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Quality approved by SD BIOSENSOR | For *in vitro* diagnostic use only

STANDARD E

TB-Feron ELISA

REF ETBF11G

STANDARD™ E TB-Feron ELISA

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE PERFORMING THE TEST

STANDARD™

INTRODUCTION

Tuberculosis (TB) is an infectious disease, which is caused by infection with *M. tuberculosis complex organisms*. It spreads to new hosts through the air from patients who have respiratory tuberculosis disease. Individuals newly infected would get symptoms from tuberculosis within weeks to months.
STANDARD E TB-Feron ELISA is a blood assay that can help diagnose human tuberculosis and developed based on IGRA (Interferon Gamma Releasing Assay) method. An IGRA may be used in place of a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing M. tuberculosis infection. An IGRA is preferred for testing persons who have received BCG vaccine or are unlikely to return for TST reading.

INTENDED USE

STANDARD E TB-Feron ELISA is an *in vitro* diagnostic test using TB-specific recombinant protein Antigens (ESAT-6, CFP-10 and TB 7.7) to stimulate cells in heparinized whole blood. Detection of interferon-gamma (IFN-γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify *in vitro* responses to those Recombinant TB Antigens that are associated with *Mycobacterium tuberculosis* infection. The test is an sandwich test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

TEST PRINCIPLE

To measure the IFN-γ in samples, TB-Feron utilizes sandwich ELISA method using a specific to human IFN-γ antibody. It is designed especially for assessment of cell mediated immunity by measurement IFN-γ after cultivating heparin treated whole blood with stimulating antigen.
The IFN-γ is a cytokine which is used as specific marker in cell-mediated immune response. When exogenous or endogenous antigens are added to the blood, antigen specific effector/memory T lymphocyte is rapidly re-stimulated to produce interferon gamma (IFN-γ). The stimulation technology of effector T lymphocytes in whole blood with specific antigens and the accurate IFN-γ measurement in a plasma, which are the basis of the TB-Feron ELISA technology.
STANDARD E TB-Feron ELISA uses specialized blood collection tubes, which are antigen-sensitized. Incubation of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens.
The test is performed in two stages. First, whole blood is collected into each of the blood collection tubes, which include a Nil tube, TB Antigen tube, and Mitogen tube. The Nil tube adjusts for background IFN-gamma level of sample. The TB Antigen tube contains TB-specific recombinant protein antigens (ESAT-6, CFP-10, and TB7.7) to assess IFN-gamma responses in T cells from individuals infected with M.tuberculosis, but generally not from uninfected or BCG vaccinated people without disease or risk for latent TB infection. And the Mitogen tube can be used with the test as a positive control. This tube may also serve as a control for correct blood handling and incubation. These three tubes should be incubated at 37°C as soon as possible and within 16 hours of blood collection. Following 16 to 24 hours incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN-γ (IU/ml) measured by ELISA.
A test is considered positive for an IFN-γ response to the TB Antigen tube that is significantly above the Nil IFN-γ IU/ml value. A low response to Mitogen (<0.5 IU/ml) indicates an indeterminate result when a blood sample also has a negative response to the TB antigens. This pattern may occur with insufficient lymphocytes, reduced lymphocyte activity due to improper specimen handling, incorrect filling/mixing of the generate IFN-γ. The Nil sample adjusts for background, heterophile antibody effects, or non-specific IFN-γ in blood samples. The IFN-γ level of the Nil tubes is subtracted from the IFN-γ level for the TB Antigen tubes and Mitogen tubes (if used).

ACTIVE INGREDIENTS OF MATERIALS AND REAGENT PROVIDED

Component	Composition
Antibody coated microplate	96 wells coated with monoclonal anti-IFN-γ antibody
STANDARDs	Rec. Human Interferon-γ
	Preservative: Proclin 300
ELISA Diluent	Phosphate buffered saline
	Preservative: Proclin 300
Wash Buffer (20x concentrate)	PolySorbate 20
	physiological phosphate buffered saline solution conc.
	Preservative: Proclin 300
Enzyme conjugate	Mouse monoclonal anti-IFN-γ antibody : Peroxidase conjugate
	Preservative: Proclin 300
TMB substrate	Tetramethylbenzidine (TMB)
	Hydrogen peroxidase
Stop solution	1N sulfuric acid

