

URGENT: MEDICAL DEVICE CORRECTION

Friday, July 22, 2005

Dear Valued Customer,

We have identified a software bug in the "**Number of Specimens**" function of our SmartCycler[®] Dx software. This function should not be used. It has the potential to be associated with the incorrect reporting of sample results. You will be able to reliably use the SmartCycler System in your laboratory if you utilize the "**Add/Remove Sites**" function. The "**Number of Specimens**" function is specific to the SmartCycler Dx software, and is not included in the SmartCycler Life Science Research software or any GeneXpert[®] software.

We are taking this action following the receipt of a single verified report from the field which has been confirmed through our internal analysis. The company has not received any indication of adverse patient events. We are taking immediate corrective action to fix this issue, including notification to all clinical diagnostic customers, business partners, distributors, and proper regulatory bodies.

If a run is set up using the "**Number of Specimens**" feature, specimen identifications and results may be displayed incorrectly. Our internal investigations lead us to believe that the incidence of this is rare and is dependent upon how runs are initially set up. However, we wanted to contact you immediately to ensure that this does not occur in future runs.

Recommended interim corrective actions are as follows:

- 1) Cease using the "**Number of Specimens**" function immediately
- 2) Use the "**Add/Remove Sites**" function for all run set up procedures
- 3) Replace the SmartCycler Dx Operator Manual instructions for "IVD Assay Run Setup" section, Chapter 3, pp 36-40 with the pages included in this communication.

A Cepheid representative will be contacting you to answer questions and to verify your contact information in order to provide you with the described below. The utilization of these two pieces of software will provide you with a permanent correction of the software bug, in addition, will enable you to ascertain whether any past run may include incorrectly reported results.

- 1) "**SmartCycler Dx Software Upgrade**" – this replacement upgrade software is expected to arrive via Federal Express no later than August 31, 2005, and is easily installed.
- 2) "**Data Utility Software**" – use this software to identify any prior runs which may have been affected by the software bug. Expect this software to arrive via Federal Express by August 3, 2005.

We apologize for any inconvenience. We are committed to continually providing the highest in product quality to our customers. If you have any questions or concerns, please contact Cepheid's Technical Support Department at 1-888-838-3222.

Sincerely,

John L. Bishop
Chief Executive Officer
Cepheid