

URGENT: FIELD SAFETY NOTICE

Nijlen, April 13, 2012

RE: Recall for Gen-Probe GTI Diagnostics Inc.: LIFECODES® Pak2-LE®

Dear Customer:

We wish to inform you that anomalous increases in the optical density (OD) of the Negative Control used with certain LIFECODES Pak2-LE assay lots have been observed. This may result in decreased sensitivity for some analytes as the kit ages. Although the product is currently performing within package insert claims, we have decided to recall the affected lots from the market. If you have remaining inventory of these lots, we will replace them at no cost to you.

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

Affected Lots –

The following LIFECODES Pak2-LE kit lots are affected:

Catalog Number	Product Description	Kit Lot Number	Negative Control Lot Number
PAK2-LE	LIFECODES Pak2-LE	101110P2LE	NC081810
PAK2-LE	LIFECODES Pak2-LE	020711P2LEA	NC012111
PAK2-LE	LIFECODES Pak2-LE	020711P2LEB	NC012111
PAK2-LE	LIFECODES Pak2-LE	050211P2LE	NC012111

In this assay, the positive/negative cutoff for each analyte is calculated as two times the mean OD of the Negative Control in the corresponding strip. As the OD of the Negative Control increases, **decreased sensitivity is possible for analytes wherein the Negative Control value used to calculate the cutoff for that analyte is elevated.** In the affected lots, the increase in the Negative Control value seen in some analyte rows may anomalously be greater than the increase in the Negative Control value seen in the row used to determine run validity.

Actions Required –

- 1) Stop using the lots identified above.
- 2) Review results for valid assays run using the affected lots to determine if the mean Negative Control OD exceeded the following value:

Analyte	Negative Control OD Limit
HLA Class I	≥ 0.150

If the mean Negative Control OD value exceeded this limit, the sensitivity of the assay for this or other analytes may have been affected. In this case, we recommend that you notify the referring physician about the possibility of decreased sensitivity if a negative result near the cutoff was reported.

- 3) Check any remaining inventory per the following instructions and complete the included Customer Response Form.

If you have remaining inventory of the LIFECODES Pak2-LE kits noted above:

- Count the number of unused kits in inventory.
- Check the second box on the enclosed form and enter the number of unused kits in the space labeled “Qty On-Hand.”

- Sign, date and return the form to Gen-Probe Belgium via fax to +32 14 22 58 10 or scan and email to eulifecodesordering@gen-probe.com.
- **Discard all reagents for these affected kits.**
- Gen-Probe will provide replacements for the discarded inventory of affected LIFECODES Pak2-LE kits at no charge.


If you have no remaining inventory of the LIFECODES Pak2-LE kits noted above:

- Check the first box on the enclosed form.
- Sign, date and return the form to Gen-Probe Belgium via fax to +32 14 22 58 10 or scan and email to eulifecodesordering@gen-probe.com.

We are taking appropriate actions to prevent future occurrence of this issue and will notify you in a few weeks as more information becomes available.

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 your regional Responsible with any questions.

Sincerely,


Director Europe, Lifecodes Products