DIAZYME

CARDIOVASCULAR MARKER

HOMOCYSTEINE 3 REAGENT ENZYMATIC ASSAY

Three Reagent Liquid Stable

Diazyme's Homocysteine 3 Reagent Enzymatic Assay features convenient ready to use reagent, calibrators and controls for the quantitative determination of total L-homocysteine in serum or plasma. Diazyme's proprietary Enzyme Cycling methodology is an excellent choice for cost conscious laboratories of all sizes due to a wide variety of instrument specific packaging options. The assay requires minimal patient sample and provides fast, accurate and precise results. A wide variety of reliable instrument parameters means the assay is readily available for installation on most automated clinical chemistry analyzers.

DIAZYME HOMOCYSTEINE 3 REAGENT ASSAY ADVANTAGES

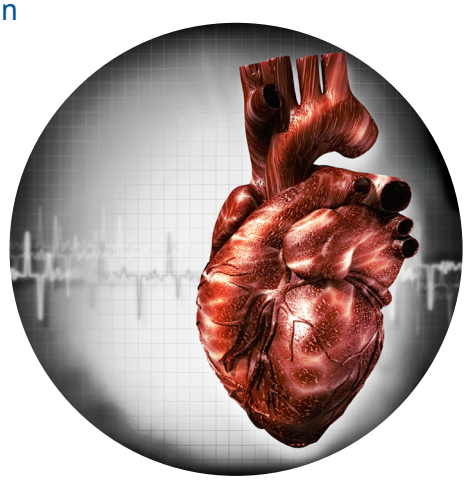
- Award winning Homocysteine recognized by the American Association of Clinical Chemistry (AACC) for outstanding contribution to scientific research
- Innovative enzyme cycling based technology for accurate and reliable results
- Excellent correlation to HPLC and immunochemical methods
- No "carry over" issues with iron or lipase reagents
- Test renal patients with confidence since there is no interference from cystathionine which affects some other less specific methods
- 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) Cleared Health Canada Registered CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Modular P
  - Integra
  - Cobas
  - Hitachi
- **Beckman**
  - Synchron
- **Siemens**
  - Dimension



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ASSAY SPECIFICATIONS

Method	Diazyme Patented Enzyme Cycling
Sample Type & Volume	• Serum • Plasma - EDTA - Li-heparin Sample Volume 18 µL
Method Correlation	N = 66 y-intercept = 0.87 Slope = 0.98 R^2 = 0.976
Linear Range	up to 50 µmol/L
LOD	<1.5 µmol/L
Calibration Levels	5-Point Calibration
Reagent On-Board Stability	Opened: At least 100 days (Analyzer Dependent)

*Homocysteine 3 Reagent Assay Procedure**

***Analyzer Dependent**

Parameter questions for Enzymatic Homocysteine 3 Reagent Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

1. *Vilaseca et al. Clin. Chem. 43: 690-692 (1997)*
2. *Faure-Delanef et al. Am. J. Hum. Genet. 60: 999-1001 (1997)*

ASSAY PRECISION

Precision studies were conducted according to the NCCLS EP-5 protocol. Within precisions (CV%) for three levels of Hcy controls are 2.2% for 7 µM Hcy, 3.0% for 12 µM Hcy and 1.8% for 29.5 µM Hcy. Total imprecision for three levels of Hcy controls are 4.1% for 7 µM Hcy, 5.9% for 12 µM Hcy and 4.0% for 29.5 µM Hcy.

HCY Concentration	**7 µM N = 40**	**12 µM N = 80**	**29.5 µM N = 80**
Within-Run Imprecision CV%	2.2	3.0	1.8
Total Imprecision CV%	4.1	5.9	4.0

ASSAY INTERFERENCE

An interference study was performed by testing a serum sample spiked with varied concentrations of endogenous substances. The following substances normally present in the serum produced less than 10% deviation when tested at the stated concentrations:

NH4Cl:	500 µM
NaPi:	1 mM
NaF:	1 mM
Triglycerides:	2500 mg/dL
Bilirubin:	20 mg/dL
Hemoglobin:	1200 mg/dL
*Glutathione:	0.5 mM
Ascorbic Acid:	10 mM
L-Cysteine:	1 mM
S-Adenosylmethionine (SAM):	20 µM
**Adenosine:	100 µM
**Cystathionine:	100 µM

* Glutathione was originally tested at 1 mM level, the interference was +13.5%. When retested at 0.5 mM level, the interference was less than 10%.

** The concentrations tested are about 5-10 times higher than the normal range of serum levels.

REFERENCE RANGE

In most of the U.S. clinical laboratories, 15 µmol/L is used as the cut-off value for normal level of Hcy for adults.[1-2] In Europe, 12 µmol/L is used as the cut-off value. However, each laboratory is recommended to establish a range of normal values for the population in their region.

DIAZYME LABORATORIES

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