SIEMENS

ADVIA Centaur® XPT

Immunoassay System

Software Version 1.7 Release Notes

Introduction

Siemens Healthineers is introducing ADVIA Centaur® XPT Immunoassay System software version 1.7. This document describes the technical enhancements in this software version.

This document is a supplement to the ADVIA Centaur XPT Immunoassay System Operator's Guide. Place this document in your ADVIA Centaur XPT Immunoassay System Operator's Guide and inform everyone in your laboratory of this supplement. If you have any questions or concerns regarding this bulletin, contact your local technical support provider or distributor.

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Installation

Install ADVIA Centaur XPT Immunoassay System software 1.7 as an upgrade on systems running version 1.5.1 SP1 or as a full installation.

During the software installation upgrade, the customer must enter the original PHI key. Failure to have the original PHI key will result in permanent loss of patient health data that was tied to that key.

Cybersecurity Update

Software Version 1.7 supports the following updated software:

• Support for McAfee SolidCore Version 8.3.x

New Features

Ambient Temperature Monitoring Feature

This software version includes an enhancement that monitors ambient temperature for a subset of temperature-sensitive assays with operating ranges of 20–25° C.

See the following list of assays for which this feature applies:

- BNP
- CA19-9 ™
- CA19-9A ™ (Japan only)
- DIGITOXIN
- DHEAS
- DHEAS04
- Folate
- Folate BA
- PCT
- THEO2

By default, the ADVIA Centaur XPT Immunoassay System does not make Calibration, Patient, and Control results available that were run when the ambient temperature is outside the operating range of 20–25° C. When running these temperature-sensitive assays, the system ensures the temperature is within the acceptable temperature limits by collecting 30 minutes of temperature data before the system runs these assays. Therefore, the system cannot run temperature-sensitive assays for the first 30 minutes after startup or when Mechanics On is selected. Ambient Temperature monitoring is controlled by the assay-specific Test Definitions in conjunction with this software version enhancement.

If the ambient temperature is outside the acceptable range, the system displays an error message stating that the temperature of the laboratory is beyond the operating range for the system, which is $20-25^{\circ}$ C. Testing of the temperature-sensitive assays is suspended until the operator confirms the laboratory temperature is within the acceptable range. Operators can continue to create orders and query orders from the LIS. However, the system will not aspirate samples for temperature-sensitive assays if the ambient temperature is outside the $20-25^{\circ}$ C range.

Due to a variety of environmental factors, the temperature as measured by the system may differ from other temperature monitors in the laboratory. In these instances, Laboratory Managers must first confirm that the ambient temperature is within the operating range for temperature-sensitive assays. To enter an adjusted Ambient Temperature, navigate to **Setup > System Configuration > System Settings**.

All entries are recorded by the system and included in the audit trail for record-keeping purposes. The temperature entered by the laboratory manager cannot be more than 3°C (5.4°F) different from the temperature read by the system.

Remaining OBS of Diluents with Multiple Master Curve Cards

The **Reagents > Status** tab displays the real-time status of Primary, Primary Wash, Ancillary, Ancillary Wash, and Diluent packs. The Remaining OBS field displays the number of hours remaining until the onboard stability of a reagent pack expires. When a diluent or shared reagent is currently on-board the system and a new master curve card is scanned, the Remaining OBS value updates using the following rules:

- If the first instance of a new master curve card scan has an OBS value of 0, the system allows use of the multi-diluent (MDIL) pack one time and then marks the pack as expired.
- If the new master curve card has an OBS value other than 0, the system uses the smallest OBS value available from the existing valid, non-expired master curves.

Selecting the Use Results Screen Selections and Filter

The Use Results Screen Selections and Filter option has been added to the Results Export window for use when exporting the Test Results data for patient and control results.

Use the following steps to export the Test Results data from the Results Export window:

- 1. On the command bar, select **Test Results** > **Overview**.
- 2. Select the checkbox for each result to be exported, or use **Filter** to filter the information.
- 3. Select Export.
- 4. On the Export Test Results window, select Use Results Screen Selections and Filter.
- 5. Select **Export**.

