

Theranos Assay System Validation Report: Human TNF- α Assay
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Assay Specification:

The assay is designed to measure active TNF- α in human blood, plasma and serum. Reportable ranges and limits of detection are:

Sample type	Low, pg/mL	High, pg/mL
Human plasma	1.6	17,662
Human serum	2.0	17,662

Specificity:

This assay recognizes both natural and recombinant human TNF- α and does not significantly cross react with human human: TNF-b, TNF RI, TNF RII, TNF RII/Fc Chimera. It does not cross react with mouse, rat or canine TNF- α .

Precision:

8 samples were assayed on multiple instruments (N = 3).

Inter-instrument CV: 6.4 %

Total CV (any cartridge, any instrument): 6.4 %

Sensitivity: Limit of detection in plasma (95% confidence) = 1.3 pg/mLpg/mL

Dilution linearity: A pooled plasma sample was spiked with TNF- α then diluted to the specified target concentrations with the results shown below. The TNF- α values from the Theranos system agree within < 10 % of the target.

Target (pg/mL)	Result (pg/mL)
422.11	433.11
85.71	86.63
22.64	21.62
8.62	8.57
3.95	4.30
1.61	1.57

Interfering substances: The assay was tested for Rheumatoid Factor interference – no interference from Rheumatoid Factor occurred.

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