

URGENT FIELD SAFETY NOTICE

12 June 2014

Product Name	Cat. Number
BD Totalys™ SlidePrep (Software version 1.1.0.0-015)	491386

Dear Cytology Lab Manager,

BD has confirmed a software anomaly on the BD Totalys™ SlidePrep that only occurs when multiple, replicate slides are made from a single specimen in the Non-GYN mode. This anomaly results in the application of too much sample on the first slide and too little sample on the last slide prepared. Sample is added correctly to all other slides. The GYN mode is not affected by this anomaly.

The Non-GYN process can be utilized in **single slide mode** without any performance issues to provide your site with the ability to continue testing until a software fix is available which is anticipated in late June.

In the case of Non-GYN processing when multiple replicate slides are generated, the patient diagnosis is not dependent on a single slide but rather on the evaluation of multiple slides that have been processed for various staining or immunocytochemical tests. This multiplicity of testing inputs lowers the potential risk that a patient will be managed inappropriately due to the increased variability of only one of the multiple slides generated.

Our records indicate you have a BD Totalys™ SlidePrep instrument that may be impacted by this software anomaly. Please discontinue multi-slide use of the instrument in Non-GYN mode at this time. A BD representative will contact you when the software fix becomes available to schedule the update at your site.

Please complete the attached verification form so that we may acknowledge your receipt of this Field Safety Notice. It is not necessary to contact BD by telephone. Simply complete and fax the form to the **attention of XXX; Regulatory Compliance, Fax: XXXXXXXX.**

If further assistance is needed, please contact your local BD representative. For all other inquiries, please contact the BD Technical Services Department.

Please accept our apology for any inconvenience this may cause. BD is committed to providing you with the highest quality products. Thank you for your continued support.

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Helping all people
live healthy lives

Fax to: BD Regulatory Compliance

Fax #: FILL IN YOUR LOCAL FAX NR

PLEASE FILL OUT AND RETURN THIS FORM SO THAT WE MAY ACKNOWLEDGE YOUR RECEIPT OF THIS NOTIFICATION

Please do not send multiple forms.

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Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Fax No.:** _____

Signature: _____ **Date:** _____