DIAZYME

INTRODUCING A NEW HIGH SENSITIVITY TROPONIN I (hs-cTnI) ASSAY

Diazyme is introducing a new High Sensitivity Troponin I (hs-cTn I) assay that is run on a fully automated Chemiluminescence Immunoassay (CLIA) analyzer, Maglumi 2000 plus (DZ-Lite 3000). The assay is for research use only in U.S.

Maglumi 2000 Plus (DZ-Lite 3000 Plus)

ABOUT hs-cTnI ASSAY

Studies indicate that due to its high tissue specificity, cardiac Troponin I (cTnI) is a specific and sensitive marker for the detection of myocardial damage.[1]

Studies report that high sensitive troponin I (hs-cTnI) assay improves early diagnosis of acute myocardial infaction and risk stratification, regardless of the time of chest-pain onset.[2]

A recent clinical study suggested that cTnI assessed by a high-sensitivity assay is prognostic beyond traditional cardiovascular risk factors for HF and mortality in the general HF-free community. The prognostic utility of hs-cTnI goes beyond that of NT-proBNP, and the data suggest that these 2 assays are complementary in identification of at-risk individuals in the general community.[3]

hs-cTnI ASSAY

ASSAY SPECIFICATIONS

Method:
Immunoluminescent (CLIA)

Sample:
Serum

LOQ:
~3.2 pg/mL (CV<20%)

LOD:
~1.0 pg/mL

Dynamic Range:
Up to 2000 pg/mL cTnI

Throughput:
90 tests/hour

99% Value:
7.0 pg/mL

CV% at 99% Value:
<8%

Traceable to NIST SRM 2921

PRECISION

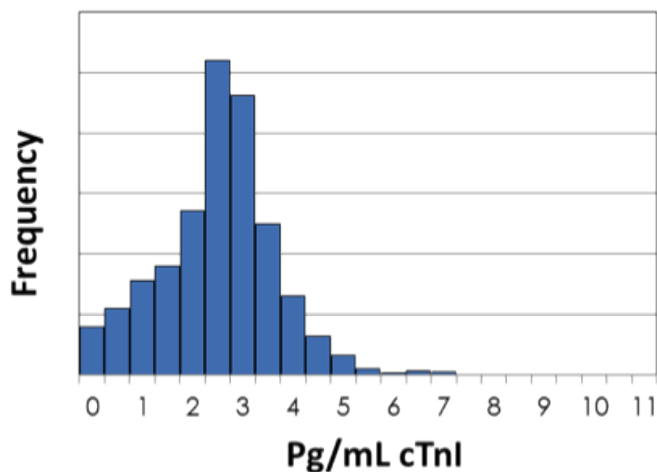|	Sample 1	Sample 2	Sample 3
Average (pg/mL)	2.14	7.53	14.99
SD (pg/mL)	0.17	0.35	0.20
CV%	7.74%	4.71%	1.36%

DISTRIBUTION

DIAZYME LABORATORIES

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1.) Mair J, Wagner I, Puschendorf B, Mair P, Lechleitner P, Diensti F, et al. Cardiac troponin I to diagnose myocardial injury (letter). Lancet 1993;341:838-839

2.) Till Keller, Tanja Zeller, Dirk Peettz et al. Sensitive Troponin I Assay in Early Diagnosis of Acute Myocardial Infarction. N Engl J Med. 2009, 361: 868-77

3.) Paul M. McKie, Omar F. AbouEzzeddine et al. High-Sensitive Troponin I and Amino-Terminal Pro-B-Type Natriuretic Peptide Predict Heart Failure and Mortality in the General Population. Clin. Chem. 2014, 60:9, 1225-1233.

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