

3rd January 2019

**URGENT      FIELD      SAFETY      NOTICE**

**Thermo Scientific™ BRILLIANCE™ CLARITY UTI / STAPH-STREP CNA (MOD) BIPLATE**

**PB1155E lot 2512670 Expiry 17<sup>th</sup> December 2018**

**DESCRIPTION**

Customers are to be advised of the following:

A technical investigation has confirmed that Thermo Scientific™ *Brilliance*™ Clarity UTI / Staph-Strep CNA (mod) Biplate PB1155E Lot 2512670 may not grow *Escherichia coli* on the *Brilliance* Clarity UTI agar side and that gram-negative organisms may not be inhibited on the Staph-Strep CNA (mod) side.

**RISK OF USE**

Thermo Scientific™ *Brilliance*™ Clarity UTI / Staph Strep CNA (mod) Biplate is for:

*Brilliance*™ Clarity UTI agar is for the isolation and presumptive identification of common urinary tract infection isolates.

Staph- Strep CNA (mod) is a selective medium for the isolation of staphylococci and streptococci.

Use of this lot may result in false negative results on the *Brilliance* Clarity UTI agar with the potential for overgrowth of non-target organisms on the Staph-Strep CNA agar. There are no expected long term health consequences. The immediate consequences are likely to be limited to possible minor delays in identification of an infecting gram-negative bacillus in a urinary infection. The gram-negatives still grow on the CNA side of the biplate, but not on the *Brilliance* Clarity UTI side. Subculture and primary identification may have been necessary to confirm the identity as *E. coli* from the urine sample.

**ACTIONS TO BE TAKEN**

Our records indicate that you have received the above product.

Requirement for review of reported test results should be determined by the appropriate technical expert.

The Medicines and Healthcare products Regulatory Agency MHRA will be informed of this Field Safety Corrective Action.

This notice needs to be passed on to all who need to be aware within your organisation or to any organisation where the potentially affected lots have been transferred.

If you have any questions, please contact our Technical Support Department on +44 (0)1256 694238, or at [microbiology.techsupport.uk@thermofisher.com](mailto:microbiology.techsupport.uk@thermofisher.com).

You should complete the accompanying Acknowledgement Form in regard to inventory you have received and/or which is still in stock.

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,

**Vice President, Quality and Regulatory MBD**

3rd January 2019

**ACKNOWLEDGEMENT FORM**

**Re. ThermoScientific™ BRILLIANCE™ Clarity UTI / Staph-Strep CNA (MOD) Biplate, PB1155E lot 2512670 Expiry 17<sup>th</sup> December 2018**

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall ThermoScientific™ *Brilliance*™ Clarity UTI / Staph-Strep CNA (mod) Biplate PB1155E Lot 2512670, manufactured and sold between November – December 2018.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this letter and F.S.N by emailing back a completed, signed copy of this Acknowledgement Form to the Customer Services Department on Fax no. +44(0)1256 479525 **by 31st January 2019.**

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at [microbiology.techsupport.uk@thermofisher.com](mailto:microbiology.techsupport.uk@thermofisher.com). Any other assistance, please contact your Customer Services Representative on **Contact No.**

Yours sincerely,

**Signed :**  
**Title :**  
**Company :**

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**CONFIRMATION OF RECEIPT**

I confirm receipt of the F.S.N. for ThermoScientific™ *BRILLIANCE*™ Clarity UTI / Staph-Strep CNA (MOD) Biplate, PB1155E lot 2512670, dated 3rd January 2019.

Signed..... Name (please print)..... Position.....  
Date..... Email Address/Telephone Number.....