LIOFeron® TB/LTBI

HUMAN BLOOD STIMULATION TUBES

Instructions for Use

22 Tests **REF LIO-Feron 01_22**

Interferon Gamma Release Assay for the detection of an infection with *Mycobacterium tuberculosis*.

For use with LIOFeron® TB/LTBI HUMAN IFN-γ ELISA.

Abbreviated instructions, for a detailed description of LIOFeron® TB/LTBI please refer to the instructions for use of the LIOFeron® TB/LTBI IFN-γ ELISA (available at www.lionex.de).

IVD In vitro diagnostic medical device

CE

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Document Revision History

Date	Revision	Changes
2025-09-02	EN_A	General revision for adaptation to the regulation (EU) 2017/746 on in vitro diagnostic medical devices

Intended Use

LIOFeron® TB/LTBI is an in vitro diagnostic medical device for the quantitative determination of Interferon Gamma (IFN-γ) in human blood after stimulation with specific antigens of *Mycobacterium tuberculosis*.

LIOFeron® TB/LTBI is a 2-component kit, consisting of the components HUMAN BLOOD STIMULATION TUBES and HUMAN IFN-γ ELISA. Both components are needed for the test procedure. The test is for professional use only. The test is NOT for self-testing.

Application field and und test principle

For a description of the application field and the test principle including information on the pathogen refer to the instructions for use of the LIOFeron® TB/LTBI HUMAN IFN-γ ELISA.

Materials provided with the kit

HUMAN BLOOD STIMULATION TUBES:

Component	Symbol	Cap colour	Contained amount
	Σ		22 tests
Negative control, contains lithium heparin	NC		22 tubes
TB Antigen A, contains lithium heparin and antigens CFP10, ESAT6 and TB 7.7, which contain CD4 epitopes and cover all peptides pertaining to these antigens	TB A		22 tubes
TB Antigen B, contains lithium heparin and LIONEX-Antigen with CD8+ epitopes which covers all peptides pertaining to these antigens	TB B		22 tubes
Positive control, contains lithium heparin and mitogen	PC		22 tubes
Instructions for Use			1x

All tubes are single use only!

Materials required but not provided

- LIOFeron® TB/LTBI HUMAN IFN-γ ELISA (REF LIO-Feron 02_22 / LIO-Feron 02_44)
- Disposable gloves; container for waste and potentially contaminated material
- Blood collection equipment and blood collection tubes containing lithium heparin
- Container for plasma collection and dilution (optional), e.g. sterile 1,5 mL vials
- Incubator 37 °C (± 0,5 °C), CO2 not necessary
- Centrifuge, suitable for blood collection tubes (RCF range from 2000 to 3000)

Stability and storage conditions

Store at 2 – 30 °C. Do not expose the test components to temperatures above 30 °C. Unopened kit components are best before the expiry date printed on the label. Do not use expired or incorrectly stored components.

Warnings and precautions

Only for in vitro diagnostic use! Not for self-testing!

Follow the instructions for the test procedure carefully! In accordance with Good Laboratory Practice (GLP) all laboratory devices used should be maintained regularly and calibrated for accuracy and precision. Do not ingest or swallow! Do not eat, drink or smoke in the laboratory! Always wear protective clothing while working (disposable gloves, safety goggles and lab coat)! Only use components within their expiry period (printed on the labels). Bring all kit components to room temperature (preferably 15 – 30 °C). The test is sensitive towards temperatures above 30 °C. Only use fresh blood samples containing lithium heparin as anticoagulant. Other body fluids than blood with lithium heparin are not validated and can yield incorrect results! Store blood samples at room temperature (preferably 15 – 30 °C)! Do not store blood samples below 15 °C! Only use the blood samples within 16 hours of the venipuncture. Do not use reagents from different kits or batches and do not mix reagents of different kits or batches. To avoid contamination of the samples, work under aseptic conditions. Avoid usage of turbid samples, as those samples might be contaminated with bacteria. Only use the clear supernatant for IFN-γ determination. Avoid contamination with red blood cells while collecting the supernatant. Separate the red blood cells from the plasma by centrifugation if necessary. Avoid touching the inside of the screw caps to reduce risk of contamination. Single use only. Do not use if tubes are damaged or opened.

For more information, please contact sales@lionex.de per e-mail.

MSDS are available for download at www.lionex.de.

ATTENTION:

Treat human blood and plasma as potentially infectious!

