Quanterix™
The Science of Precision Health

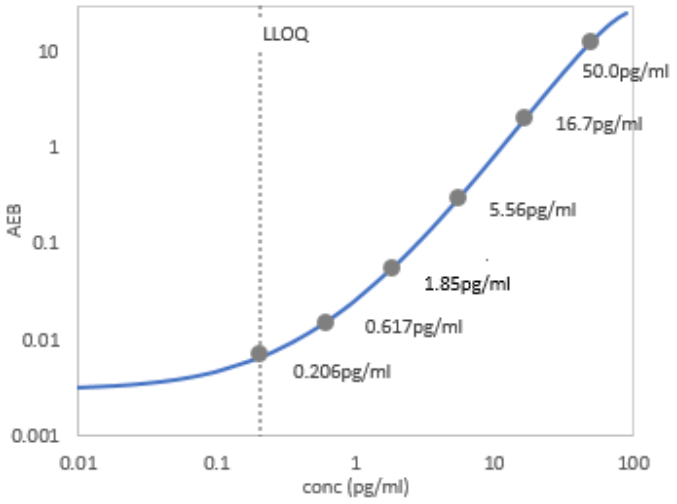
Simoa® NT-proBNP Discovery Kit
HD-1/HD-X Data Sheet

Item 102713

Description

Natriuretic peptides are produced primarily within the heart and released into the circulation in response to increased wall tension, reflecting increased volume or pressure overload.[1] Under pathologic stimuli, the prohormone of BNP is synthesized, cleaved to BNP, the biologically-active peptide, and inactive fragment NT-proBNP, a 76aa amino terminal peptide.[2] Both BNP and NT-proBNP are released predominantly by the ventricles in response to stretch, and are used for the diagnosis of systolic heart failure.[3] NT-proBNP circulates at higher plasma concentrations and has a longer half-life when compared with BNP.[4] Both peptides have proved equally useful for the diagnosis of ambulatory patients with heart failure and left ventricular dysfunction.[5]

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted (Cubic fitting).



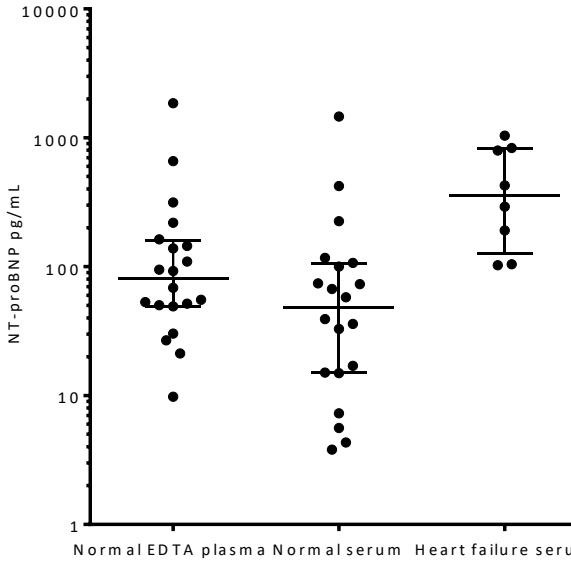
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve for 5 runs using 1 reagent lot on 3 instruments. The LLOQ is determined as the lowest dilution with a pooled CV ≤ 20% and sample concentration recovery between 80-120% of the expected.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration over 5 runs for 1 reagent lot on 3 instruments.

LLOQ	**0.206pg/mL** pooled CV 15.8%, mean recovery 101.9%
LOD	**0.0433 pg/mL** range 0.0071-0.1190 pg/mL
Sample range	0–500 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=20) and serum (n=20), and Heart failure samples (n=8) were measured. Bars depict median with interquartile range.



Human samples	Mean pg/mL	Median pg/mL	% Above LOD
EDTA plasma	265.2	93.7	100%
Serum	200.9	70.6	100%
Heart failure serum	473.4	359.2	100%

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Precision: Measurements of 3 serum or plasma based panels. Triplicate measurements were made for 5 runs using 1 reagent lot and 3 instruments (5 runs total, 15 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV
Panel 1	7.347	6.0%	7.7%
Panel 2	30.67	2.7%	8.7%
Panel 3	172.6	2.7%	7.5%

Spike and Recovery: 4 serum samples were spiked at high and low concentrations within the range of the assay.

Dilution Linearity: 1 endogenous plasma sample was diluted 2x serially from MRD (10x) to 320x with Sample Diluent.

Spike and Recovery	**96.4%** Range 87.8%-109.5%
Dilution Linearity (Plasma, 320x)	**84.3%** Range: 72.0%-98.4%

Specificity: Normal serum (n=3) were directly incubated with 20X capture beads and run at MRD. Average knock-down was **93.3%** with a range of **92.2% -94%**.

References:

1. Kinnunen P, Vuolteenaho O, Ruskoaho H. Mechanisms of atrial and brain natriuretic peptide release from rat ventricular myocardium: effect of stretching. Endocrinology1993;**132**:1961–70
2. Agency for Health Care Policy and Research*Heart failure evaluation and care of patients with left ventricular systolic dysfunction*1994Rockville, MDAgency for Health Care Policy and Research.
3. Mair J, Hammerer-Lercher A, Puschendorf B. The impact of cardiac natriuretic peptide determination on the diagnosis and management of heart failure. Clin Chem Lab Med 20001; 39:571-588
4. Downie PF, Talwar S, Squire IB, Davies JE, Barnett DB, Ng LL. Assessment of the stability of N-terminal pro-brain natriuretic peptide in vitro: implications for assessment of left ventricular dysfunction. Clin Sci (LOND) 1999; 97:255-258
5. MassonS.VagoT. BaldiG.Comparative measurement of N-terminal pro-brain natriuretic peptide and brain natriuretic peptide in ambulatory patients with heart failure*Clin Chem Lab Med*2002**40**761763

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