Changing (Customizing) the Specimen Type for Assays

The Lab manager can add specimen types in addition to the Siemens-approved specimen types, for example, the configuration can include lab-defined specimen types. Lab-defined specimen types are applied to assays, and the result for the test is to produce a result with the lab-defined specimen flag for those specimen types that were not Siemens-approved.

When the Lab manager changes the settings for specimen type, there is a confirmation popup message that confirms the settings. Saving this setting creates an audit trail entry with the user name, date/time, previous, and saved settings (for the specimen types).

NOTE: The laboratory is responsible to validate the lab-defined specimen type before use.

Additional Messaging when Creating or Changing a PHI Key

The system software has been enhanced to include additional messaging to notify you of the results of changing a PHI key or creating a new one. The new message provides the following caution:

CAUTION

Before changing the PHI Key, move all data to Historical. After the operator enters a different PHI Key than the PHI key currently in use:

- The system can no longer access or display patient names and PIDs on the screens or logs, including the LIS log.
- The system cannot access or display Delta Checking results from previous orders.

After changing the PHI Key, the system will automatically restart. Select OK to change the PHI Key.

The PHI key can be changed or you can create a new one.

- To change the PHI Key, use the following steps: Setup > Security > Settings > Change PHI Key.
- To create a new PHI key, use the following steps: Setup > Security > Settings > Create PHI Key

NOTE: Subsequent patient health data and results will be tied to the new or updated PHI key. Data tied to the previous PHI key cannot be retrieved using the new or updated PHI key.

Pre-eclampsia Ratio Tests

The system software has been enhanced to include pre-eclampsia ratio tests.

Update to ELF Ranges

The system software has been enhanced to remove the predefined interpretation flags when the ELF score is reported.

Improvements

Passwords

Forgot Password

The system software has been enhanced to include helpful information about passwords, for example, "Ensure that the operator ID is correct," and "Passwords are case-sensitive." If you need help with entering your password, select **Need Password Help?**

Password Confirmation Field when Exporting Patient Results

The system software has been enhanced so that when you export patient-related data, a confirmation field displays that lets you re-enter your password, and see the password that you entered.

Calibrations

Exporting all Calibration Data

The system software has been enhanced so that you can export all calibration data including invalid calibrations.

Calibration Data Report and User Interface (UI) Correctly Display CV%

The system software has been enhanced so that the Calibration Data Report and UI display the CV values for each calibration (low and high) and for each related replicate.

Printing Calibration Data Details Report

The system software has been enhanced so that the measured ranges of the Relative Light Unit (RLU) display on the printed Calibration Data Details Report and on the UI.

Historical Calibration Data Included in the Archive and Delete Maintenance Activity

The system software has been enhanced to allow the Archive and Delete maintenance activity to support the archiving and deletion of Calibrator Material Definition Data with the following conditions:

- there are no active workorders for the calibrator material
- there are no historical workorders for the calibrator material
- there is no calibration data on the system for the calibrator material
- the calibrator lot has expired

Reporting of Observed Ranges on the Calibration Data Details Report

The system software has been enhanced so that the observed ranges print on the Calibration Data Details Report only after the fourth valid calibration completes.

Moving a Calibration Workorder to Historical from the Test Results Screen

The system software has been enhanced so that a calibration workorder can be moved to Historical from the Test Results screen as well as from the Calibration Results screen if ordered by rack ID and position.

Exporting Calibration Results

The system software has been enhanced so that Calibration Results can be exported to either a .txt file or an .xml file using the following steps:

- 1. Select Calibration > Calibration Results Overview tab.
- 2. Select **Export**.
- 3. Select **All** or a range of calibration order data using **Calibration Order Data Range** (From and **To**).
- 4. Select the file type:
 - Text
 - XML Data
- 5. Enter a file destination folder as Save in: file location. You can use **Browse** to select a destination file folder.
- 6. Select **Export**.

Verify your file in the destination folder you selected to determine the file contents are in the correct file format.

Recalibration Required Function on the Calibration Summary Screen Restricted to CSE-Login Level

The system software has been enhanced so that the Recalibration Required function is available only to Siemens customer support specialists (CSEs). This function is not available to operators.

