linearity sample.

(5) Repeat the same steps 1 thru 4 with the remaining L2 – L3 – L4 NOD® A1c linearity vials using a new set of disposable pipettes – sample cuvettes – and or slide covers.

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(REV 3-10-2021)

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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® DIABETES A1c LINEARITY 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
NOD® DIABETES A1c LINEARITY is manufactured in accordance with industry guidelines and standards. To perform as intended, the linearity requires proper storage and handling as described in this package insert.

WARNING
Biological source material, treat as potentially infectious. Each serum/plasma donor unit used in manufacturing this product was 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 agent, and handled with the same precautions used in handling patient specimens.

For In Vitro Diagnostic Use

METHOD	UNITS	LEVEL 1 4586A20002 TARGET VALUES	LEVEL 2 4587A20002 TARGET VALUES	LEVEL 3 4588A20002 TARGET VALUES	LEVEL 4 4589A20002 TARGET VALUES
INSTRUMENT/KIT					
A1C NOW	%A1c	4.9	6.0	7.5	9.5
Siemens DCA Vantage	%A1c	5.4	7.0	8.5	11.4
Tosoh G8	%A1c	5.3	6.6	7.9	10.5
Trinity Premier	%A1c	5.4	6.5	7.8	10.2
Sebia Capillarys2	%A1c	5.3	6.4	7.6	10.5

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