MATERIALS PROVIDED

STANDARD E TB-Feron ELISA	2 plates/Kit	5 plates/Kit	10 plates/Kit
Antibody coated microplate	2 ea	5 ea	10 ea
STANDARDs	6 ea	15 ea	30 ea
ELISA Diluent	30mL/bottle X 1	60mL/bottle X 1	60mL/bottle X 2
Wash Buffer (20x concentrate)	100ml/bottle X 1	250ml/bottle X 1	250ml/bottle X 2
Enzyme conjugate	200µl/tube X 1	500µl/tube X 1	1mL/tube X 1
TMB substrate	30ml X 1	80ml X 1	80ml X 2
Stop solution	30ml X 1	80ml X 1	200ml X 1
Adhesive plate sealer	4 ea	10 ea	20 ea
Instructions for use	1 ea	1 ea	1 ea
STANDARD E TB-Feron Tubes (Sold separately)	**TB-Feron Tubes 100**	**TB-Feron Tubes 200**	**TB-Feron Tubes 300**
Mitogen tubes	100	N/A	100
TB Antigen tubes	N/A	100	100
Nil tubes	N/A	100	100

MATERIALS REQUIRED BUT NOT PROVIDED

1. Heparin blood collection tubes
2. Calibrated micropipets (10µl to 1000µl) with disposable tips
3. Incubator capable of maintaining temperature at 37±1°C/96.8~100.4°F
4. Distilled or deionized water
5. Absorbent paper or paper towel
6. Microplate washer (automated plate washer recommended)
7. ELISA plate reader with 450nm filter (A reference wavelength between 620nm and 650nm)
8. Timer
9. Waste discard container with suitable fresh disinfectant
10. Personal Protective Equipment(PPE)

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Icteric, lipaemic, heamolytic or contaminated sample must not be used.
3. Do not use expired date reagents.
4. Do not mix reagent of different lots.
5. Keep remaining wells after use in their sealed bag with desiccants.
6. Use thoroughly clean glassware. Free from contamination of metal ions or oxidation substances.
7. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. As TMB is susceptible to contamination from metal ions, do not allow the working TMB come into contact with metal surfaces. Avoid prolonged exposure to direct light.
10. Sodium azide inhibits conjugate activity. Clean pipette tips must be used for the conjugate addition so that sodium azide is not carried over from other reagents.
11. Use separate disposable materials for each sample in order to avoid cross-contamination which can cause erroneous results.

STORAGE AND STABILITY

[STNADARD E TB-Feron Tubes 100, 200, 300]
1. Store TB-Feron Tubes 100, 200, 300 at 2~25°C.
2. This test kit is stable through the expiration date printed in the package and in the label of each tube.

[STANDARD E TB-Feron ELISA]
1. This test kit is stable through the expiration date printed in the package and in the label of each material/reagents as unopened state.
2. Store at 2-8°C/36-46°F.

SPECIMEN COLLECTION AND STORAGE

[Plasma]
1. Collect the venous whole blood and incubate collected blood in the STANDARD E TB-Feron Tubes. Then, Centrifuge blood for 15 minutes at RCF 2200 to 2300g to get supernatant plasma specimen.
2. If plasma in an anti-coagulant tube is stored at 2-8°C, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be stored at below -20°C.

Caution
- Blood refrigeration and freezing are not allowed.
- Heparin tubes MUST BE ONLY USED when collecting whole blood. Other anticoagulant tubes (EDTA, sodium citrate, etc.) must not be used.

PREPARATION OF REAGENTS

1. Reconstituted STANDARDs: Add 0.5ml of the distilled or deionized water per one vial of STANDARDs before use. The fully dissolved STANDARD solution is 16 IU/ml. DO NOT re-use the STANDARDs.
2. Preparation of diluted wash buffer.
   The 20X concentrated wash buffer must be diluted 1 to 19 using distilled/deionized water before use. For example, mix 50ml of wash buffer(20x concentrate) with 950ml of distilled/deionized water.
3. Preparation of Working Detector solution
   1) Prepare Working Detector solution as necessary before use.
   2) Enzyme conjugate should be diluted 1:250 with ELISA Diluent to prepare Working Detector solution.
   [Example: If the required Working Detector solution is 10ml, add 40µl of Enzyme conjugate to the 10ml of ELISA Diluent and mix well.]

Reagent	Storage	Stability
Diluted Wash Buffer	Room Temp.(15~25°C)	1 week
Working Detector Solution	2~8°C	4 hours

TEST PROCEDURE

NOTE
- Ensure all reagents equilibrated room temperature (15-25°C/59-77°F) before testing.
- Do not open a container including STANDARDs tubes until it is equilibrated to room temperature(15~25°C/59~77°F).

