

July 2024

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**VITROS® Immunodiagnostic Products Folate Reagent Pack 1/2**  
**Increase in Incidence of Condition Code TM5-4MB**

Dear Valued Customer,

This notification is to inform you that QuidelOrtho™ has confirmed an issue involving the VITROS® Immunodiagnostic Products Folate Reagent Pack 1/2 (VITROS Folate) regarding generation of condition code "TM5-4MB" (uIA metering Aspirate Middle Ring – Bubble) when processing on the VITROS® 3600 Immunodiagnostic Systems and 5600/XT 7600 Integrated Systems.

Affected Product Name	Product Code (Unique Device Identifier)	Affected Lot(s)
<b>VITROS Immunodiagnostic Products Folate Reagent Pack 1/2</b>	<b>1513266 (10758750009237)</b>	<b>All expired, current, and future lots</b>

Impacted Product Name	Product Code (Unique Device Identifier)	Affected Lot(s)
<b>VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3</b>	<b>1142561 (10758750008476)</b>	<b>All expired, current, and future lots</b>
<b>VITROS Immunodiagnostic Products Red Cell Folate Pack</b>	<b>1107804 (10758750008407)</b>	<b>All expired, current, and future lots</b>

**Summary**

QuidelOrtho investigated customer complaints regarding generation of condition code "TM5-4MA" or "TM5-4MB" when testing the VITROS Folate on 3600 Immunodiagnostic Systems and 5600/XT 7600 Integrated Systems. The investigation confirmed that fibrinogen in patient plasma samples precipitates out of solution upon addition of folate stabiliser reagent in the pre-treatment process in the MicroWell incubator middle ring. Plasma from patients with elevated fibrinogen levels may post "TM5-4MA" or "TM5-4MB" condition codes.

**Impact to Results**

Results for a sample are not generated when the condition codes "TM5-4MA" or "TM5-4MB" occurs. This may cause a delay in reporting test results due to the need to retest the sample.

As of 07-JUL-2024, we have received 65 complaints related to the increase in incidences of TM5-4MB condition code being generated when processing testing for VITROS Folate.

**REQUIRED ACTION**

- If retesting the sample leads to repeated "TM5-4MA" or "TM5-4MB" condition codes, it may not be possible to generate a result with this sample on the VITROS 3600 Immunodiagnostic Systems or VITROS 5600/XT 7600 Integrated Systems.
- Use serum samples instead of plasma if repeat "TM5-4MA" or "TM5-4MB" condition codes are noted with a particular patient plasma sample.
- Complete the enclosed Confirmation of Receipt form no later than **1 Aug 2024**.
- Please forward this notification if the affected product was distributed outside of your facility.

**Contact Information**

We apologise for the inconvenience this will cause your laboratory. If you have further questions or wish to report an adverse event, please contact your local QuidelOrtho representative or the Global Services Organisation.

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)

Enclosure:  
*Confirmation of Receipt (Ref. CL2024-166\_Conf)*

*Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.*

## Questions and Answers

1. What are middle ring condition codes?
  - a. Two specific aspiration condition codes are implicated by the investigations into this issue.
    - i. TM5-4MA: uIA METERING Aspirate MIDDLE RING – Plugged tip
    - ii. TM5-4MB: uIA metering Aspirate Middle Ring – Bubble
  - b. TM5-4MB condition codes are more commonly encountered.
2. Can other scenarios cause these condition codes?
  - a. The system monitors the pressure inside the VersaTip during MicroWell aspiration and abnormal pressure profiles may generate these condition codes. The following is a list of additional potential causes of these abnormal pressure profiles (from V-Docs):
    - i. Clots, Gel, Fibrin, or Particles in the pre-treated sample in the MicroWell
    - ii. High total protein
    - iii. Bubble in the MicroWell
    - iv. A leak in the uIA METERING air pathway (condition codes would not be limited to aspirations only from the middle ring with this failure mode)
3. What assays have a sample pre-treatment step that utilises the middle ring?
  - a. VITROS Immunodiagnostic Products Folate
  - b. VITROS Immunodiagnostic Products Vitamin B12