



July 2024

Subject: Product Availability Notification; Xpert *C. difficile* BT (GXCDIFFBT-CE-10)

Attention: To Whom it May Concern

Dear Valued Customer,

This letter is to inform you that we are facing a short-term supply disruption for Xpert *C. difficile* BT (GXCDIFFBT-CE-10) and request your patience as we resolve the matter.

It's come to our attention that the instructions for use provided on the CD include inconsistencies regarding the qualified manufacturing site of our test and the inadvertent omission of performance data. To maintain our quality standards, we are working to make corrections, resulting in a short-term supply disruption. Ongoing corrections pertain solely to regulatory compliance; therefore, there is no safety risk to the current test results.

Thank you for your continued business and interest in our products. We appreciate the partnership we have formed and will continue to strive to bring you the highest-quality systems and tests.

For additional questions regarding this matter, please reach out to your local Cepheid contact.

Kind Regards,

Cepheid Global Product Management

CE-IVD. In Vitro Medical Device. May not be available in all countries.

P +33.563.82.53.00
F +33 563 82 53 01

www.Cepheidinternational.com

Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

au capital de 43.000,00 €
APE : 4646Z
RCS Castres 444 404 941 –
2002 B 286
N° TVA : FR81444404941