The Recalibration Required button is intended for use only when a major hardware component is replaced, for example, replacing the Luminometer.

To avoid the inadvertent deletion of all calibrations, this feature is to be used only in cases where the deletion of all calibrations and observed ranges is intended. In these cases, the reagent lots onboard the system have to be recalibrated.

Maintenance

- Database Backup, which could previously be performed only when the system was in Ready state, can now be performed in any state other than In Process.
- Database Integrity Check maintenance task checks for database corruption (see About Database Integrity Check).

• Database Repair maintenance task repairs corruption found in database integrity check (see About Database Repair).

About Database Integrity Check

Database Integrity Check verifies whether or not the database is corrupted. It is set to run automatically at the following times:

- Daily at 12:00 a.m.
- When the system starts up after an unexpected shutdown.
- After the Database Restore task is performed.

Duration is less than 1 minute if no database corruption is found or approximately 2–3 minutes if there is corruption.

If the system state is In Process, Database Integrity Check fails. If it fails, perform Database Integrity Check manually when the system is not processing.

When Database Integrity Check is in process, it cannot be cancelled, and no other task can be performed. A maintenance log entry is generated each time Database Integrity Check is performed. If database corruption is detected, an error message displays. Perform the Database Repair maintenance activity.

About Database Repair

If Database Integrity Check detects database corruption, perform the Database Repair maintenance task. Duration is approximately 2–10 minutes, depending on the extent of the corruption.

System state must be Disconnected. If the system is in any other state, Database Repair fails.

When Database Repair is in process, it cannot be cancelled, and no other task can be performed.

A maintenance log entry is generated each time Database Repair is performed. If Database Repair is performed and fails to fix the corruption, an error message displays. Contact local Siemens technical support provider. Do not process samples until database corruption is fixed.

Performing Daily Database Maintenance Tasks

Schedule daily maintenance tasks in the following sequence:

- 1. Database Integrity Check
- 2. Database Backup
- 3. Daily Maintenance
- 4. Move to Historical
- 5. Database Archive and Delete

NOTE: Siemens recommends not changing the frequency of these tasks from Automatic to Manual.

Laboratory Information System (LIS)

System Displays Valid Patient Date of Birth

The system software has been enhanced so that workorders coming from the LIS display the patient date of birth correctly.

Messages

QC Scheduler Event Message Enhancement

The system software has been enhanced so that the for Auto-scheduling QC with the QC Scheduler the error message, "EVT_Operation Error" no longer displays.

Patient Identification Information (PID) No Longer Displays in the Event Details Field

The system software has been enhanced so that when patient demographic information for manually-created workorders (for example, date of birth) is edited or saved, the PID information no longer displays in the Event Details screen and in the event log.

QC

Running QC on an Inactive Reagent Pack

The system software has been enhanced to allow for running QC on inactive reagent packs.

NOTE: It is the responsibility of the operator to ensure that, for QC, the correct pack is being used.

Transmission of QC Results to the LIS

The system software has been enhanced so that QC results in error are no longer transmitted to the LIS following the re-establishment of the LIS connection. QC resulting in error will only be transmitted to the LIS when they are resulted.

Deleting QC Definitions

The system software has been enhanced to allow the user to delete old QC definition lots.

Reagents

Immediate Removal of Reagents

The system software has been enhanced to allow for the immediate removal of reagent packs.

Editing and Saving Ancillary Reagent Pack Information

The system software has been enhanced to allow for editing and saving of the ancillary reagent pack information. The volume information and onboard stability of the pack can only be decreased.

Deactivating Reagent Packs

The system software has been enhanced so that the operator can deactivate an onboard reagent pack where the lot is inactive and when there are no tests in process that require that pack.

Automatic Dilution Option (ADO) for the QHBs Assay

The system software has been enhanced to repeat the test with the correct dilution factor for the QHBs assay when the automatic dilution option is triggered by the system.

Reports

Formatting Consolidated Reports

The system software has been enhanced so that the Consolidated Reports can be displayed and printed in either landscape or portrait orientation.

