

Supplier: Cepheid High Burden Developing Country (HBDC) Programme

Subject: Discontinuation of the Xpert MTB/RIF test and transition to the Xpert MTB/RIF Ultra test

Context: In May 2022, Cepheid HBDC informed GDF that Cepheid would be discontinuing the sale of the Xpert MTB/RIF test by 31 May 2023 and transitioning to the Xpert MTB/RIF Ultra test. Cepheid has confirmed the Xpert MTB/RIF Ultra test will be offered at the same terms as the Xpert MTB/RIF test under Cepheid's HBDC programme.

The World Health Organization's (WHO) Global TB Programme recommends the Xpert MTB/RIF Ultra test as one of the molecular WHO-recommended rapid diagnostics tests for the initial diagnosis of tuberculosis.¹ The WHO Guidance also provides additional information on the differences between the two tests. The WHO has also confirmed that recommendations apply to the use of the Xpert MTB/RIF Ultra test on both 6-color and 10-color GeneXpert Instruments.²

The Global Laboratory Initiative has published a guide to support programmes to transition to Xpert MTB/RIF Ultra tests.³

Deadline: Cepheid will no longer accept new procurements for Xpert MTB/RIF tests from 31 May 2023.

GDF Actions:

- GDF will continue to procure Xpert MTB/RIF tests up until the transition deadline.
- GDF will inform clients placing new orders for the Xpert MTB/RIF test about the transition to Xpert MTB/RIF Ultra.
- GDF will feedback any client concerns about the planned transition (e.g., need for local registration of the Xpert MTB/RIF Ultra test) to Cepheid so the concerns can be addressed.

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 gdf@stoptb.org

Date first posted: 12 July 2022

Date of last update: 08 June 2023

Status: Closed

¹ WHO consolidated guidelines on tuberculosis. Module 3: diagnosis - rapid diagnostics for tuberculosis detection, 2021 update. Geneva: World Health Organization; 2021. Available here: <https://www.who.int/publications/i/item/9789240029415>

² Use of Xpert MTB/RIF and Xpert MTB/RIF Ultra on GeneXpert 10-colour instruments: WHO policy statement. Geneva: World Health Organization; 2021. Available here: <https://www.who.int/publications/i/item/9789240040106>

³ Planning for country transition to Xpert MTB/RIF Ultra cartridges. Geneva; Global Laboratory Initiative, 2017. Available here: https://stoptb.org/wg/gli/assets/documents/GLI_ultra.pdf