

# NOVA-ONE<sup>®</sup>

## DIAGNOSTICS

Delivering Innovative Medical Diagnostics Everyday

Whole Blood Kit (HbA1c) LINEARITY 4 LEVEL  
Part No: NOD Hbl-G04041-100 Lot 4500M001

Product	Lot Number	Expiration Date
NOD <sup>®</sup> DIABETES A1c LINEARITY IA, Level 1	4539M001	04/2013
NOD <sup>®</sup> DIABETES A1c LINEARITY IA, Level 2	4540M001	04/2013
NOD <sup>®</sup> DIABETES A1c LINEARITY IA, Level 3	4541M001	04/2013
NOD <sup>®</sup> DIABETES A1c LINEARITY IA, Level 4	4542M001	04/2013

### INTENDED USE

NOD<sup>®</sup> DIABETES A1c LINEARITY IA is intended for use as quality control material to monitor linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) determination methods using protocols established in individual laboratories.

### SUMMARY AND PRINCIPLE

NOD<sup>®</sup> DIABETES A1c LINEARITY is provided at four levels ranging across the reportable range of HbA1c to assist in calibration linearity procedures.

### REAGENT

NOD<sup>®</sup> DIABETES A1c LINEARITY IA is prepared from human whole blood to which stabilizers are added. The product is in liquid form for user convenience.

### STORAGE AND STABILITY

Unopened NOD<sup>®</sup> DIABETES A1c LINEARITY is stable until the expiration date printed on the container when stored frozen at – 20 C. Upon opening containers, 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<sup>®</sup> DIABETES A1c LINEARITY should be treated in the same manner as patient samples in accordance with instructions for determination method being used. Frozen Linearity should be thawed at room or refrigerator temperature and mixed by gentle inversion prior to use.

### 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<sup>®</sup> 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<sup>®</sup> DIABETES A1c LINEARITY IA 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.

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	LEVEL 2	LEVEL 3	LEVEL 4
		4539M001 TARGET VALUES	4540M001 TARGET VALUES	4541M001 TARGET VALUES	4542M001 TARGET VALUES
<b>INSTRUMENT/KIT</b>					
BAYER A1C NOW	% A1c	5.4	6.9	8.4	10.5
SIEMENS DCA 2000	% A1c	5.1	6.6	8.0	9.4
Tosoh G7	% A1c	5.3	6.8	8.3	10.1
Tosoh G8	% A1C	5.5	6.9	8.4	10.1
Variant II	% A1C	5.4	6.7	8.4	10.1
Trinity Ultra2	% A1C	5.3	6.7	8.3	10.2