

## URGENT: FIELD SAFETY NOTICE

6<sup>th</sup> August 2012

**RE: Recall for Certain Lots of the LIFECODES PAK Product Line**

Dear Customer:

We wish to inform you that anomalous decreases in the average optical density (OD) have been observed with certain kits within the LIFECODES PAK Product Line. We believe the decrease in OD was caused by a chemical reaction with an unknown compound that was introduced into the manufacturing process when faulty vials supplied by a third party were used to contain the substrate buffer kit component. A single lot of faulty vials were identified and approximately 35% of vials in that lot were defective and have the potential to decrease OD values. The decrease in OD may result in an increase in invalid assay runs and/or a decreased sensitivity for samples with average OD values near the assay cutoff; therefore, we are voluntarily recalling all products containing the affected lot of substrate buffer.

If you have remaining inventory of the kit lot numbers identified below, we will replace the substrate buffer component at no cost to you. **The replacement substrate buffer can be used with any kits you have remaining in your inventory and without restriction.**

Please note the following important details and inform your colleagues of them:

***Affected Lots –***

The following lots for the LIFECODES PAK products listed below are affected:

Catalog Number	Product Description	Kit Lot Number	Substrate Buffer Lot Number
PAK12	LIFECODES PAK12	011012-P12	SB092011
PAKAUTO	LIFECODES PAKAUTO	090111-PAB	SB092011
PAKAUTO	LIFECODES PAKAUTO	090811-PA	SB092011
PAK2-LE	LIFECODES PAK2-LE	092011-P2LE	SB092011
PAKPLUS	LIFECODES PAKPLUS	092211-PP	SB092011
PAKAUTO	LIFECODES PAKAUTO	100611-PA	SB092011
PAK12	LIFECODES PAK12	101811-P12	SB092011
PAK12	LIFECODES PAK12	101911-P12	SB092011
PAKAUTO	LIFECODES PAKAUTO	102011-PA	SB092011

During internal testing, the average OD values for the Positive Control were lower than expected in these lots. In most cases the lower reactivity led to invalid assay runs. In a few instances the assays were considered valid, but due to the lower than expected reactivity the **sensitivity may have been decreased for samples with average OD values near the assay cutoff.**

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 BNP Paribas France IBAN FR76 3000 4009 0200 0101 0040 153 BIC BNPAFR33LIL  
 RFR ANTWERPEN BTW/TVA: BE 451 988 353

**Actions Required –**

- 1) Stop using the lot(s) identified above until you have replaced the substrate buffer component with new substrate buffer provided by us.
- 2) Review the results of past valid assay runs and compare Positive Control values obtained with recalled kits against historical trend data. If you identify average Positive Control OD values for recalled kits that are out of trend, then the results of those runs may be suspect. In this case, we recommend that you notify the referring physician about the possibility of decreased sensitivity if a negative result with average OD values near the assay cutoff was obtained.
- 3) Check any remaining inventory per the following instructions and complete the Customer Response Form included as part of this notification.

**If you have remaining inventory for the LIFECODES PAK product lines noted above:**

- Count the number of unused kits in inventory so that we know how much substrate buffer to send you.
- Check the second box on the Customer Response Form and enter the number of unused kits in the space labeled “Qty On-Hand.”
- **Check the third box on the Customer Response Form indicating that you have followed these instructions.**
- Sign, date and return the form to LIFECODES Technical Support via fax to 0032-14225810 or scan and email to [brooke.conway@gen-probe.com](mailto:brooke.conway@gen-probe.com).
- **Discard the substrate buffer for all affected kits.**
- Gen-Probe will provide replacement substrate buffer for the affected Pak product kits at no charge.

**If you have no remaining inventory for the LIFECODES PAK product lines noted above:**

- Check the first box on the Customer Response Form.
- **In addition, make sure to check the third box on the Customer Response Form indicating that you have followed these instructions.**
- Sign, date, and return the form to LIFECODES Technical Support via fax to 0032-14225810 or scan and email to [brooke.conway@gen-probe.com](mailto:brooke.conway@gen-probe.com)

We are taking appropriate actions to prevent future occurrence of this issue. We appreciate the trust and confidence you place in Gen-Probe and look forward to a continuing successful partnership. Please do not hesitate to contact LIFECODES Technical Support at 0032-14225110 or [brooke.conway@gen-probe.com](mailto:brooke.conway@gen-probe.com), with any questions.

Sincerely,



Dr. Christine Heylen  
Director Europe, Lifecodes Products

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