

Frequently Asked Questions

QuantiFERON-TB[®] Gold

TBoss: TB Operation Support Solution



QuantiFERON®-TB Gold In-Tube (QFT®) is an innovative whole-blood test that measures the cell-mediated immune response of tuberculosis (TB) infected individuals.

Approved by the FDA—and CE marked—QFT, like the TST, can be used as an aid in the diagnosis of latent tuberculosis infection and TB disease.

This document has been compiled as a result of common questions posed in contact investigations.

Questions and Answers

1. What is TBoss and how can it be utilized in a Public Health setting?

TBoss is a service specifically for Health Departments. It is one of the ways in which Cellestis is giving back to the community, by making QuantiFERON-TB Gold (QFT) available at every contact investigation. Cellestis provides a Clinical Coordinator to assist the Health Department with needs assessment as it relates to the contact investigation, helps to identify gaps, and provides certain resources. Among those resources are QFT tubes, and the option of using a preferred laboratory to run the QFT tests.

TBoss is structured and geared towards assisting Public Health in their contact investigations. It is not at this point intended for the private sector.

2. Some public health clinics do not have trained phlebotomists; how can those facilities find and secure the services of phlebotomists that are trained to collect blood for QFT testing?

One such provider is Phlebotomy Services International (PSI). Cellestis has provided extensive training to PSI staff to ensure that their phlebotomists can effectively collect and manage QFT specimens.

3. How will Departments of Health (DOH) pay for the cost of phlebotomy services used during a contact investigation?

For a limited time, Cellestis is providing a grant to DOH to cover the cost of phlebotomy services.

4. Would Cellestis give the grant to a DOH that did not use PSI, but instead use in-house phlebotomists, or phlebotomists from another agency?

Yes, Cellestis would still give the grant to the DOH. In fact, Cellestis recently participated in one such contact investigation in which TBoss services were requested. The phlebotomists were from a local lab with which the DOH already had an established relationship. In these situations, Cellestis would provide phlebotomy training specific to QFT requirements to assure proper procedures.

5. Sometimes checks are sent to DOHs for specific purposes, but they end up in Finance departments and are directed to be used for other purposes, based on the needs of the DOH. Would Cellestis be willing to state in a cover letter, or otherwise, that the grant/check they are providing is specifically for the particular contact investigation they are supporting?

Cellestis will be guided by the TB Program Manager of the DOH in how the grant is to be directed, so that it goes towards covering the cost of phlebotomy services incurred during the supported contact investigation.

6. How many phlebotomists per contact investigation will TBoss provide?

PSI will provide up to three phlebotomists for an eight hour day of screening.

7. If a health department chooses to use in-house phlebotomists who do not have experience in drawing blood for QFT would Cellestis be willing to provide training to these phlebotomists?

The Cellestis Clinical Program Coordinator will provide training in blood collection and handling. This training can be prior to the contact investigation, or, it can be just-in-time training at the site of the contact investigation.

8. What are the costs for the TBoss services?

Cellestis is offering TBoss as a service to Public Health, in an effort to make their Contact Investigations more manageable and more efficient. The only costs Public Health will need to bear are those associated with Laboratory running the test.

9. Can you provide the names and locations of the Preferred Laboratories?

This is a dynamic list/group. Several major labs are already participating, and others are working out the details of participating. The Clinical Program Coordinator will be happy to connect you with a preferred lab in your area. For more information on where to find QFT in your area, please visit the Find QFT in My Area page on www.quantiferon.com.

10. If our public health lab already runs QFT do we need to send our tests out to a preferred lab?

If you have the equipment in place to run the test, your lab staff is trained to run the test and it is cost-effective for you to run it in your lab rather than send it to a preferred lab, then you can do so.

11. If we were interested in using the services of TBoss, but we did not have a lab within close enough proximity, what would be our option?