Accessing and Printing the Historical Daily Average Report

The system software has been enhanced so that the historical daily average report can be accessed and printed from the Reagent Status screen.

General Improvements

Multiple PHI Keys no Longer Prevents Software Installation

The system software has been enhanced so when there are multiple PHI keys on the system, the software can be installed.

Date and Time Format Consistently Localized

The system software has been enhanced so that the date and time are formatted correctly for each translation of the user interface.

Sample Integrity Algorithm Change

The system software has been enhanced to change the way that sample integrity is verified and this reduces the frequency of sample integrity errors.

Creating Batch Workorders

The system software has been enhanced to allow for the creation of batch workorders for all rack numbers.

Resolved Issues

For some of the following issues, an Urgent Medical Device Correction/Urgent Field Safety Notice (UMDC/UFSN) or Customer Notification (CN) was issued by Siemens or it was described in previous system software release notes. Because these issues are now resolved, you no longer need to perform the procedures in the published communication.

Onboard Stability for the HBsll Ancillary Reagent

When the Confirmatory assay is enabled on the system, scanning its Master Curve Card will change the OBS of the HBsII ancillary reagent and the reagent to 42 days in accordance with the requirements for the Confirmatory assay Instructions for Use (IFU). The reagent Onboard Stability (OBS) is controlled by the system and therefore cannot be changed.

The IFU for the HBsII ancillary reagent define the Onboard Stability (OBS) as 60 days. However, refer to Customer Bulletin, *Updated Software Issue Information for ADVIA Centaur XPT Software Version 1.2*, dated September 2016, SMN 11223783, Rev. B.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UMDC/UFSN, CSW-15-04.A.OUS, dated November, 2015 Item 17, has been resolved.

Event Log Messages for EHIV Check Ranges

There is a system-defined low limit for the EHIV check range, and the system displays the correct event log messaging related to the check ranges.

There is no need to follow the instructions provided in ADVIA Centaur XPT Software Version 1.5 Release Notes and ADVIA Centaur XPT Software Version 1.5.1 Release Notes for EHIV check ranges.

Editing Infectious Disease (ID) Assay Orders

If the ID assay test is modified in the UI, the ID assay result correctly displays. There is no need to rerun the test order.

There is no need to follow the instructions provided in *ADVIA Centaur XPT Software Version 1.3 Release Notes* for editing ID assay orders.

Daily Cleaning Procedure (DCP) Runs as Expected

The DCP procedure is improved and completes all stages of the DCP.

The issue of sporadic error conditions produced during DCP, reported in CN CSW 20-01.A.US and CN CSW 20-01.A.OUS, has been resolved.

Scanning New Calibration Definitions

The operator was unable to scan new calibration definitions or delete old or expired definitions when the system reached the maximum number of definitions allowed or when there were duplicate lot numbers.

This issue, reported in CN CSW 20-01.A.US and CN CSW 20-01.A.OUS, has been resolved.

Issues Resolved in Version 1.5.1

The following resolved issues were introduced in version 1.5.1 and are included in version 1.6.1:

Editing Control Definitions within the QC Scheduler

Previously, when the QC Scheduler is setup to be enabled by Control, the QC could not be automatically scheduled after editing the QC Definition range that is being used within the QC Scheduler feature.

Now, this happens automatically. You no longer have to use the steps to avoid this issue described in the V1.4 Release Notes documentation.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-16-03.A.OUS and UMDC, CSW-16-03.A.US, dated June, 2016, Item 3, has been resolved.

Editing a QC Profile

When adding a new test to an existing QC profile, in the Orders section of the Edit QC profile screen, the UI now shows all available control levels of a new test.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-17-02.B.OUS and UMDC, CSW-17-02.B.US, dated April, 2018, Item 3, has been resolved.

Uses Correct Onboard Stability (OBS) for Multi-Diluent 15

The system software has been enhanced so that the system is using the correct OBS for Multi-Diluent 15.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-18-01.A.OUS and UMDC, CSW-18-01.A.US, dated December, 2017 Item 1, has been resolved.

