

**Question:** *Where do I find the Lot number on the tubes?*

**Answer:** The lot number is located on the bottom of the individual TB-Antigen tube or on the polybag enclosing the 50 tube pack.

**Question:** *I have tubes from Lot # (different lot #) what do I need to do?*

**Answer:** Nothing. Only tubes in Lots A111103N and A111103M (high altitude) are affected by the voluntary market withdrawal

**Question:** *What other Lots have been checked?*

**Answer:** Several other available lots have been tested. Within the investigation into the batches of tubes in question, several other available lots of tubes were tested and results indicate that no other currently available lot is likely to be affected

**Question:** *How can you be sure that other lots of tubes are free from contamination?*

**Answer:** We increased in-process testing: More samples are being tested and we increased the amount of sampling across the manufacturing process. The result of these changes is that Cellestis is better able to initiate real-time investigational work to quickly respond to a customer inquiry.

- Improvements to the release test for tubes means that future batches are more extensively tested prior to release
- Some of these process improvements were introduced in early 2012, so recent lots of tubes will have been tested by these methods
  - Lots A111103N and A111103M were manufactured in 2011 prior to the improvements
- Even more stringent changes have taken place in response to this product withdrawal and the benefits of this testing will be seen in all future batches

**Question:** *How do I get a replacement for the affected tubes?*

**Answer:** Your local representative will assist with arranging for replacement tubes.

**Question:** *What tubes will be replaced?*

**Answer:** For tubes that have not been distributed or used by customers, Cellestis will issue replacement tubes. If customers require testing supplies for retesting, Cellestis will supply both replacement tubes and ELISA kits. If tubes are pre-packaged “dispenser kits” Cellestis will supply replacement dispenser kits (min qty 25). If tubes are in bulk, Cellestis will supply only replacement TB-Antigen tubes (min qty 50).

Cellestis will replace the necessary number of tubes required for retesting. Cellestis will NOT replace all used tubes. Cellestis will assume that the customers are honest in their request for replacement materials and will honor the requested replacement material quantities.

**Question:** *How do I dispose of the affected tubes?*

**Answer:** Tubes should be disposed per institutional safety protocols. Customers who elect to destroy the affected tube lots are required to complete a Certificate of Disposal, which will be provided by Cellestis Customer Service or your Local Account Manager.

**Question:** *I understand that you will replace the tubes and the ELISA kits required to perform the retesting of patients, what about the labor costs we have incurred?*

**Answer:** Cellestis will not be providing financial compensation outside of any contractual obligations.

**Question:** *How can we be sure our positives are truly positive?*

**Answer:** There is no gold standard for latent TB infection (LTBI) testing. QFT should only be used as an aid to identifying TB infection and a positive result should not be the sole basis of diagnosis of either latent or active TB.

Patient retesting, using a different Lot of QFT TB-Antigen tubes, should be considered if a false positive result is suspected.

If and when a retest is required, Cellestis will provide replacement materials.

**Question:** *We want to retest all of our patients who tested positive using the affected lots. Will you provide the necessary kits to retest all positive results?*

**Answer:** Yes, you (the customer) can choose to retest all patients you deem appropriate. Cellestis will replace the tubes and ELISA kits necessary to retest as many patients as the customer feels is necessary.

**Question:** *How can we be sure our patients who tested negative are truly negative?*

**Answer:** There is no gold standard for latent TB infection (LTBI) testing. QFT should only be used as an aid to identifying TB infection. Regarding the market withdrawal of these lots, negative results are not affected by the suspected contamination. The tubes in the affected lots behave in the same manner as all other batches of tubes tested.

The issue is localized to the TB-antigen tubes and not the nil tubes (i.e., no elevated levels of interferon gamma have been observed in the nil tubes tested). Hence, an individual with interferon gamma levels below the cut-off are clearly negative.

Cellestis's stance is that when in doubt, patients should be retested with a different lot of tubes.

**Question:** *Is this contamination issue linked to a higher number of indeterminate results?*

**Answer:** No. The control tubes (Nil and Mitogen) are not implicated in this situation.

**Question:** *What do I tell the blood collection center?*

**Answer:** If your blood collection center receives their supply of tubes from your laboratory please notify them that they should discontinue use of any tubes from Lots A1111103N or A1111103M (high altitude).

**Question:** As a lab, how should we inform our clinical customers?

**Answer:** Our manufacturing partner for the QuantiFERON-TB Gold test has found a contaminant in a specific lot of tubes we have had in a field. The laboratory will have to decide how to handle the situation. Should the laboratory choose to make a recommendation to the physicians with patients that have had positive results from the affected TB-Antigen Lot #, you are welcomed to speak with someone from Cellestis who can help draft language for your announcement. Work with your Local Representative to help facilitate that discussion or get more details.

**Question:** *What is being done to notify the regulatory agencies?*

**Answer:** In this situation, Cellestis is not required to contact or notify regulatory agencies of a voluntary market withdrawal.

**Question** *I'm very concerned, why shouldn't I just change to some other test?*

**Action:** We understand your concerns and take the matter very seriously. We have responded very quickly to a single inquiry. At this time we have received a very low number of customer inquiries throughout the world regarding these lots and have acted quickly to initiate this voluntary market withdrawal. Annually we manufacture 4 million tests. Greater than 300 publications have reported on the specificity of QFT. The advantage of QFT is that we have a QA/QC process that can detect issues with the product and/or the process that then can be rectified. This is not the case with all other TB tests. Cellestis/QIAGEN scientific and regulatory staff is continuously seeking ways to improve the QFT assay and its quality assurance. Wherever a customer reports an issue we have reacted quickly and efficiently with attention to resolution.