N-acetyl-β-D-glucosaminidase (NAG) Assay
Catalog Number: BQ062A-EAKP

Intended Use
The N-acetyl-β-D-glucosaminidase (NAG) assay kit is for determination of NAG in patient urine samples. NAG is a lysosomal enzyme involved in the breakdown metabolism of glycoproteins. Increased NAG levels in urine are an early indication of renal disease and can serve as a valuable renal monitoring test in disorders such as nephritic syndrome, glomerulunephritis, drug abuse associated nephrotoxicity, diabetes-associated nephropathy, hypertension and urinary tract infections.

Assay Principle
The reagents of the assay kit are in stable liquid formulation that allows ease of use coupled with enhanced performance characteristics. NAG hydrolyses 2-methoxy-4-(2'nitrovinyl)-phenyl 2-acetamido-2-deoxy-β-D-glucopyranoside (MNP-GlcNAc) to 2-methoxy-4-(2'-nitrovinyl)-phenol product. The product formation is detected by development of color at 505nm upon addition of alkaline buffer.

Specimen Collection and Handling
Fresh urine samples should be used when possible. However, urine samples can be stored for one week at 40C or up to 1 month at -20 °C without significantly affecting NAG activity. Samples containing low amount of preservative can be used (less than 0.02% sodium azide). NAG activity is pH-sensitive, hence urine samples should have a pH range between 4.0 – 8.0.

Catalog No.	BQ062A-EAKP
R1	1 x 75 mL
R2	1 x 15 mL
R3	1 x 30 mL
Calibrator	1 vial

Warnings
1. For in vitro diagnostic use.
2. Specimens and reagents containing human sourced materials should be handled as if potentially infectious, using safe laboratory procedures such as those outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93-8395).
3. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
4. Avoid swallowing and contact with skin or mucous membranes.

Instructions For Reagent Handling
For BQ062A-EAKP
Reagents are ready-to-use. Reagents are light sensitive. Reagents are stable until the expiration indicated on the package label when unopened and stored at 2 – 8 °C. Once opened reagents are stable for 1 month at 2 – 8 °C in original bottles, if closed tightly after use. Reagents from different lots must not be interchanged. After reconstitution, leave standard and control at 4 °C 24 hours to equilibrate.

Controls
Bio-Quant Controls are available and sold separately.

Assay Procedure
See attached program parameters for COBAS and Hitachi systems.

Normal range
Healthy subjects have a NAG activity in the range of 0.3 -12 IU/L. There is no apparent significant difference in NAG excretion between males and females. NAG activity is known to vary with age and diuresis, hence a NAG index (ratio of NAG activity to urinary creatinine) is often used to minimize variability (Yuen CT et al, 1982).

Interferences
No significant interference from hemoglobin or albumin. Interference from bilirubin occurs only at levels higher than 5 mg/L.

References

- Price, R.G. & Whiting, P.H., Urinary Enzymes (1992), 203-221. Eds: Jung, K, Matteheimer and Burchardt H. Springer-Verlag, Berlin
- Yuen CT et al, Clin Chem Acta (1982) 124: 195-204

Instrument Parameter Settings

Cobas Mira S Parameters	NAG
Measurement Mode	Absorb
Reaction Mode	R-S-SR1
Calibration Mode	Slope Avg
Reagent Blank	Reag/DIL
Cleaner	No
Wavelength	500 nm
Decimal position	3
Unit	U/L
Sample cycle	1
Sample volume	10.0 uL
Sample dilution	H_2O
Dilution volume	0.0 uL
Reagent cycle	1
Reagent 1 (solution mix) volume	150 µL
Dilution volume	0.0 µL
Start R1 (reagent 3) cycle	13
Reagent volume	50 µl
Dilution volume	0.0 µL
Sample limit	No
Reaction direction	Increase
Convers. factor	1.0000
offset	0.0000
Test range low	0.000 U/L
Test range High	200.00 U/L
Number of steps	1
Calc. Step A	Endpoint
Readings first	12
Readings last	13
Calibration	
Cali. interval	Each day
time	No
Blank	
Reagent range low	0.0
high	3.5
Blank range low	-0.04
high	3.5
Standard pos	1
Standard-1	*
Replicate	Dupl

Attention:

(1) * Standard concentration based on label on the bottle. Entered By Operator.

(2) Each cycle is 25 seconds on COBAS MIRA S analyzer.

HITACHI 717 Parameters

HITACHI 717 Parameters	NAG
Test	NAG
Assay Code	2 Pinot
Assay Point	(24)-(26)
Wavelength	800/505
Calibration Method	Linear
Unit	U/L
Sample volume	(10)(10)
Reagent vol. R1 (mix solution)	(150)(100)(NO)
Reagent vol. R3	(50)(100)(NO)
STD (1) CONC. -POS	(0)-(1)*
STD (2) CONC. -POS	(45.8)-(2)*
ABS.Limit	32000-Increse
Expected value (normal Value)	0.3-12
Tech Limit	0-200

Attention: * Entered By Operator. Conc. based on bottle labeling.
Hitachi 717: Read for each cycle 12 second.