Step 1 : Incubation of blood sample and collecting of plasma
1. STANDARD E TB-Feron ELISA should use the following tubes.
   1) Mitogen tubes (purple cap)
   2) TB Antigen tubes (red cap)
   3) Nil tubes (gray cap)
2. Take out the TB-Feron Tubes at room temperature (15-25°C/59-77°F) for 15~30 minutes before using, and inject the blood without cold air.
3. Collect blood from the patient and inject respectively 1ml into each TB-Feron Tube (Nil tube, TB Antigen tube, and Mitogen tube).
   1) Insert a needle into the tube for 2~3 seconds after the injection is completed in order to collect the correct volume.
   2) The black line on the side of the tube indicates 1.0ml.
   3) When using Butterfly needle, Purge tube must be used.
   4) If the tubes are not filled to the black line due to vacuum, open the cap and fill it up with additional blood up to the black line.
4. As soon as the tube is filled with blood, shake it 10 times gently or use a Roller-rocker to allow the entire surface of the tube to be immersed in blood so that it can mix well with the antigen on the tube wall.
   - DO NOT SHAKE THE TUBE EXCESSIVELY to prevent blood cells from breaking. Since it is an experiment that requires living lymphocytes, it should be mixed to the extent that cell damage does not occur. Also, Excessive shaking may cause gel disruption and could lead to accurate results.
5. Incubate the well-mixed blood tubes at 37°C for 16 to 24 hours. When incubating, the tubes should be inserted into a rack vertically.
   * When it is difficult to incubate right after blood collection, it should be stored at room temperature (15-25°C/59-77°F). The tubes must be incubated within 16 hours after collection.

NOTE
- If it is difficult to inject blood into each TB-Feron Tube, collect blood in the blood collection tube containing heparin. Collect a least 3.5ml of blood in a heparin tube and shake it gently up and down blood to dissolve the heparin. It prevents blood from clotting. After blood collection, it should be stored at room temperature (15-25°C/59-77°F). Within 16 hours after collection, dispense 1ml into each TB-Feron Tube with pipette, mix well and start incubating. When dispensing blood with pipette after opening the cap of the TB-Feron Tubes, sterile tips must be used so that blood could be dispensed in an aseptic.

6. After incubation of the tubes at 37°C, collect plasma by centrifuging tubes for 15 minutes at RCF 2200 to 2300g.
   - When collecting plasma, DO NOT pipetting or plasma mixing in the tube and spearing the gel with pipette tip.

Step 2 : Human IFN-γ ELISA
1. Preparation of STANDARD solution
   1) Label S1, S2, S3, S4 on 4 empty tubes.
   2) Add 300µl of ELISA Diluent to each tube.
   3) Add 100µl of Reconstituted STANDARDs to STANDARD tube1 (S1) and mix thoroughly. (S1 contains 4 IU/ml.)
   4) Transfer 100µl of the STANDARD tube1 (S1) solution to STANDARD tube 2 (S2). (S2 contains 1 IU/ml.)
   5) Transfer 100µl of the STANDARD tube2 (S2) solution to STANDARD tube 3 (S3). (S3 contains 0.25 IU/ml.)
   6) ELISA Diluent serves as a zero STANDARD (S4).
2. Working Detector solution & Sample incubation
   1) Dispense 50µL of prepared Working Detector solution into each of the wells.
   2) Dispense 50µL of The STANDARD 1 to 4 and samples into the plate wells respectively. (Refer to recommended plate layout below.)
   3) Lightly beat the frame and mix well. Cover the plate with the attached plate sealer and incubate at 37±1°C for 1 hour.

Table 2.1 Reference: Recommended plate layout (28 tests per plate)
When Nil, TB Antigen and Mitogen tubes are used
S1 (Standard 1), S2 (Standard 2), S3 (Standard 3), S4 (Standard 4)
1N (Sample. Nil plasma), 1T (Sample. TB Antigen plasma), 1M (Sample. Mitogen plasma)

	1	2	3	4	5	6	7	8	9	10	11	12
A	1N	1T	1M	S1	S1	S1	13N	13T	13M	21N	21T	21M
B	2N	2T	2M	S2	S2	S2	14N	14T	14M	22N	22T	22M
C	3N	3T	3M	S3	S3	S3	15N	15T	15M	23N	23T	23M
D	4N	4T	4M	S4	S4	S4	16N	16T	16M	24N	24T	24M
E	5N	5T	5M	9N	9T	9M	17N	17T	17M	25N	25T	25M
F	6N	6T	6M	10N	10T	10M	18N	18T	18M	26N	26T	26M
G	7N	7T	7M	11N	11T	11M	19N	19T	19M	27N	27T	27M
H	8N	8T	8M	12N	12T	12M	20N	20T	20M	28N	28T	28M

