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Roche Diagnostics

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Analyzer Bulletin

CoaguChek® XS Plus system — CLIA Waiver Granted

Important Update

Roche Diagnostics is proud to announce that a CLIA waiver has been granted by the FDA to the CoaguChek XS Plus system. The CoaguChek XS Plus system joins the CLIA-waived family of CoaguChek systems.

The CLIA waiver is posted to the FDA's CLIA categorization website*:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

About the CoaguChek XS Plus System

The CoaguChek XS Plus system's exclusive smart technology uses built-in quality controls to help ensure the accuracy of every result, and its data management features help you with compliance and practice management.

- Accurate results in 1 minute with 97% correlation to the lab method using the Dade Sysmex 560 Analyzer and the Dade Innovin[1]
- Flexible QC options for any testing environment: automatic, onboard controls and optional liquid controls[1]
- Stores 1,000 patient and 500 optional liquid QC test results
- Operator and QC lockout capabilities

Updated Labeling

Until labeling containing the CLIA waiver is available to be packed into kits, this Analyzer Bulletin serves as notice of the CLIA waiver on the CoaguChek XS Plus system.

Action Required

File this Analyzer Bulletin for future reference.

Questions

Please contact Roche Diagnostics Point of Care Technical Service at 1-800-428-4674 if you have questions about the information contained in this Analyzer Bulletin. To get started with the CoaguChek XS Plus System, contact your distributor, call your Roche representative at 1-800-852-8766, or visit www.poc.roche.com.

*Link tested 09/24/2012.
1. CoaguChek XS PT Test package insert, literature number 05967716001(02). Indianapolis, IN. Roche Diagnostics Corporation, 2010.

☑ CoaguChek XS
☑ CoaguChek XS Plus