

# NOVA-ONE Diagnostics®

Delivering Innovative Medical Diagnostics Everyday

## DIABETES A1c LINEARITY 4 LEVEL Part No: HBL-G04041-100 Kit Lot # 5077P001

Kit Product HBL-G04041-100	Kit Lot Number 5077P001 Contents	Expiration Date
NOD® DIABETES A1c LINEARITY IA, Level 1	4539P001	October 2011
NOD® DIABETES A1c LINEARITY IA, Level 2	4540P001	October 2011
NOD® DIABETES A1c LINEARITY IA, Level 3	4541P001	October 2011
NOD® DIABETES A1c LINEARITY IA, Level 4	4542P001	October 2011

### INTENDED USE

NOD® 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® 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 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® 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 180days when stored at 2-8°C in tightly closed containers.

### PROCEDURE

NOD® 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® 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 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

NOD® HBL-G04041-100 Lot Number 5077Q001 METHOD INSTRUMENT/KIT	UNIT	LEVEL 1 4539P001 TARGET VALUES	LEVEL 2 4540P001 TARGET VALUES	LEVEL 3 4541P001 TARGET VALUES	LEVEL 4 4542P001 TARGET VALUES
BAYER A1CNow+	%A1c	5.1	7.7	10.4	12.5
TOSOH 2.2 HPLC	%A1c	5.8	8.8	11.8	14.5
TOSOH G7 HPLC	%A1c	5.4	8.2	11.1	13.9
TOSOH G8 HPLC	%A1c	5.3	8.3	11.1	14.3
VARIANT II	%A1c	5.5	8.2	11.0	13.5
PRIMUS ULTRA2	%A1c	5.3	8.1	11.0	13.9
DCA 2000	%A1c	5.2	8.0	10.8	> 14
COBAS INTEGRA 400	%A1c	5.6	8.7	11.0	13.4
*					

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

NOVA-ONE Diagnostics®, LLC  
22287 Mulholland Hwy, CA 91302  
818-348-1543  
(REV 3/25/2010)  
[www.NOVA-ONE.COM](http://www.NOVA-ONE.COM)