Table 2.2. Reference: Recommended plate layout (44 tests per plate)
When Only Nil and TB Antigen are used
S1 (Standard 1), S2 (Standard 2), S3 (Standard 3), S4 (Standard 4)
1N (Sample. Nil plasma), 1T (Sample. TB Antigen plasma)

	1	2	3	4	5	6	7	8	9	10	11	12
A	1N	5N	9N	13N	17N	S1	S1	25N	29N	33N	37N	41N
B	1T	5T	9T	13T	17T	S2	S2	25T	29T	33T	37T	41T
C	2N	6N	10N	14N	18N	S3	S3	26N	30N	34N	38N	42N
D	2T	6T	10T	14T	18T	S4	S4	26T	30T	34T	38T	42T
E	3N	7N	11N	15N	19N	21N	23N	27N	31N	35N	39N	43N
F	3T	7T	11T	15T	19T	21T	23T	27T	31T	35T	39T	43T
G	4N	8N	12N	16N	20N	22N	24N	28N	32N	36N	40N	44N
H	4T	8T	12T	16T	20T	22T	24T	28T	32T	36T	40T	44T

3. Washing Procedure
   1) Wash the wells five times with 350µl of diluted wash buffer and aspirate all liquid from the wells. Or, wash the wells using an automatic washer with 350µl of diluted wash buffer. An automated plate washer is recommended.
   2) Leave the wash buffer in each well for 4-5 seconds per washing cycle and then empty the wells.
   3) After washing (either by manual or automated washer), thoroughly dispose of all liquid from the microplate by tapping it on absorbent paper with the openings facing downwards to remove all residual wash buffer.

NOTE
- Residual liquid in the reagent wells after washing can interfere with the TMB substrate and lead to false low extinction values. Insufficient washing (e.g., less wash cycles, too small wash buffer volumes, or too short residence times) can lead to false high extinction values.

4. TMB Substrate incubation
   1) Add 100µl of TMB substrate into each of the wells.
   2) Incubate for 30 minutes at room temperature (15-25°C/59-77°F) in the dark.
5. Stopping the reaction
   1) Add 100µl of stop solution into each of the wells in the same order and at approximately same speed as the TMB substrate in step 6. Mix by gentle shaking.
6. Measurement
   1) Read the absorbance values of the wells at 450nm in a ELISA plate reader (with reference wavelength between 620nm and 650nm) right after from the end of assay, within 30 minutes

QUALITY CONTROL OF TEST

The accuracy of the test results depends on the generation of accurate standard curves. Therefore, results derived from the standards (S1, S2, S3, S4) must be examined before test sample results can be interpreted.

1. The mean O.D value for S1 must be more than 0.600.
2. The %CV of O.D value for S1 and S2 replicate OD values must be 15% or less.
3. The difference between each O.D values of S3 and S4 must be less than 0.040.
4. The mean O.D value for S4 must be 0.150 or less.
5. The correlation coefficient (r) of the standard curve obtained from each mean value should be 0.980 or more.

INTERPRETATION OF TEST RESULT

1. Check the results using the STANDARD E ANALYSIS SOFTWARE.
2. Results of the STANDARD E should be judged according to the following criteria.

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 STANDARD E TB-Feron ELISA results.

Table 1. When Nil, TB Antigen and Mitogen tubes are used

Nil [IU/mL]	TB Antigen - Nil [IU/mL]	Mitogen - Nil [IU/mL][1]	STANDARD E Result	Report/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[2]	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	

[1] 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.

[2] When M.tuberculosis infection is not suspected, initial positive results can be confirmed by re-testing the original plasma samples. If the repeated test results of the replicates are positive, they should be considerd as positive.