Dispose of leftover human blood and plasma samples as well as materials that have come into contact with them in accordance with local regulations.

Sample collection

The LIOFeron® TB/LTBI works best with fresh blood samples.
A minimum of 4.5 mL human blood is required. Collect the sample under standard laboratory conditions (aseptic, avoid haemolysis) using lithium heparin blood collection tubes. Venipuncture should only be performed by appropriately qualified personnel. Comply with legal regulations and requirements for blood collection.

If the blood sample cannot be applied to the HUMAN BLOOD STIMULATION TUBES immediately after blood collection, the whole blood can be stored up to 16 hours at 15 – 30 °C.

Use and storage of stimulated plasma

It is recommended to pipette the plasma directly after centrifugation of the tubes onto the ELISA plate and perform the HUMAN IFN-γ ELISA.
If the HUMAN IFN-γ ELISA cannot be performed immediately after stimulation, the tubes can be stored up to 4 days at 2 – 8 °C.
For longer storage, separate the plasma from the red blood cells and store at 2 – 8 °C (up to 28 days). However, this may lead to a decreased IFN-γ concentration. Separated plasma samples can be stored for a longer period at below -20 °C. Before use, frozen samples must be thawed and thoroughly mixed. Avoid repeated freezing and thawing of samples!

Test procedure HUMAN BLOOD STIMULATION TUBES

The test procedure requires approx. 10 minutes for each sample.
Incubation time: 16 - 24 hours.

1. Take the required amount of HUMAN BLOOD STIMULATION TUBES NC, TB A, TB B and PC from the kit. Place the tubes upright in a suitable rack. Label the HUMAN BLOOD STIMULATION TUBES appropriately, e.g. with a sample number or ID. Remove the cap by pulling up (no screwing) and place the cap inside up on a clean, flat surface.
2. Mix the blood sample in the lithium heparin blood collection tube by carefully inverting the tube (approx. 10 times). Pipette 1 mL of the blood sample into each HUMAN BLOOD STIMULATION TUBE (NC, TB A, TB B und PC) and close them. Attention! There are 2 closure points. Push the cap completely down!
3. Mix each HUMAN BLOOD STIMULATION TUBE filled with 1 mL blood by gently inverting 10 times. Avoid vigorous shaking to prevent haemolysis of the blood cells!
4. Place the rack with the HUMAN BLOOD STIMULATION TUBES (filled with 1 mL lithium heparin blood each) upright in an incubator at 37 °C (± 0.5 °C). Incubate the tubes for at least 16 hours. The maximum incubation period is 24 hours.
5. Finally, remove the rack with the HUMAN BLOOD STIMULATION TUBES from the 37 °C incubator (without shaking!). It is possible to harvest the plasma without centrifugation but pay attention not to contaminate the plasma sample with red blood cells. The red blood cells are separated from the plasma by the gel.

   Important note: If the plasma is contaminated with red blood cells, centrifuge the tube for 15 minutes at 2000 to 3000 RCF (g) before harvesting the plasma. After centrifuging, avoid pipetting up and down or mixing the plasmas by any means. Always ensure that the plasma does not mix with the red blood cells on the surface of the gel.
6. The plasma samples should only be harvested using a pipette. The plasma can be transferred directly from the HUMAN BLOOD STIMULATIONS TUBES to the HUMAN IFN-γ ELISA plate. Pipette 50 µL of the clear supernatant from the HUMAN BLOOD STIMULATION TUBES into the wells of the microtiter plate and continue with step 5 of the "*HUMAN IFN-γ ELISA Test Procedure*" (see instructions for use of the LIOFeron® TB/LTBI HUMAN IFN-γ ELISA).

   Note: It is possible, to use an automated ELISA-Workstation.

