N-ACETYL-ß-D-GLUCOSAMINIDASE (NAG) ASSAY

Renal and Pancreatic Marker



Urinary excretion of the lysosomal enzyme N-Acetyl-ß-D-Glucosaminidase (NAG) has been proposed as a biomarker of impaired renal tubular function and damage. Studies in literature show that determination of urinary NAG activity provides a very sensitive and reliable indicator of renal damage, such as injury or dysfunction due to diabetes mellitus, nephrotic syndrome, inflammation, hypertension, heavy metals poisoning and treatment with nephrotoxic drugs. NAG activity can serve as a valuable renal monitoring test in disorders such as nephrotic syndrome, glomerulonephritis, drug abuse associated nephrotoxicity, diabetes-associated nephropathy, hypertension and urinary tract infections.¹ There is also increasing evidence that it has a predictive value on functional outcome and response to therapy.²

Diazyme's NAG Assay is a cost effective test used for the determination of NAG in urine samples.

DIAZYME NAG ASSAY ADVANTAGES

- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Fast test results (under 5.5 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

FU: CE IVD SKU For Export Only. Not for Distribution in the USA.

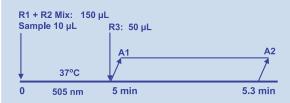


NAG ASSAY

ASSAY SPECIFICATIONS

Method	Colorimetric (Enzymatic cleavage of a colorimetric substrate)
Sample Type & Volume	• Urine Sample Volume 10 µL
Linearity	Up to 200 U/L
LOQ	1.64 U/L
Calibration Levels	1-Point Calibration
Reagent On-Board Stability	Opened: 1 month when stored at 2-8°C

NAG Assay Procedure*



*Analyzer Dependent

Parameter questions for NAG Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email <u>support@diazyme.com</u>

- Skalova, S. The Diagnostic Role of Urinary N-Acetyl-β-D-Glucosaminidase (NAG) Activity in the Detection of Renal Tublar Impairment. NCBI National Library of Medicine.2005. 48(2):75-80.
- Bazzi, C. et al. Urinary N-acetyl-β-glucosaminidase excretion is a marker of tubular cell dysfunction and a predictor of outcome in primary glomerulonephritis. NCBI National Library of Medicine. (2002) 17: 1890-1896

ASSAY PRECISION

In the study, two levels of NAG controls and one NAG urine sample containing 40.9 U/L, 124.0 U/L and 9.64 U/L NAG respectively were tested on a Hitachi 917 in one run with 20 in replicates.

WITHIN-RUN PRECISION:

	Sample 1	Sample 2	Sample 3
N	20	20	20
Mean (U/L)	38.99	119.71	9.68
SD (U/L)	0.39	1.16	0.41
CV (%)	0.99%	0.97%	4.23%

ASSAY INTERFERENCE

The common urine interfering substances triglyceride, ascorbic acid, free bilirubin, and conjugated bilirubin showed no significant interference (≥10%) up to the concentrations summarized below.

Triglyceride:	1000 mg/dL
Ascorbic Acid:	0.500 mg/dL
Bilirubin:	5 mg/dL
Bilirubin Conjugated:	5 mg/d

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