Supplier: QIAGEN GmbH

Subject: Supply delays for the QIAreach QuantiFERON TB test

Context: Qiagen Gmbh has been forced to temporarily pause the commercialization of QIAreach QuantiFERON TB tests (QIAreach e-hub and QIAreach QuantiFERON TB). QIAreach QFT is manufactured by Ellume Ltd., which has recently entered bankruptcy protection. Until the ongoing voluntary administration process at Ellume Ltd. is completed and Qiagen GmbH gains increased clarity on manufacturing and supply chain constraints, Qiagen GmbH has suspended all future commercial activity for the products until further notice.

GDF Product code	Product name
103936	QlAreach e-Hub
106937	QIAreach QuantiFERON-TB, 50 test

However, please note that all ongoing clinical activities with QIAreach QFT are not affected by this decision. This suspension also does not impact the supply of QuantiFERON TB Gold Plus (QFT Plus). QFT Plus is manufactured by QIAGEN GmbH.

Extent of supply delays: Delays will affect all QIAreach products (e.g., e-hub and QIAreach QuantiFERON TB test)

Expected duration of supply delays: Indefinite. GDF will update this notice when new information about the duration of the supply delay is available.

GDF Mitigation Actions:

- GDF will no longer provide new quotes for the procurement of the QIAreach QuantiFERON TB tests (QIAreach e-hub and QIAreach QuantiFERON TB) until further notice.
- GDF will temporarily remove the QIAreach QuantiFERON TB tests (QIAreach e-hub and QIAreach QuantiFERON TB) from its <u>Product Catalog</u> and <u>Diagnostic Ordering List</u> until further notice.
- GDF will advise clients to procure alternative Interferon Gamma Release Assays (IGRAs) for detection of Tuberculosis infection.

Contact Information: For additional or more detailed information; or, if you need support with order planning, please contact the GDF Country Supply Officer for your programme or <u>gdf@stoptb.org</u>

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Status: No change