

## STANDARD E

## TB-Feron Tubes

TB-Feron Tubes

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

## NOTE

- Please read this information before using TB-Feron Tubes.
- For more information on performing, carefully read the package insert for STANDARD E TB-Feron ELISA.

## INTRODUCTION

## [INTENDED USE]

TB-Feron Tubes is intended to collect blood specimen for use with STANDARD E TB-Feron ELISA.

## [PRODUCT DESCRIPTION AND TEST PRINCIPLE]

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- $\gamma$  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 tubes, TB Antigen tubes, and a Mitogen tubes. The Mitogen tubes can be used with the test as a positive control. This tubes may also serve as a control for correct blood handling and incubation. The tubes should be incubated at 37°C as soon as possible after injection, and within 16 hours of collection. Following 16 to 24 hours incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN- $\gamma$  (IU/ml) measured by ELISA.

Nil Antigen tube (Gray cap)

TB antigen tube (Red cap)

Mitogen tube (Purple cap)



This is used to adjust for background noise  
INF- $\gamma$  as negative control.



This is used to assess INF- $\gamma$  response to  
specific TB antigens.



This can be useful as positive control to  
check patient's immune status.

## [MATERIALS PROVIDED]

Cat. No.	Product Name	Contents
07TBFA30	TB-Feron Tubes 300	100 x TB-Feron Nil Antigen tubes 100 x TB-Feron TB Antigen tubes 100 x TB-Feron Mitogen tubes
07TBFA20	TB-Feron Tubes 200	100 x TB-Feron Nil Antigen tubes 100 x TB-Feron TB Antigen tubes
07TBFA10	TB-Feron Tubes 100	100 x TB-Feron Mitogen tubes

## PRECAUTION

- TB-Feron Tubes is for use with the STANDARD E TB-Feron ELISA.
- TB-Feron Tubes should be stored at 2°C to 8°C (36°F to 46°F).
- TB-Feron Tubes is stable through the expiration date printed in the package and in the label of each tube.
- Do not use beyond the expiration date.
- It is for single use only. Do not reuse.
- Discard the used tubes according to your local guideline.

## TEST PROCEDURE

- STANDARD E TB-Feron ELISA should use the following tubes.
  - Mitogen tubes (purple cap)
  - TB Antigen tubes (red cap)
  - Nil Antigen tubes (gray cap)
- 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.
- Collect blood from the patient and inject respectively 1ml into each TB-Feron Tube (Nil Antigen tube, TB Antigen tube, and Mitogen tube).
  - Insert a needle into the tube for 2~3 seconds after the injection is completed in order to collect the correct volume.
  - The black line on the side of the tube indicates 1.0ml.
  - When using Butterfly needle, Purge tube must be used.
  - 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.
- 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.

- 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.

- 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.

## SYMBOL

	Catalogue Number		Consult Instructions for Use
	Batch code		In vitro Diagnostics
	Manufacturer		Authorized Representative in the European Community
	Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Date of manufacture
	Contains Sufficient for <n> Tests		Do not reuse
	Use by		To indicate the temperature limitations in which the transport package has to be kept and handled



## Manufactured by SD Biosensor, Inc.

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