Unknown State

Software Processing Error (Unknown State) When Processing a BNP or TSH3-Ultra Onboard Dilution

The system would enter an Unknown state when scanning the Master Curve Card of ADVIA Centaur BNP kit (lots ending in 193 or higher) or ADVIA Centaur TSH3-Ultra (kit lots ending in 301 or higher) and performing an onboard dilution of a sample.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-18-01.A.OUS and UMDC, CSW-18-01.A.US, dated December, 2017 Item 1, has been resolved.

Software Processing Error (Unknown State) Following a Reset Queue

The following system process error (unknown state) has been resolved so that the system does not enter an unknown state when the system transitions from the In Process state to the Ready state while processing a Reset Queue function.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-17-02.B.OUS and UMDC, CSW-17-02.B.US, dated April, 2018 Item 1, has been resolved.

Index Tests with Replicates

The %CV value is not displayed on the UI or in the Printed Report for tests with result type Index when multiple replicates are run.

This issue is now resolved, and you no longer need to perform the procedures in the notification.

Note that UFSN, CSW-16-03.A.OUS and UMDC, CSW-16-03.A.US, dated June, 2016 Item 2, has been resolved.

Avoiding Canceled Tests Due to Expired Calibration

Aspirated samples will no longer be canceled for an assay if the Assign Cal setting is disabled for that assay in the **Setup > Test Definition > Calibration** tab and the associated calibration expired between the time the sample was aspirated and the primary reagent was dispensed.

You do not have to cancel samples if a calibration expired during sample processing.

Processing a Workorder When There are No Unexpired Lots Onboard

Correct system messaging displays if all lots of an assay that are loaded onto the system expire while a workorder requiring that assay is entered. The workorder will be flagged.

Printing Reports to File

In both Traditional and Simplified Chinese, the operator can print reports to the printer or to a file.

Known Issues

The following are known issues in ADVIA Centaur XPT Immunoassay System Version 1.7. Use the suggested actions provided to avoid these issues.

Printing Daily Maintenance Logs

Due to a limitation of the system software, the Maintenance Log does not print when it is filtered and the activity name supplied exceeds 40 characters. In addition, for all Unicode languages, the maintenance logs cannot be printed if they are filtered by activity name.

To avoid this issue, you should not filter the Maintenance Log.

Some Reports Cannot be Exported as .XML

Some reports cannot be exported as .xml files for some languages. These reports include Reagent Status, Calibration Results, and Calibration Summary. However, the reports can be exported as text (.txt file).

Control Bracket QC Must Use Barcodes

If the system cannot read the SID label on the sample tube, you cannot manually enter the QC SID for control brackets.

To avoid issues with QC control bracketed tests, check the label or try a new label from the same control lot.

Visual Status Light Indicator Displays without Other User Notification

The system can display a red status warning light on the instrument, but there is no warning indicator displayed in the user interface. For example, when the QC was out of range, the visual status light on the instrument is red, but no other UI warning (triangle symbol) displays.

Perform the following steps if the visual status light is red, but no UI notification displays:

- 1. Select **QC Statistics**, and select **All** in the drop down menu.
- 2. Determine if there is any QC that is not reviewed.
- 3. Select **Review** for the unreviewed QC.
- 4. Verify that there is no remaining unreviewed QC.
- 5. Select Close.

LAS Subsystem Filtering of Event Log Messages

When filtering the User Event Log for LAS-related messages, select both the Lab Automation and Laboratory Automation Subsystem filters to see all LAS-related events.

Sending ID Test Results after Reconnecting to the LIS

This workaround only applies to systems operating under all of the following conditions:

- Infectious Disease (ID) assays are performed.
- Final Result Rule is disabled for ID assays (initial and repeat results are sent to the LIS).
- The LIS is set to auto-validate results.

If initial and repeat test results are generated while the system is disconnected from the LIS, the first ID test result received after the LIS is reconnected may not be the initial result. Certain LIS systems, such as the CentraLink [™] Data Management System, may auto-validate the first result received if it is not in the repeat range.

Do not process ID tests if the system is not connected to the LIS.