One aspect of the TBoss service is to provide Departments of Health with the option to use a "Preferred Laboratory". These laboratories are located in several different regions. Cellestis' Clinical Program Coordinator will work with Public Health and the Preferred Lab to coordinate handling (to incubate or not to incubate) and pick-up/shipment of samples. The lab will perform testing on samples and report results directly to Public Health.

12. How are you able to draw blood for contact investigation in middle schools? Those children are minors.

TB is a matter of public concern, and when a school is under investigation, the administrators, teachers and parents are informed and educated about the details and the process of the contact investigation. As part of this process, the school administrators and teachers work with parents to secure signed permission slips, to allow for the blood draw. In some cases, parents choose to be present at blood draw. This helps to calm and reassure the younger children. Cellestis can provide references of Public Health professionals who have used QFT in school-associated TB infection testing.

13. For those school administrators and parents who are more familiar with TST, how do you get their buy-in, when it comes to using QFT?

By engaging the school administrators and parents in discussions around QFT, and emphasizing QFT's advantages over TST, and sending awareness letters home to parents, they become knowledgeable enough about the benefits of QFT to accept its use over TST. Case studies of schools using QFT for TB infection screening may be available.

14. In a Contact Investigation, if someone reports a history of a positive skin test, would you now screen them using QFT? If so why?

Having a history of a positive TST does not necessarily mean the person has/had a tuberculosis infection. If the client is an immigrant or refugee who had been BCG vaccinated, or whose BCG vaccination status is unknown, there is compelling reason to screen using QFT. A previous positive result may have been influenced by prior BCG vaccination. The client could also have previously been exposed to Non-Tuberculosis Mycobacterium (NTM); QFT's high specificity (>99%¹) compared to that of TST (as low as 59% in BCG vaccinated²) allows for better discrimination between true tuberculosis infection and cross-reactivity that often results in TST false positive results. All of this makes QFT the test of choice.

15. How can we get access to TBoss webinars that Cellestis has presented?

These can be accessed from: www.cellestis.com/TBoss.

16. What is the start date and end date for the TBoss service?

The services provided by TBoss began on July 1, 2011 and will continue in its present form until at least June 30, 2012. However, for those clients who continue to need the services beyond this date, an agreement will be worked out between those clients and Cellestis as to the terms and conditions of the services.

17. Is there a limit on the number of collection tubes that Cellestis will give? What if a school of 500 students needs to have all the students screened?

Cellestis will provide the blood collection tubes needed in the contact investigations. If there are several large investigations by the same organization, such as is alluded to in the question, they will be handled on a case-by-case basis.

18. Is there a limit on the number of contact investigation that Cellestis will support?

No, there is no limit on the number of contact investigations that Cellestis will support. This includes second round testing when these are needed.

19. How soon should a Department of Health contact Cellestis to request TBoss support? What happens when Cellestis is called?

As soon as the health department realizes that it has a pending contact investigation, contact the TBoss coordinator (TBoss@cellestis.com, 1-855-QFT-TBoss). This way, early needs assessment can be done, gaps can be determined, and resources identified to fill the gaps. In addition, Cellestis recommends that DOH, which expect to handle contact investigations, proactively contact the TBoss Coordinator to make introductions and preliminary planning.

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Please contact Cellestis for more information on the TBoss service

TBoss@cellestis.com • www.cellestis.com/TBoss • 1-855-QFT-TBoss

References

1. QuantiFERON®-TB Gold US Package Insert, July 2011, available from www.cellestis.com.
2. Pai et al. Ann Intern Med. 2008;149: 177-84.

QFT is approved by the US FDA

QFT is approved by FDA as an *in vitro* diagnostic aid for detection of *Mycobacterium tuberculosis* infection. It uses a peptide cocktail simulating ESAT-6, CFP-10 and TB7.7(p4) proteins to stimulate cells in heparinized whole blood. Detection of IFN- γ by ELISA is used to identify *in vitro* responses to these peptide antigens that are associated with *M. tuberculosis* infection. FDA approval notes that QFT is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations. QFT Package Inserts, available in up to 25 different languages, can be found at www.cellestis.com.

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