

URGENT FIELD SAFETY NOTICE

Date: xx July 2010

Attention: Laboratory Director
PCR Laboratory

Subject: Cepheid kit stability issues may result in invalid runs due to out-of-range calibrators and/or controls.

Issue

Cepheid AB has confirmed kit stability issues with:

- Cepheid LightCycler[®] CMV Quant Kit –IVD (OEM), M/N 04 845 854 001, lot 70012203
- Cepheid LightCycler[®] CMV Quant Kit –IVD (OEM), M/N 04 845 854 001, lot 70012207
- Cepheid LightCycler[®] EBV Quant Kit –IVD (OEM), M/N 04 846 818 001, lot 70012205
- Cepheid LightCycler[®] VZV Qual Kit –IVD (OEM), M/N 04 846 788 001, lot 70012206

Invalid runs have been reported using the above Cepheid LightCycler[®] kit lots on the LightCycler[®] 2.0 instrument with the LightCycler[®] Software 4.05 or higher. The invalid runs are due to Cp values out-of-range and have been reported for the Internal Control (IC), Positive Control (PC) or the calibrators (Cal 1-Cal 4), which results in an invalid run.

Investigation

The issue is currently under investigation. Changes have been made to the Master Mix base buffer and, as an interim measure, the shelf life has been decreased for all products to six months. Note that no complaints have been received for any of the affected lots; this issue was observed through internal stability testing.

Impact on Results

The slope of the curves change and the calibrators and/or controls fall out-of-range due to kit stability issues. This will invalidate all test results.

For the LightCycler[®] VZV Qual test, the Positive Control and Internal Control (IC) are used for checking the validity of the run. If either of the controls Cp is out-of-range, the test results are invalid and must be repeated. See section 6.3 2 *Interpretation of Results* in the User Manual.

For the LightCycler[®] CMV and EBV Quant assays, the calibrators and Internal Control (IC) are used for checking the validity of the run. The validity of the calibrators is determined by the respective macro. If the Cp value for one or more of the calibrators is outside the range as determined by the macro, the test results are invalid and must be repeated. In addition, if the Internal Control is invalid, the test result is invalid and must be repeated. See section 6.3 2 *Interpretation of Results* in the respective User Manual.

If reagents from the kit lots listed above have already been used, and valid run results were generated, these results can be accepted and reported.

- All results from expired kit lots that have been used, and valid run results were generated, remain valid and results are acceptable.
- All additional in-date kit lots (those lots not listed above) are not affected by stability issues as they have reduced shelf-life and changed Master Mix base buffer and can continue to be used; all valid results can be accepted and reported.

The kit stability issues described above will not result in the generation of false-positive or false-negative results. Invalid controls/calibrators will invalidate the run in all cases, which represents customer inconvenience and potential for repeat testing, delayed communication of results, and/or delay in patient medical management decisions.

Follow-up Actions

- Discontinue use of the following Cepheid LightCycler® kit lots on the LightCycler® 2.0 instrument with the LightCycler® Software 4.05 or higher:
 - Cepheid LightCycler® CMV Quant Kit –IVD (OEM), M/N 04 845 854 001, lot 70012203
 - Cepheid LightCycler® CMV Quant Kit –IVD (OEM), M/N 04 845 854 001, lot 70012207
 - Cepheid LightCycler® EBV Quant Kit –IVD (OEM), M/N 04 846 818 001, lot 70012205
 - Cepheid LightCycler® VZV Qual Kit –IVD (OEM), M/N 04 846 788 001, lot 70012206
- Quarantine and discard remaining inventory and contact Roche Diagnostics for replacement material.

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