

URGENT: FIELD SAFETY NOTICE

Nijlen, April 13, 2012

RE: Market Withdrawal for Gen-Probe GTI Diagnostics Inc.: LIFECODES® QuikScreen®

Dear Customer:

We wish to inform you that anomalous increases in the optical density (OD) of the Negative Control used with a certain LIFECODES QuikScreen assay lot have been observed. This may result in an increase in invalid runs as the kit ages. Therefore, we have decided to withdraw the affected lot from the market. If you have remaining inventory of this lot, 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 QuikScreen kit lot is affected:

Catalog Number	Product Description	Kit Lot Number	Negative Control Lot Number
QS12G	LIFECODES QuikScreen QS12G	063011-Q12G	NC031611

Use of this Negative Control lot may lead to an increase in QuikScreen invalid assay runs. **There is no risk to patient results because the control failure will invalidate the run.**

Actions Required –

- 1) Stop using the lot identified above.
- 2) Check any remaining inventory per the following instructions and complete the included Customer Response Form.

If you have remaining inventory of the LIFECODES QuikScreen kit 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 this affected kit.**
- Gen-Probe will provide replacements for the discarded inventory of affected LIFECODES QuikScreen kits at no charge.


If you have no remaining inventory of the LIFECODES QuikScreen kit 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

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