Table 2. When Only Nil and TB Antigen are used

Nil [IU/mL]	TB Antigen - Nil [IU/mL]	STANDARD E Result	Report/Interpretation
≤ 8.0	< 0.35	Negative	M. tuberculosis infection NOT likely
	≥ 0.35 and < 25% of Nil value	Negative	
	≥ 0.35 and ≥ 25% of Nil value	Positive	M. tuberculosis infection likely
> 8.0	Any	Indeterminate	Results are indeterminate for TB Antigen responsiveness

3. If not using the STANDARD E ANALYSIS SOFTWARE, creation of the STANDARD curve
   1) Measure the mean OD values of the STANDARDs.
   2) Construct a log(e)-log(e) STANDARD curve by the log(e) plot of the mean OD (y-axis) against the log(e) value (x-axis) of the IFN-γ concentration of the STANDARDs, removing the zero STANDARD from these calculations. Calculate the most suitable STANDARD curve by regression analysis.
   3) Use the STANDARD curve and OD value of the sample to measure the IFN-γ concentration (IU/ml) for each of the test plasma samples.
   4) These calculations can be performed using software available with microplate readers, standard spreadsheet and statistical software (ex: Microsoft Excel). It is recommended that these packages be used to calculate the regression analysis, the coefficient of variation (%CV) for the standards and the correlation coefficient (r) of the STANDARD curve.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results sections for this test kit must be followed closely when testing.
2. Testing could be performed on patients with clinical symptoms on when exposure is suspected.
3. Unreliable or indeterminate results may occur due to:
   1) Excessive levels of circulating IFN-γ or presence of heterophile antibodies.
   2) The TB-Feron tubes must be incubated within 16 hours after blood collecting.
4. Test results must be considered with other clinical data available to the physician.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended

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SYMBOLS ON THE PRODUCT LABELS

The following symbols may have been used in the labeling of this product.

MW Ab	Microplate coated with antibodies
STANDARDS	STANDARDs
ELISA DIL	ELISA Diluent
WASH BUF 20x	Wash buffer 20X
CONJ	Enzyme conjugate
SUBS TMB	Substrate hydrogen peroxidase and Tetramethylbenzidine (TMB)
SOLN STOP	Stop solution
	Xi = Irritant

Product Disclaimer
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the manufacturer and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The manufacturers and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

ABBREVIATED TEST PROCEDURE

To measure the IFN-γ in samples, TB-Feron utilizes sandwich ELISA method using a specific to human IFN-γ antibody. It is designed especially for assessment of cell mediated immunity by measurement IFN-γ after cultivating heparin treated whole blood with stimulating antigen.

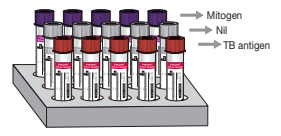
* Blood Stimulating Tube System
STANDARD E TB-Feron ELISA uses lithium heparin tubes as a blood anticoagulant or SD BIOSENSOR TB-Feron 3 kinds of Tubes (Mitogen, TB antigen, Nil) for accurate results. TB-Feron ELISA requires 3 ml whole blood - each 1 ml blood in each of the 3 tubes.

Nil tube (Gray cap)	TB antigen tube (Red cap)	Mitogen tube (Purple cap)
		
This is used to adjust for background noise INF-γ as negative control.	This is used to assess INF-γ response to specific TB antigens.	This can be useful as positive control to check patient's immune status.

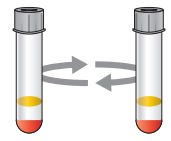
Blood incubation and Harvesting

1. Blood collection in 3 tubes. (Nil, TB Antigen, Mitogen).

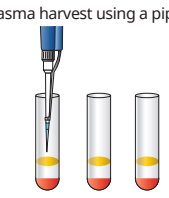
2. Incubate for 16-24hrs in 37°C incubator.



3. Centrifuge tubes about 15 min.

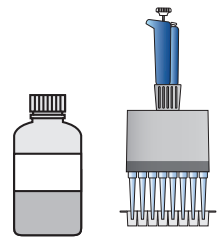


4. Plasma harvest using a pipet.

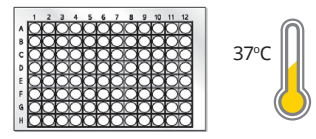


Human IFN-γ ELISA

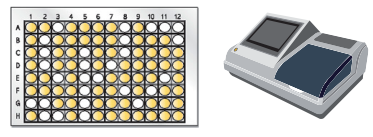
1. Sample preparation (Standard, Plasma of 3 tubes).



2. IFN-γ ELISA Testing.



3. Mearsure the optical density (OD).



4. Calculation and Test Interpretation.

CE

EC REP **Authorized Representative** MT Promedt Consulting GmbH
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REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | NOTE | Do not re-use | Xi = Irritant | To indicate the temperature limitations in which the transport package has to be kept and handled. | Use by | LOT Batch code | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices | Manufacturer | Date of manufacture | EC REP Authorized Representative