

U-CyTech BV

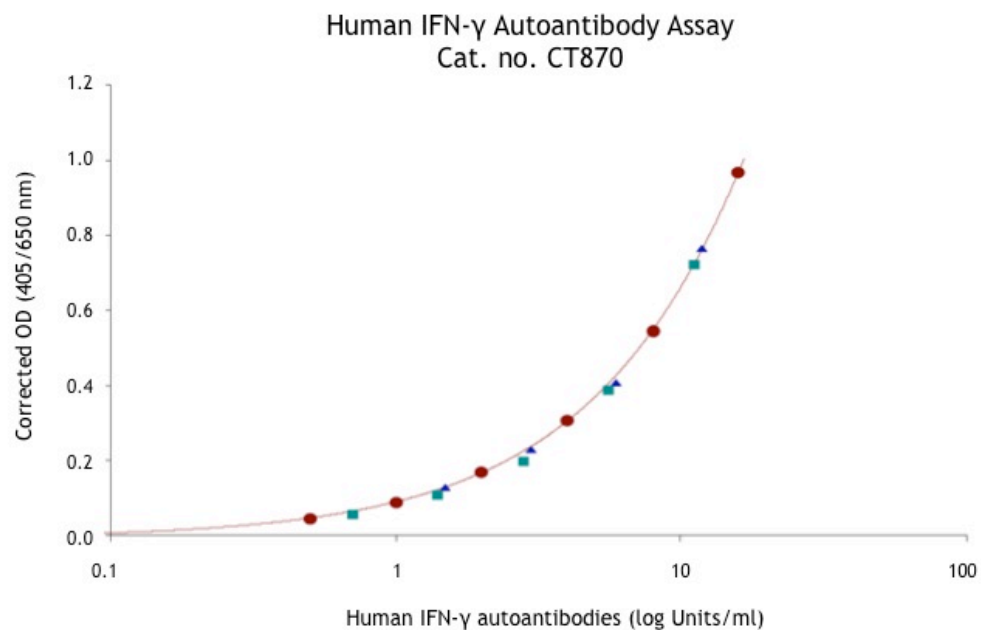
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Typical data Human IFN- γ Autoantibody Assay

Catalogue no.: CT870 (1-plate format)

Validated for:

Autoantibodies directed to Human IFN- γ (IFAA)



Example of the standard curve (●) of the Human IFN- γ Autoantibody Assay (using a 4-parameter logistic fit). To demonstrate parallelism, two positive human serum samples (■ and ▲) are serially diluted throughout the quantitative range of the assay.

Assay range:	0.5-16 U/ml.
Sensitivity:	0.5 U/ml.
Specificity:	natural autoantibodies directed to human IFN- γ .
Calibration:	monoclonal antibody to human IFN- γ .
Type of sample:	serum, plasma (heparin).

Intra-Assay precision	< 7%
Inter-Assay precision	< 15%

The Human IFN- γ Autoantibody Assay is calibrated in relative arbitrary units, since no international reference preparation is available for this assay. One Unit (U) is arbitrarily defined as the amount of anti-human IFN- γ binding activity that equals the binding activity of 1 ng of mouse anti-human IFN- γ monoclonal antibody in the same assay.

Expected values

In a normal range study with serum from healthy donors and patients with proven increased natural autoantibodies directed to human IFN- γ (IFAA) values the following cutoff has been established with this Human IFN- γ Autoantibody Assay using a serum dilution of 1:300:

Normal value in serum < 1000 U/ml
Elevated levels in serum \geq 1000 U/ml

Please note that each laboratory should establish its own normal and pathological reference ranges for IFAA levels. Also, it is recommended to use your own panel of control serum or plasma samples in this assay. Note: not all serum samples may dilute in a linear way according to the standards of the kit.

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Interfering substances

Interfering effects have been found with the use of EDTA coagulant and should therefore not be used. In addition, it is recommended to avoid hemolyzed or lipemic samples.

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for three positive IFAA samples from the results of 8 determinations in a single run. Results for the precision within one assay are shown in the Table below.

Inter-assay precision: CV was calculated for three samples from the results of 24 determinations in 3 different runs. Results for run-to-run are shown in Table below.

Sample	Intra-Assay (n=8)		Inter-Assay (n=24)	
	Mean U/ml	CV (%)	Mean U/ml	CV (%)
1	2.3	6.9	2.4	7.5
2	13.3	3.1	13.5	8.8
3	7.0	4.2	7.8	11.9