Notification of Field Safety Corrective Action (FSCA) for APTIMA Urine Collection Kit

Catalogue Number: 301040

«Customer_Name»

28 April 2014

Dear Customer

The purpose of this notification is to inform you that we have been notified by a contract manufacturer of a labelling error. Therefore, we have initiated a voluntary Field Safety Corrective Action regarding the APTIMA Urine Collection Kit; Catalogue Number 301040. See Table 1 for affected lots.

Table 1 – Lot Numbers of the Impacted Kits

Catalogue #	Impacted Lot Number
301040 Component ID #: 301040-01	27231
	27232
	27233
	27234

This voluntary Field Safety Corrective Action has been initiated because incorrect labelling was used on each pouch of the affected lots of APTIMA Urine Specimen Collection Kits for Male and Female Urine Specimens. The outer box of the kit is identified correctly as APTIMA Urine Collection Kits; however, the inner pouches are incorrectly labelled as APTIMA Unisex Swab Collection Kit for Endocervical and Male Urethral Swab Specimens.

The components of the incorrectly labelled pouches of the APTIMA Urine Collection Kit are shown in Figure 1. The correctly labelled APTIMA Urine Collection Kit is shown in Figure 2.

Figure 1: Incorrectly Labelled APTIMA Urine Collection Kits in Impacted Lots.

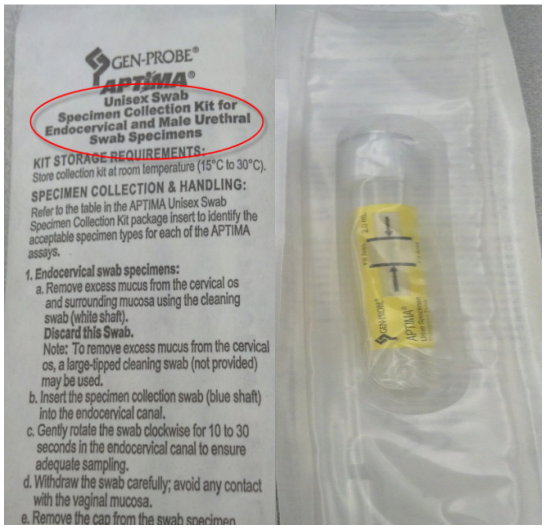
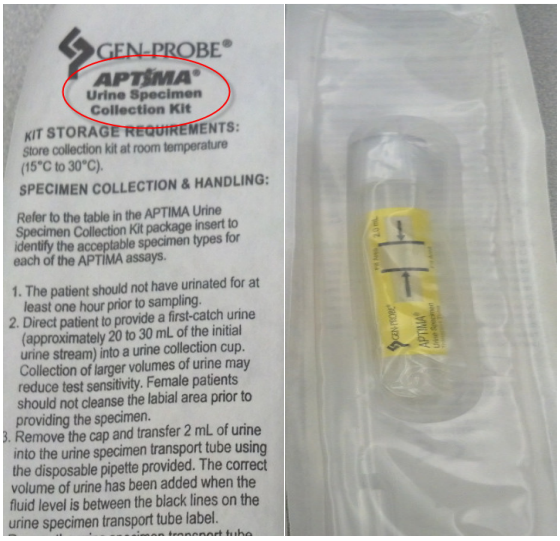


Figure 2: Correctly Labelled APTIMA Urine Collection Kits



Hologic has identified the root cause of the problem and an investigation and corrective action are in process to prevent recurrence.

To date, there have been no reported complaints or injuries. The components in the affected kit(s) (APTIMA urine specimen transport tube and transfer pipette) are the correct components for urine collection and processing. The contents of the pouch cannot be used as a unisex swab collection method. If the product in the impacted kits was utilized to collect and process urine in accordance with the APTIMA assay package inserts, assay results would not be impacted by the labelling issue.

Hologic requests that all impacted customers discontinue the use of the identified kit lots. Hologic will work with each impacted customer to replace the affected product. With this Field Safety Notice, Hologic is requesting that you segregate the entire contents of the affected kit lots listed on the Customer Response Form. After segregation is complete, please reconcile and destroy all partial and/or full kits that you have left in inventory and document the amount destroyed on the Customer Response Form. If the urine collection kits were further distributed to other collection sites by your organization, please notify them of this issue. Once the form is completed, please sign and return to Hologic Molecular Support via the contact information provided below.

Tel: +49 6122 7076451

Fax: +49 6122 7076155

Email: EUTechnicalSupport@hologic.com

For additional information, questions, or concerns, please contact Hologic Molecular Support using the details above.

Yours sincerely

Derek McLean

Director, Quality Assurance - International

Customer Response Form

Hologic Deutschland GmbH
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65205 Wiesbaden
Nordenstadt
Germany

Technical Support Phone: +49 6122 7076451
Technical Support Fax: +49 6122 7076155
Technical Support E-mail: EUTechnicalSupport@hologic.com

Customer Contact Information	Instructions
«Customer_Name» «Address» «City» «Zip» «Country»	Please follow all instructions detailed in the accompanying letter and then complete, sign and return this Customer Response Form to Hologic Molecular Support using the above contact details. Please notify us if there are any changes to your contact information so we can update our database.

Please check the appropriate boxes below:

☐ We have zero of the product listed below on hand.

☐ We have followed the enclosed instructions

☐ We have documented our remaining inventory for each of the affected lots in the "Quantity On Hand" column in the table below

Completed By:

Print Name ..... Phone .....

Signature ..... Date: .....

Comments:

Item Description	Batch / Lot Number	Delivery Qty	Qty On-Hand
«Item_Description»	«Lot_Number»	«Qty»	

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