



Gujarat Blood Bank, Pathology Laboratory & Diagnostic Center



To,
The Drugs Controller General (India)
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of health & Family Welfare
FDA Bhawan, Kotla Road, ITO,
New Delhi-110002

20.12.2017

Subject: Evaluation of **Standard E TB-Feron ELISA** (Enzyme Linked Immuno Sorbent Assay) kit

Dear Sir,

With reference to the license no **TL-85/17** regarding evaluation of the above-mentioned kit from manufacturer M/s SD Biosensor Inc., 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea and Imported by SD Biosensor Healthcare Pvt. Ltd. Plot No 38, Sec-4, IMT Manesar, Gurgaon. Please find the below detailed report.

Lot Number: ETB117002-3

Expiry: 29/08/18

Packing: Micro wells packed with desiccant

Storage: 2°-8°C

Reference Method: ELISA

Number of Positive samples: 51

Number of Negative samples: 69

Sample Volume/Type: 50µl Plasma

Time for result: 1 Hr 45 Min

Result Interpretation for Standard E TB- Feron ELISA:

When using Nil, Antigen and Mitogen Tubes:

Nil (IU/MI)	TB Antigen- Nil (IU/MI)	Mitogen- Nil (IU/MI)*	Standard E Result	Result/Interpretation
≤ 8.0	< 0.35	≥ 0.5	Negative	M. tuberculosis infection not likely
	≥ 0.35 and < 25% of Nil Value	≥ 0.5	Negative	
	≥ 0.35 and ≥ 25% of Nil Value	Any	Positive**	M. tuberculosis infection likely
	< 0.35	< 0.5	Indeterminate	Results are indeterminate for TB Antigen responsiveness
	≥ 0.35 and < 25% of Nil Value	< 0.5	Indeterminate	
> 8.0	Any	Any	Indeterminate	



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*Responses to the Mitogen positive control and occasionally TB Antigen can be commonly outside the range of the Microplate Reader. This does not affect the test results.

** When M. tuberculosis infection is not suspected, initial positive results can be confirmed by retesting the original plasma samples. If the repeated test results are of the replicates are positive, they should be considered as positive

Positive Sample Comparison (Sensitivity) with Standard E TB-Feron ELISA and QuantiFeron -TB Gold ELISA

S.NO	Reference Results	Standard E TB-Feron ELISA (ETB117002-3)	QuantiFeron-TB Gold
1	Positive	Positive	Positive
2	Positive	Positive	Positive
3	Positive	Positive	Positive
4	Positive	Positive	Positive
5	Positive	Positive	Positive
6	Positive	Positive	Positive
7	Positive	Positive	Positive
8	Positive	Positive	Positive
9	Positive	Positive	Positive
10	Positive	Positive	Positive
11	Positive	Positive	Positive
12	Positive	Positive	Positive
13	Positive	Positive	Positive
14	Positive	Positive	Positive
15	Positive	Positive	Positive
16	Positive	Positive	Positive
17	Positive	Positive	Positive
18	Positive	Positive	Positive
19	Positive	Positive	Positive
20	Positive	Positive	Positive
21	Positive	Positive	Positive
22	Positive	Positive	Positive
23	Positive	Positive	Positive
24	Positive	Positive	Positive
25	Positive	Positive	Positive
26	Positive	Positive	Positive
27	Positive	Positive	Positive
28	Positive	Positive	Positive
29	Positive	Positive	Positive
30	Positive	Positive	Positive
31	Positive	Positive	Positive
32	Positive	Positive	Positive
33	Positive	Positive	Positive
34	Positive	Positive	Positive



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35	Positive	Positive	Positive
36	Positive	Positive	Positive
37	Positive	Positive	Positive
38	Positive	Positive	Positive
39	Positive	Positive	Positive
40	Positive	Negative	Negative
41	Positive	Positive	Positive
42	Positive	Positive	Positive
43	Positive	Positive	Positive
44	Positive	Positive	Positive
45	Positive	Positive	Positive
46	Positive	Positive	Positive
47	Positive	Positive	Positive
48	Positive	Positive	Positive
49	Positive	Positive	Positive
50	Positive	Positive	Positive
51	Positive	Positive	Positive

