

## Factsheet: LIOFeron TB/LTBI IGRA Test

### 1- What kind of test is it?

LIOFeron<sup>®</sup>TB/LTBI is an immunological test diagnosing infection with latent tuberculosis, more scientifically called Latent tuberculosis Infection (LTBI).

### 2- Can LIOFeron<sup>®</sup>TB/LTBI also diagnose active TB?

Yes, but this test, similar to all other IGRA tests on the market, cannot differentiate between active TB and LTBI.

### 3- What is the difference between the well-known QuantiFERON test of Qiagen GmbH and LIOFeron<sup>®</sup>TB/LTBI of Lionex GmbH?

Both tests are IGRA based (Interferon-Gamma Response Assay), which detect IFN-Gamma in whole blood after stimulation with TB specific antigens, absent in the TB vaccine strain BCG.

QuantiFERON tests contain selected peptides of TB specific antigens. In contrast, LIOFeron<sup>®</sup>TB/LTBI contains full-length antigens as highly purified recombinant proteins.

The idea behind using whole antigens is that these antigens mimic the natural interaction between the pathogens and the human immune system, and hence LIOFeron<sup>®</sup>TB/LTBI may prove to be more sensitive and accurate than the peptide based IGRA tests. This has to be proven by further clinical studies.

### 4- Both QuantiFERON TB Gold Plus and LIOFeron<sup>®</sup>TB/LTBI contain 4 tubes. Are the tubes containing TB-Antigens identical?

No, LIOFeron<sup>®</sup>TB/LTBI tube "Antigen A" contains fusion protein of three antigens, and the tube "Antigen B" contains a Lionex proprietary antigen containing CD8 epitopes.

### 5- Have clinical studies been done with LIOFeron<sup>®</sup>TB/LTBI?

Yes, it has been evaluated in three independent TB hospitals. Many more studies are in progress.

### 6- How high is the concordance between QuantiFERON TB-Gold Plus and LIOFeron<sup>®</sup>TB/LTBI?

Taking TB and LTBI patients together, concordance is more than 95% - which is a very significant value.

### 7- What if the QuantiFERON TB Gold Plus and LIOFeron<sup>®</sup>TB/LTBI results are different?

In such cases, one has to consider results of further tests, such as microscopy, culture, PCR tests, skin Test and clinical symptoms.

### 8- Which antigens Tube is more important for LTBI diagnosis by LIOFeron<sup>®</sup>TB/LTBI?

The tube containing Antigen A proteins.

**9- Can we exchange the tubes and ELISA kits of QuantiFERON TB gold Plus and LIOFeron TB/LTBI?**

No, if you do that – it is your own responsibility.

**10- Can we use Instruments, ELISA readers of different manufacturers?**

Yes, the current version of LIOFeron<sup>®</sup>TB/LTBI can be used on any open system.

**11- Is there any software to automatically analyse the results of LIOFeron<sup>®</sup>TB/LTBI?**

Yes, we have developed a STAND-ALONE SOFTWARE called LIOFERON, which can automatically analyse the results.

**12- Do we need additional reagents while using the LIOFeron TB/LTBI kit?**

No, all reagents and components are provided with the LIOFeron<sup>®</sup>TB/LTBI kit (Blood stimulation tubes and ELISA kit).

**13- Can we collect blood directly in the LIOFeron<sup>®</sup>TB/LTBI kit tubes?**

No, blood must be collected first in proper Li-Heparin tubes and then dispensed into the tubes provided in the LIOFeron<sup>®</sup>TB/LTBI kit according to the instructions for use provided in the kit.

**14- Are these screw-cap blood stimulation tubes?**

No, you have to pull the caps to open and press tightly to close the caps.

**15- Do we need a CO<sub>2</sub> incubator?**

Not necessary, but you can use one, if available.

**16- What is the reason for using IGRA tests in endemic countries with a very high proportion of LTBI?**

Such tests are helpful if clinical symptoms indicate active TB, since a positive result of an IGRA test shall confirm infection with MTB to a high degree.

**17- Are such IGRA tests useful for population screening with TB-prevalence in mind?**

No, such IGRA tests are not specific for active TB and hence, cannot be used for determining prevalence of active TB in a population.

**18- Is the sensitivity of QuantiFeron TB Gold-Plus and LIOFeron<sup>®</sup>TB/LTBI the same in active TB and Latent TB?**

No, all published results show that the sensitivity of QuantiFERON IGRA tests is considerably less in active TB patients. Same is expected for LIOFeron<sup>®</sup>TB/LTBI. But the results of the 4<sup>th</sup> tube containing Antigen B with CD8 epitope in LIOFeron<sup>®</sup>TB/LTBI is yet to be evaluated. It is quite possible that the LIOFeron<sup>®</sup>TB/LTBI proves to be much more sensitive in active TB patients than the QuantiFeron TB Gold-Plus. But this is yet to be proven by clinical studies.

**19- How should we compare QuantiFeron TB Gold/-Plus with LIOFeron<sup>®</sup>TB/LTBI?**

The best comparison is to use the same blood sample for **QuantiFeron TB Gold-Plus** and **LIOFeron<sup>®</sup>TB/LTBI** tubes containing antigens. Next day, take the plasma from all tubes and test these in the corresponding ELISA kits. Finally, the results should be compared and interpreted as mentioned in the instruction manuals of the corresponding kit.

**20- Is it useful to test the LIODetect<sup>®</sup>TB-ST rapid test of LIONEX with the serum or blood of the same subjects for which QuantiFeron TB Gold-Plus and LIOFeron<sup>®</sup>TB/LTBI are used?**

Yes, because if both IGRA and **LIODetect<sup>®</sup>TB-ST** tests yield positive results, the diagnose of active-TB is quite reliable. When used alone, the tests cannot diagnose active-TB with high sensitivity and specificity.