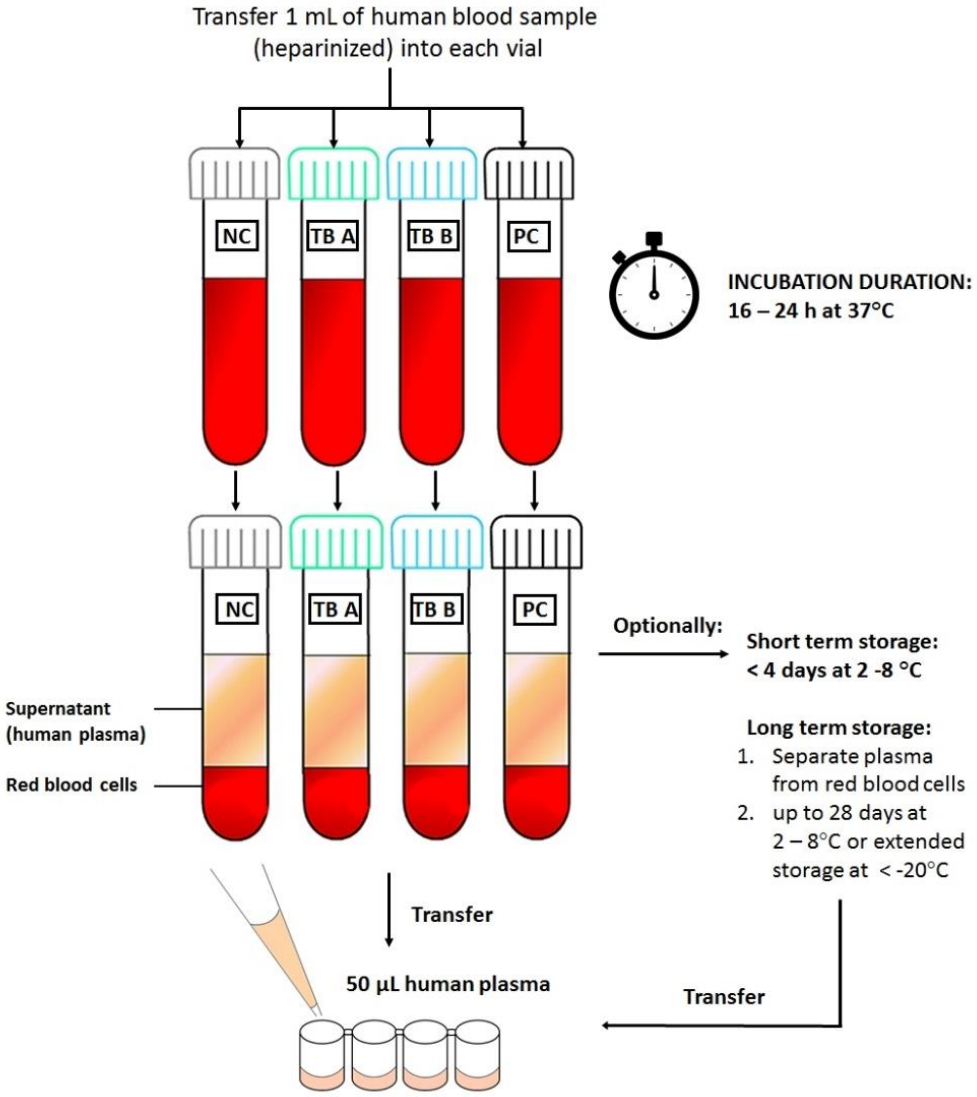

Figure 1: Quick guide for using the HUMAN BLOOD STIMULATION TUBES

Limitations

Follow the instructions of the test procedure carefully! Only use fresh blood samples with lithium heparin as anticoagulant (e. g. citrated blood inhibits test performance). The test was developed for detecting IFN-γ in human plasma. The test is not validated for detecting IFN-γ in other body fluids than human plasma and may produce incorrect results. Do not use haemolysed or lipemic samples. HUMAN BLOOD STIMULATION TUBES are meant to be used in combination with the HUMAN IFN-γ ELISA and cannot give a test result on their own. For further limitations of the LIOFeron® TB/LTBI IGRA refer the instructions for use of the HUMAN IFN-γ ELISA (available at www.lionex.de)

Performance characteristics

For detailed information on the performance characteristics of the LIOFeron® TB/LTBI refer to the instructions for use of the HUMAN IFN-γ ELISA.

Symbols

CE	Compliant with IVD Directive 98/79/EG		Manufacturer		Expiry date
REF	Catalogue number	Σ	For <x> number of tests		Consult instructions for use
LOT	Batch number		Single use only		Do not use if outer packaging is damaged
PC	Positive control	IVD	Only for in vitro diagnostic use	2°C 30°C	Store at 2 – 30 °C
TB B	TB Antigen B	NC	Negative control	TB A	TB Antigen A

Trademarks:
LIONEX®, LIOFeron®, Microsoft®, Excel® (Microsoft), QuantiFERON® (Qiagen)

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