DIAZYME

CARDIOVASCULAR MARKER

HOMOCYSTEINE 2 REAGENT ENZYMATIC ASSAY

Dual Vial Liquid Stable

Diazyme's Homocysteine 2 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 HOMOCYSTEIN 2 REAGENT ASSAY ADVANTAGES

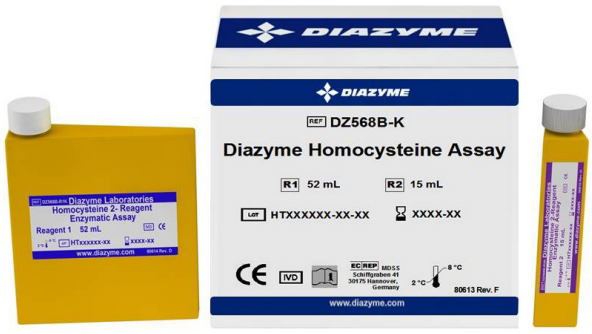
- Award winning Homocysteine recognized by the American Association of Clinical Chemistry (AACC) for outstanding contribution to scientific research
- Innovative enzyme cycling based technology for accurate and reliable results
- Excellent correlation to HPLC and immunochemical methods
- No "carry over" 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**
  - Hitachi
- **Beckman**
  - AU Series



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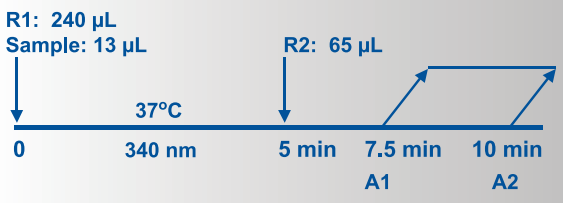
ASSAY SPECIFICATIONS

Method	Diazyme Patented Enzyme Cycling
Sample Type & Volume	• Serum • Plasma - EDTA - Li-heparin Sample Volume 13 µL
Method Correlation	N = 40 y-intercept = 1.05 Slope = 0.94 R^2 = 0.99
Linear Range	Up to 50 µmol/L
LOD	0.4 µmol/L
Calibration Levels	5-Point Calibration
Reagent On-Board Stability	Opened: At least 60 days (Analyzer Dependent)

*Homocysteine 2 Reagent Assay Procedure**



***Analyzer Dependent**

Two Reagent System

Parameter questions for Enzymatic Homocysteine 2 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. Four HCY serum samples containing 7.0, 12.0, 15.6, and 29.0 µM HCY were tested.

HCY Concentration	**7 µM**	**12 µM**	**15.6 µM**	**29 µM**
Within-Run Imprecision CV% N = 20	4.5	1.87	3.04	2.4
Total Imprecision CV% N = 30	5.87	4.88	5.51	2.57

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:

Bilirubin:	*40 mg/dL*
Triglycerides:	*1000 mg/dL*
Hemoglobin:	*500 mg/dL*
Bilirubin Conjugate:	*40 mg/dL*
Ascorbic Acid:	*10 mM*
Cystathionine:	*100 µM***

***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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