ELISA Report Result

Run Date:
Operator:
Run Number:
Kit Batch Number:

Version: 1.1.5.61

Valid ELISA test run.

Results (IU/mL)

Subject ID	Nil	TB Ag	Mitogen	TB Ag-Nil	Mitogen-Nil	Result
ID 1	0.11	5.74	> 10	5.62	> 10	POSITIVE
ID 2	0.10	0.24	> 10	0.14	> 10	NEGATIVE
ID 3	0.08	0.08	> 10	0.00	> 10	NEGATIVE
ID 4	0.10	0.08	> 10	-0.02	> 10	NEGATIVE
ID 5	0.11	> 10	> 10	> 10	> 10	POSITIVE
ID 6	0.08	0.09	> 10	0.00	> 10	NEGATIVE
ID 7	0.04	0.90	> 10	0.85	> 10	POSITIVE
ID 8	0.12	1.00	> 10	0.87	> 10	POSITIVE
ID 9	0.09	> 10	> 10	> 10	> 10	POSITIVE
ID 10	0.09	> 10	> 10	> 10	> 10	POSITIVE

Signature _____ **Date** _____

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Valid ELISA test run.

Std	Conc	% CV	Mean	QC Result
S1	4.00	0.3	1.09	Pass
S2	1.00	1.2	0.35	Pass
S3	0.25	N/A	0.18	Pass
S4	0.00	N/A	0.12	Pass

Intercept: -0.8890 Slope: 0.6448 Correlation Coefficient: 0.99 (Pass)

Raw Data(OD)

	1	2	3	4	5
A	**1.093**	0.100	9.000	0.087	0.088
B	**0.352**	1.305	0.094	9.000	2.035
C	**0.180**	9.000	0.079	0.055	9.000
D	**0.122**	0.092	9.000	0.385	0.085
E	**1.088**	0.163	0.096	9.000	3.065
F	**0.346**	9.000	2.096	0.106	9.000
G	**0.185**	0.082	9.000	0.413	N/S
H	**0.123**	0.083	0.081	9.000	N/S

ELISA Report results are interpreted as follows:

NOTE: Diagnosing or excluding tuberculosis disease, and assessing the probability of LTBI, Requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting ELISA Report results.

Nil (IU/mL)	TB Antigen minus Nil (IU/mL)	Mitogen minus Nil (IU/mL)	ELISA Report Result	Report/Intepretation
≤ 8.0	< 0.35	≥ 0.5	Negative	*M.tuberculosis* infection NOT likely
	≥ 0.35 and < 25% of Nil value	≥ 0.5		
	≥ 0.35 and ≥ 25% of Nil value	Any	Positive	*M.tuberculosis* infection likely
	< 0.35	< 0.5	Indeterminate	Result are indeterminate for TB Antigen responsiveness
	≥ 0.35 and < 25% of Nil value	< 0.5		
>8.0	Any	Any		

Nil control must be ≤ 8.0 IU/mL and Mitogen - Nil must be ≥ 0.5 IU/mL OR TB Antigen - nil must be ≥ 0.35 IU/mL for a subject to have a valid ELISA Report result.

The Mitogen control generally elicits the greatest IFN-gamma response of the 3 samples from each subject. In some cases, the Mitogen control OD value will be above the limit of the microplate reader; this has no impact on the test interpretation. The IFN-gamma level of the Nil control is considered background and is subtracted from the TB Antigen and Mitogen results for that blood specimen. In clinical studies, less than 0.25% of subjects had IFN-gamma levels of > 8.0 IU/mL for the Nil control.

The cut-off for the ELISA Product test is 0.35 IU/mL above the Nil control (and TB Antigen minus Nil is ≥ 25% of the Nil control) for the TB Antigen stimulated plasma sample. Individuals displaying a response to the TB Antigen above this cut-off are likely to be infected with *M.tuberculosis*.

The magnitude of the measured IFN-gamma level cannot be correlated with stage or degree of infection, level of immune responsiveness, or likelihood for progression to active disease. A positive ELISA Report result does not necessarily indicate the presence of active tuberculosis disease. Other diagnostic procedures, such as X-ray examination of the chest and microbiological examination of sputum, should be used when TB disease is suspected.

More detailed information can be found in the "Interpretation of Result' section of then ELISA Product Package Insert.