

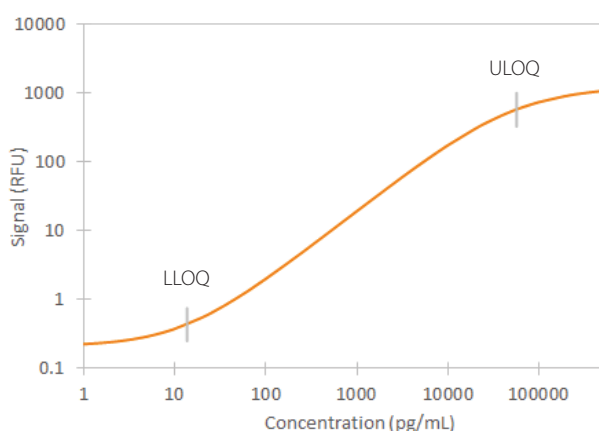
Human Proprotein Convertase 9

Simple Plex assay for the detection of human PCSK9 in serum and plasma (EDTA/Heparin)

For research use only. Not for use in diagnostic procedures.

Calibration Curve

The factory generated calibration curve shown below was compiled by averaging 5 replicates of each calibrator from multiple runs. The 5PL curve fit shows calibrator concentration as a function of signal intensity (relative fluorescent units, RFU).



Limit of Quantitation

Data shown represents typical performance results for Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) for PCSK9.

	CONC. (pg/mL)
LLOQ	13.6
ULOQ	56,970

Limit of Detection

The limit of detection (LOD) of human PCSK9 is 4.32 pg/mL. The LOD was calculated by adding three standard deviations to the mean background signal determined from multiple runs.

Endogenous Levels

Endogenous levels were calculated from multiple samples. Samples were from apparently healthy volunteers. No medical histories were available for the donors in this study.

SAMPLE TYPE	MEAN (pg/mL)	RANGE (pg/mL)	STD DEV (pg/mL)
Serum (n=10)	240,442	176,550-338,527	56,035
EDTA Plasma (n=10)	211,002	125,503-279,164	54,719
Heparin Plasma (n=10)	224,738	166,416-278,311	42,757

Precision

Intra-assay Precision: Each control was tested 16 times in one assay.

Inter-assay Precision: Replicates of each control were tested in multiple assays performed by at least three technicians using two lots of reagents.

PARAMETER	LOW QC	HIGH QC
Intra-Mean (pg/mL)	296	17,116
Intra-assay SD	19.6	842
Intra-assay CV (%)	6.6	4.9
Inter-Mean (pg/mL)	292	17,472
Inter-assay SD	18.3	1101
Inter-assay CV (%)	6.3	6.3

Correlation

This assay has been correlated to the Quantikine® ELISA Kit with a slope of 0.9-1.1 and an R² value greater than 0.9.

Recovery

Recovery was not necessary as PCSK9 shows natural linearity data from a neat sample to a 1:16 dilution.

Linearity

Samples containing and/or spiked with high concentrations of human PCSK9 were serially diluted with Sample Diluent to produce samples within the dynamic range of the assay.

DILUTION	PARAMETER	SERUM (n=4)	EDTA PLASMA (n=4)	HEPARIN PLASMA (n=4)
1:2	Avg % of Expected	112	113	96
	Range (%)	110-114	104-126	82-107
1:4	Avg % of Expected	117	110	101
	Range (%)	106-124	101-119	89-117
1:8	Avg % of Expected	120	121	99
	Range (%)	117-121	107-138	86-115
1:16	Avg % of Expected	111	110	95
	Range (%)	99-119	90-126	86-116

Specificity

This assay recognizes natural and recombinant human PCSK9. The factors listed were prepared at 50 ng/mL in Sample Diluent and assayed for cross-reactivity. Preparations of the following factors at 50 ng/mL in a rhPCSK9 control were assayed for interference. No significant cross-reactivity or interference was observed.

Recombinant human:

- LDL R
- PCSK1
- PCSK3 (Furin)
- PCSK7

Sample Collection and Storage

The sample collection and storage conditions listed below are intended as general guidelines. Sample stability has not been evaluated.

Serum: Use a serum separator tube (SST) and allow samples to clot for 30 minutes at room temperature before centrifugation for 15 minutes at 1000 x g. Remove serum and assay immediately or aliquot and store samples at $\leq -20^{\circ}\text{C}$. Avoid repeated freeze-thaw cycles.

Plasma: Collect plasma using heparin or EDTA as an anticoagulant. Centrifuge for 15 minutes at 1000 x g within 30 minutes of collection. Assay immediately or aliquot and store samples at $\leq -20^{\circ}\text{C}$. Avoid repeated freeze-thaw cycles.

Note: Grossly hemolyzed or icteric samples are not suitable for use with this assay.

Sample Preparation

Serum and plasma samples require a minimum 10-fold dilution with sample diluent. Samples above the ULOQ require further dilution.