Negative Sample Comparison (Specificity) with Standard E TB-Feron ELISA and QuantiFeron -TB Gold ELISA

S.No	Reference Results	Standard E TB-Feron ELISA (ETB117002-3)	QuantiFeron-TB Gold
1	Negative	Negative	Negative
2	Negative	Negative	Negative
3	Negative	Negative	Negative
4	Negative	Negative	Negative
5	Negative	Negative	Negative
6	Negative	Negative	Negative
7	Negative	Negative	Negative
8	Negative	Negative	Negative
9	Negative	Negative	Negative
10	Negative	Negative	Negative
11	Negative	Negative	Negative
12	Negative	Negative	Positive
13	Negative	Positive	Positive
14	Negative	Negative	Negative
15	Negative	Negative	Negative
16	Negative	Negative	Negative
17	Negative	Negative	Negative
18	Negative	Negative	Negative
19	Negative	Negative	Negative
20	Negative	Negative	Negative
21	Negative	Negative	Negative
22	Negative	Negative	Negative
23	Negative	Negative	Negative
24	Negative	Negative	Negative

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25	Negative	Negative	Negative
26	Negative	Negative	Negative
27	Negative	Negative	Negative
28	Negative	Negative	Negative
29	Negative	Negative	Negative
30	Negative	Negative	Negative
31	Negative	Negative	Negative
32	Negative	Negative	Negative
33	Negative	Negative	Negative
34	Negative	Negative	Negative
35	Negative	Negative	Negative
36	Negative	Negative	Negative
37	Negative	Negative	Negative
38	Negative	Negative	Negative
39	Negative	Negative	Negative
40	Negative	Negative	Negative
41	Negative	Negative	Negative
42	Negative	Negative	Negative
43	Negative	Negative	Negative
44	Negative	Negative	Negative
45	Negative	Negative	Negative
46	Negative	Negative	Negative
47	Negative	Negative	Negative
48	Negative	Negative	Negative
49	Negative	Negative	Negative
50	Negative	Negative	Negative
51	Negative	Negative	Negative
52	Negative	Negative	Negative
53	Negative	Negative	Negative
54	Negative	Negative	Negative
55	Negative	Negative	Negative
56	Negative	Negative	Negative
57	Negative	Negative	Negative
58	Negative	Negative	Positive
59	Negative	Negative	Negative
60	Negative	Negative	Negative
61	Negative	Negative	Negative
62	Negative	Negative	Negative
63	Negative	Negative	Negative
64	Negative	Negative	Negative
65	Negative	Negative	Negative
66	Negative	Negative	Negative
67	Negative	Negative	Negative
68	Negative	Negative	Negative
69	Negative	Negative	Negative

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Validity of result: All QC criteria as mentioned in the product IFU were met before interpreting the result:

- The mean OD value for Standard 1 must be ≥ 0.600 .
- The %CV for Standard 1 and Standard 2 replicate OD values must be $\leq 15\%$.
- Replicate OD values for Standard 3 and Standard 4 must not vary by > 0.040 optical density units from their mean.
- The correlation coefficient (r) calculated from the mean absorbance values of the standards must be ≥ 0.98 .





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Sensitivity:

Sensitivity- (TP/TP+FN) X100 %
TP=50, FN=1, Sensitivity-50/51X100= 98.03 %
Sensitivity: 98.03 %

Specificity:

Specificity-(TN/TN+FP) X100 %
TN=68, FP=1, Specificity- 68/69X100= 98.55 %
Specificity: 98.55%

TN-True Negative
FP-False Positive
TP-True Positive
FN-False Negative

Conclusion:

The **Standard E TB-Feron ELISA** Test kit using Plasma was evaluated in our laboratory with 120 specimens and the performance characteristics from this evaluation were obtained as follows:

Sensitivity – 98.03 %
Specificity -98.55%

Gujarat Blood Bank, Pathology Laboratory & Diagnostic Centre thanks you for conducting performance evaluation of **Standard E TB-Feron ELISA**.

Yours sincerely,



Dr Niraj Kothari
Consultant Pathologist/Director
Gujarat Blood Bank, Pathology Laboratory & Diagnostic Centre