

**Urgent Field Safety Notice (FSN)**

**Piccolo® General Chemistry 13**

**FSCA-identifier (2837263)**

**CORRECTIVE ACTION**

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Date: June 21, 2024

Attention: Valued Customer

**Details on affected devices:**

Name: Piccolo® General Chemistry 13

Intended use/Primary clinical purpose: The Piccolo® General Chemistry 13, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the in vitro quantitative determination of alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), calcium, creatinine, gamma glutamyl transferase (GGT), glucose, total bilirubin, total protein, blood urea nitrogen (BUN), and uric acid in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location/ near-patient testing.

REF number: 400-0029

Lot number: 4065AB8

**Description of the problem:**

It has come to our attention that Lot 4065AB8 of General Chemistry 13 for Piccolo Xpress could have reagent discs with Comprehensive Metabolic Profile Lot 4065AC1 in the pouch. This will cause results to have missing results for Amylase (AMY), Gamma Glutamyl Transferase (GGT), and Uric Acid (UA) from the Comprehensive Metabolic Profile reagent disc.

Based on the preliminary investigation, the occurrence for error is approximately less than 1%; however, we are communicating this issue out of an abundance of caution and to ensure the correct panel of tests are provided. At this time, we ask that you please take the actions listed below to ensure the situation is addressed in the most efficient and proper manner.

### **Hazard Giving Rise to FSCA:**

The hazard to the patient is that if advice is not followed and the correct reagent disc lot is not identified ahead of analysis, there will be a delay in the results for Amylase, Gamma Glutamyl Transferase, and Uric Acid.

### **Advise on actions to be taken by the user:**

1. When opening a pouch of Piccolo® General Chemistry 13 reagent discs, Lot 4065AB8, inspect the barcode ring and ensure the printed lot number matches;
2. If the lot number does not match, record the lot number, take a picture of the lot number, the top and bottom of the pouch, and all sides of the box, and contact technical support and transmit the information;
3. Discard the reagent disc appropriately per local guidelines and regulations; and
4. If a reagent disc is run on the instrument and results are missing from AMY, GGT, and UA, follow steps 2 and 3 above.

### **Contact reference person:**

**Please contact Abaxis Europe via phone +49 6155 780 21 300 or email [Int.piccolosupport@zoetis.com](mailto:Int.piccolosupport@zoetis.com)** and provide the following information:

1. Date of incident, and
2. Pictures of the disc barcode, front and back of pouch, and all faces of the box and/or print out of the erroneous tests (if applicable).

The undersign confirms that this notice has been notified to the appropriate regulatory agency.

Yours sincerely,

Abaxis Europe GmbH

## **Urgent Field Safety Notice (FSN)**

**Piccolo® General Chemistry 13**

**FSCA-identifier (2837263)**

**CORRECTIVE ACTION**

-----  
Date: June 21, 2024

Attention: Distribution Partner

### **Details on affected devices:**

Name: Piccolo® General Chemistry 13

Intended use/Primary clinical purpose: The Piccolo® General Chemistry 13, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the in vitro quantitative determination of alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), calcium, creatinine, gamma glutamyl transferase (GGT), glucose, total bilirubin, total protein, blood urea nitrogen (BUN), and uric acid in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location/ near-patient testing.

REF number: 400-0029

Lot number: 4065AB8

### **Description of the problem:**

It has come to our attention that Lot 4065AB8 of Piccolo® General Chemistry 13 for Piccolo Xpress could have reagent discs with Piccolo® Comprehensive Metabolic Profile Lot 4065AC1 in the pouch. This will cause results to have missing results for Amylase (AMY), Gamma Glutamyl Transferase (GGT), and Uric Acid (UA) from the Comprehensive Metabolic Profile reagent disc.

Based on the preliminary investigation, the occurrence for error is approximately less than 1%; however, we are communicating this issue out of an abundance of caution and to ensure the correct panel of tests are provided. At this time, we ask that you please take the actions listed below to ensure the situation is addressed in the most efficient and proper manner.

### **Hazard Giving Rise to FSCA:**

The hazard to the patient is that if advice is not followed and the incorrect reagent disc lot is not identified ahead of analysis, there will be a delay in the results for Amylase, Gamma Glutamyl Transferase, and Uric Acid.

### **Advise on actions to be taken :**

1. Leverage language from the enclosed communication to inform customers to report if they find a disc of Lot 4065AC1 when expecting 4065AB8;
2. Send confirmation notification of impacted customers to [Int.piccolosupport@zoetis.com](mailto:Int.piccolosupport@zoetis.com)
3. Notify Abaxis of any customer results that have additional results that are unexpected from a Piccolo® General Chemistry 13 reagent disc.

Please take time to review the enclosed customer communication and ensure all impacted customers are promptly notified. If you have any questions or concerns, please contact your local Abaxis commercial colleague. Thank you for your attention to this important matter.

### **Transmission of this Field Safety Notice:**

This notice needs to be passed on to those who need to be aware within your organization and all customers who received Piccolo General Chemistry 13 rotor, lot 4065AB8 or others where the potentially affected products have been transferred.

Please maintain awareness on this notice and resulting actions for an appropriate period through product expiry or stock depletion to ensure effectiveness of the corrective actions.

### **Contact reference person:**

**Please contact Abaxis Europe via phone +49 6155 780 21 300 or email**

[Int.piccolosupport@zoetis.com](mailto:Int.piccolosupport@zoetis.com) and provide the following information:

1. Date of incident, and
2. Pictures of the disc barcode, front and back of pouch, and all faces of the box and/or print out of the erroneous tests (if applicable)

The undersign confirms that this notice has been notified to the appropriate regulatory agency.

Yours sincerely,

Abaxis Europe GmbH