DIAZYME

RENAL & PANCREATIC MARKER

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

Three Vial Liquid Stable

Diazyme's NAG Assay is a cost effective test that uses a "highly sophisticated and powerful colorimetric substrate" that is not affected by urine color.[1] Each kit is supplied with a calibrator set for added convenience and controls are available separately. The test offers a wide range of instrument parameters for facilitating and simplifying implementation in the laboratory. Increased NAG levels in urine are usually an early indication of renal disease and can serve as a valuable renal monitoring test in disorders such as nephritic syndrome, glomerulonephritis, drug abuse associated nephrotoxicity, diabetes-associated nephropathy, hypertension and urinary tract infections.

DIAZYME NAG ASSAY ADVANTAGES

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

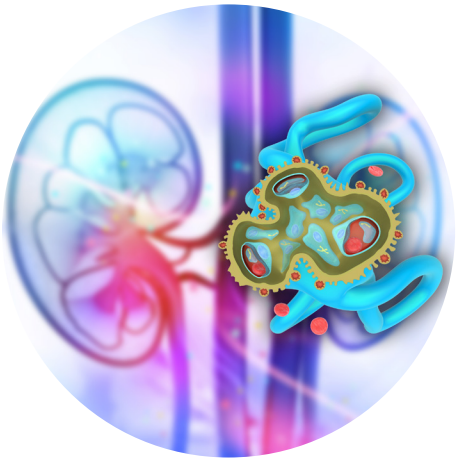
REGULATORY STATUS

510(k) Exempt

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi



NAG ASSAY
Three Vial Liquid Stable

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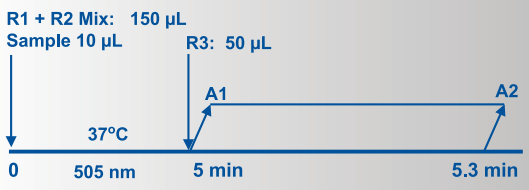
ASSAY SPECIFICATIONS

Method	Colorimetric (Enzymatic cleavage of a colorimetric substrate)
Sample Type & Volume	• Urine Sample Volume 10 µL
Linear Range	Up to 200 U/L
LOQ	1.64 U/L
Calibration Levels	1-Point Calibration
Reagent On-Board Stability	Unopened: 24 months 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 support@diazyme.com

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	38.99	119.71	9.68
Std. Dev.	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/dL

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