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Roche Diagnostics
9115 Hague Road, PO Box 50457
Indianapolis, IN 46250-0457 USA
Tel. + 1-317-521-2000
+ 1-800-428-5074



Analyzer Bulletin

CoaguChek® XS Plus System – CLIA Waiver Update

Important Update

The reason for this communication is to notify you of incorrect product labeling related to the CLIA-waived status of the CoaguChek XS Plus system. In March 2010, Roche Diagnostics announced the CoaguChek XS Plus system was granted CLIA-waived status; however, the Food and Drug Administration (FDA) recently informed us that the CoaguChek XS Plus system labeled for professional use is not CLIA-waived. There is not a concern related to meter performance.

To address the issue, Roche Diagnostics will re-file revised labeling with the FDA. In the meantime, the CoaguChek XS Plus system for professional use must be used in accordance with CLIA Moderate Complexity guidelines.

Status

A new submission with revised labeling is being compiled. Roche Diagnostics is working closely with the FDA to resolve the matter as quickly as possible. It is anticipated the system will be granted CLIA-waived status for professional use; the exact timing depends on the FDA.

We understand that this situation may cause confusion and some disruption in your operations, and we apologize for the inconvenience. We are committed to helping you maintain the highest standards in anticoagulation management and we are available to answer any questions you may have. Updated information will be provided as soon as it is available.

Actions Required

- At this time, the CoaguChek XS Plus system for professional use must be used in accordance with CLIA Moderate Complexity device operation requirements.
- Discard Analyzer Bulletin 10-056, dated 03/24/10.
- File this Analyzer Bulletin for future reference.

Questions

Please contact Roche Diagnostics Point of Care Technical Service at 1-800-428-4674 or your Roche Account Manager if you have questions about the information contained in this Analyzer Bulletin.

COAGUCHEK is a trademark of Roche.

 CoaguChek XS Plus