Singulex®

SINGLE MOLECULE COUNTING IMMUNOASSAYS

Erenna® SMC™ Cardiac Troponin-I

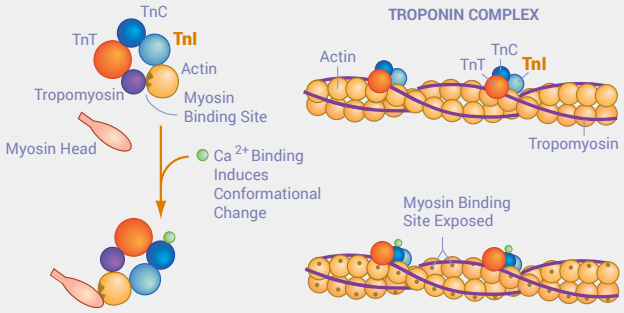
VERIFIED IMMUNOASSAY KIT
CAT.# 03-0092-xx

The Erenna SMC cTnI Immunoassay Kit has unparalleled performance in quantifying cTnI in human EDTA plasma and serum. The LLoQ of the assay (0.4 pg/mL) is well below observed human endogenous levels (median [cTnI] = 1.75 pg/mL).

BIOLOGY AND DISEASE

Cardiac Troponin-I (cTnI) is specific to cardiomyocytes and is released into the bloodstream following heart damage. Extensive studies have shown that cTnI is slowly released from damaged cardiomyocytes. This has allowed cTnI to become widely accepted in preclinical and clinical drug development settings as an indicator of myocardial damage and hence, heart damage.

The high sensitivity of the research grade Erenna cTnI assay uniquely provides utility across multiple species and matrices.



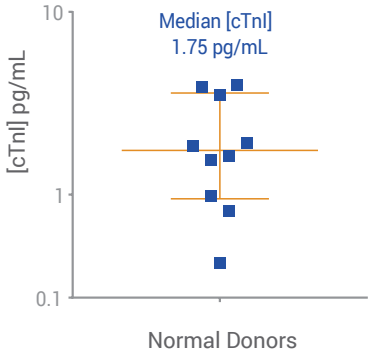
IMMUNOASSAY SPECIFICATIONS

Lower Limit of Detection	0.1 pg/mL
Lower Limit of Quantification[1]	0.4 pg/mL
Upper Limit of Quantification	600 pg/mL
Low-end CV% Range	0 - 20%
Low-end CV% Average	12%
Recommended Sample Volume	100 µL
Minimum Sample Volume Required[2]	50 µL
Species Cross-reactivity	canine, guinea pig, mouse, NHP, rat
Matrices Verified	human serum/ EDTA plasma
Assay Format	Bead

1 LLoQ ≤ 20% CV and ± 20% recovery
2 Based upon median [cTnI] in a normal reference population

ENDOGENOUS RANGE

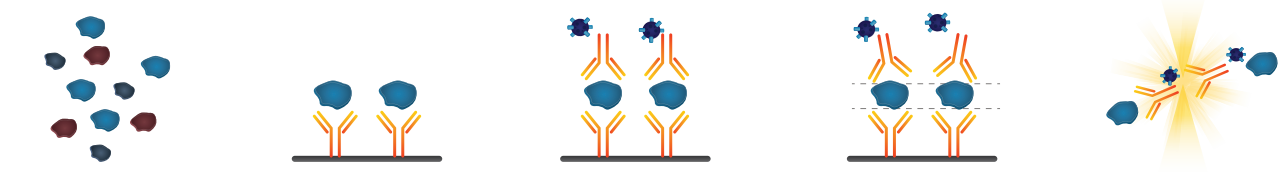
Endogenous [cTnI] in EDTA plasma from 10 donors, with median and interquartile range.



SMC TECHNOLOGY WORKFLOW

The proprietary digital SMC technology allows scientists to measure proteins with great precision, enabling unparalleled quantification at low and high levels of expression. The flexible Erenna Immunoassay System acquires data from both plate-based assays (PBA) and bead-based assays (BBA), providing choice of format depending on budget and quantification requirements.

STANDARD — PROPRIETARY



1. Analyte of Interest in Solution
2. Capture on Plate or Bead
3. Detect
4. Elute — Complex is chemically broken apart
5. Quantify — Sample flows past laser; detection tags counted

Previously undetectable, quantified. One molecule at a time.

LS LIFE SCIENCE PRODUCTS & SERVICES

Erenna® Verified Immunoassays

Singulex addresses the needs of researchers who require highly quantitative, accurate, and robust biomarker assays. Under the rigorous Singulex Quality System, assays are developed and tested in matrix by multiple operators over multiple days. A comprehensive set of criteria evaluating ultimate quantitative performance are used to qualify Verified Immunoassays.

LOWER LIMIT OF QUANTIFICATION

Lowest point on standard curve where CV is <20% and accuracy is within 20% of expected values.

INTER- AND INTRA-ASSAY PRECISION

Same samples run on multiple plates over multiple days to ensure reproducibility. Spiked and un-spiked samples report values within 20% across experiments.

SPIKE RECOVERY

Analyte added at lower end of standard curve to ensure accurate measurements for real samples. Minimum of 10 samples spiked with acceptable recovery between 80-120%.

DILUTIONAL LINEARITY

Spiked samples diluted through at least 3 dilutions. Minimum of 10 samples spiked and diluted with acceptable recovery between 80-120%.

DYNAMIC RANGE

Assays target a quantifiable range of 3-4 logs.

ENDOGENOUS RANGE

Minimum of 10 samples from individual donors assessed for ability to quantify baseline biomarker levels.

Singulex®

Get more product information **here**
singulex.com/lsresources

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