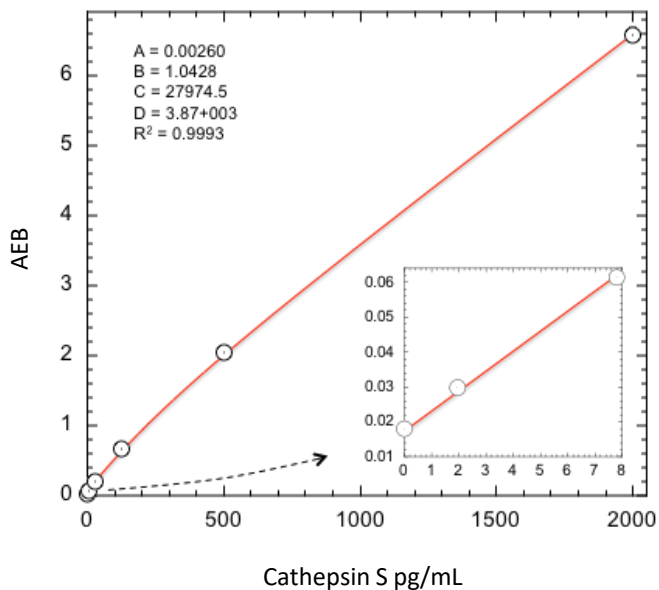


Description

Cathepsin S (CTSS) is a lysosomal cysteine protease of the papain family. It plays a major role in the processing of the MHC class II associated invariant chain. It has been implicated in the pathogenesis of several diseases such as Alzheimer’s disease and degenerative disorders associated with the cells of the mononuclear phagocytic system. Human Cathepsin S is synthesized as a pre-pro-enzyme of 331 amino acid residues consisting of a signal peptide (residues 1-16), a pro region (residues 17-114), and the mature enzyme (residues 1150-331). Cathepsin S is less abundant in tissues than Cathepsins B, L and H. The highest levels have been found in lymph nodes, spleen, macrophages and other phagocytic cells.

Calibration Curve: Four-parameter curve fit parameters are depicted.



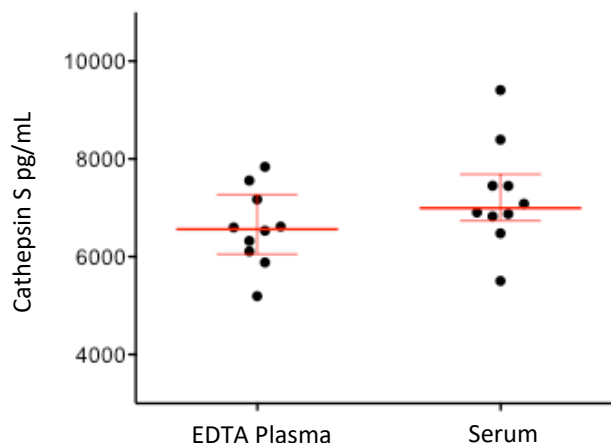
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 3 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 3 instruments (6 runs total).

LLOQ	1.95 pg/mL pooled CV 3.7% mean recovery 99.2%
LOD	0.70 pg/mL range 0.07–0.99 pg/mL
Dynamic range (serum and plasma)	0–200 ng/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median and interquartile ranges.



Sample Type	Median Cathepsin S pg/mL	% Above LOD
Serum	6,994	100%
Plasma	6,566	100%

Precision: Representative precision was estimated with repeated assay of serum panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Panel 1	4,660	3.1%	2.8%
Panel 2	4,420	5.7%	3.8%
Panel 3	6,010	4.3%	4.8%

Dilution Linearity: Serum sample diluted 2x serially from MRD (100x) to 1600x with Sample Diluent.

Dilution Linearity (1600x)	Mean = 87% Range: 84–88%
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