System Remains in the Inprocess State Due to Low Probe Wash

If there is insufficient probe wash on the system, the system remains in the Inprocess state. To avoid the low probe wash situation, make certain that sufficient wash packs are loaded onto the system before processing samples.

To come out of the Inprocess state, either select the Stop Run Immediately option on the System State screen or remove the rack using the Immediate option on the Remove Rack screen.

Cleaning Time when Starting with Dirty Cuvettes

If the state of the cuvettes is either dirty or unknown, then the maintenance procedures, for example the Daily Cleaning Procedure or the Clean Aspirate Probes procedure, take more time to complete. Timing for maintenance procedures is optimized if all the cuvettes are clean.

To minimize the time for completion of the maintenance procedures, use the Diagnostics procedure, Empty and Fill, which requires only 10 minutes, and then perform the desired maintenance procedure.

Supplemental Operating Instructions

Replacing Primary Reagent Packs

CAUTION

Only load and remove reagent packs when prompted by the system and when the LED in the primary reagent compartment turns off. Loading a reagent pack before the system indicates readiness may result in incorrect test results and may require intervention by your service provider.

Removing a reagent pack while the system is aspirating from it causes that pack and all packs that are subsequently aspirated by that probe to be marked as contaminated.

To remove a primary reagent pack, perform the following procedure:

- 1. On the command bar, select **Reagents** > **Primary Reagent Pack**.
- 2. Select a reagent pack and then select **Remove**.
- 3. When the Ready for Removal indicator displays next to the pack, remove the reagent pack.

If the system has pending ID assay results and is disconnected from the LIS, identify any samples that contain ID assays with pending initial and repeat results. Disable auto-validation on the LIS for these samples. If auto-validation cannot be disabled, delete the affected ID assay orders from the system and the LIS before reconnecting to the LIS. After reconnecting, re-order the ID assays and re-analyze them as usual.

ELF Score Interpretation

Starting with software version 1.7, ADVIA Centaur XPT software no longer provides an interpretation alongside the ELF score result. Consult the IFU (SMN 10631073) for the recommended interpretation.

Some Reports Cannot be Exported as .XML

Some reports cannot be exported as .xml files for some languages. These reports include Reagent Status, Calibration Results, and Calibration Summary. However, the reports can be exported as text (.txt file).

Disabling a Test

If you want to disable an assay, ensure that the assay is not part of the QC Scheduler, a profile, or a ratio. Remove it from the QC Scheduler prior to disabling the assay.

Unknown State

The system is designed to display "Unknown State" if an error in software processing occurs. Restart the system following the steps below to resume normal operation.

Follow the instructions in the operator's guide for turning the system off and restarting the system. Siemens recommends the following:

- Ensure that there is enough reagent volume on-board the system before starting sample processing, and avoid having numerous reagent lots that are depleted onboard.
- Ensure that all wash mitigation packs are loaded on the system before starting sample processing to ensure that all samples will be processed successfully.
- Restart the system at least once a week to improve system performance.

When disabling tests, remove the assay from the QC Scheduler, profiles, or ratios prior to disabling the assay in the Test Definition.

If Unknown Status displays during a daily cleaning or rinse operation, shutdown and restart the system, and then repeat the DCP or rinse.

- 1. On the status bar, select **System State**.
- 2. Select Turn System Off.
- 3. At the prompt, select **Yes** to continue.
- 4. Wait while the system powers down.
- 5. Check for obstructions before restarting the system.
- 6. Press the system computer power button.
- 7. Sign in with your user ID and password.
- 8. On the status bar, select **System State**.
- 9. Select Turn Mechanics On.
- 10. Select **OK**, and then select **Yes** at the confirmation window.
- 11. When the system state is Ready, resume operation.

Modifying Enhanced LAS Protocol

Whenever Enhanced LAS Protocol in the LAS Configuration screen is modified (under **Setup** > **LAS Communications** > **Enhanced LAS Protocol**) by using Deselect / Select and saving, it is necessary to select **Mechanics Off / Mechanics On** for the protocol to take effect.

To turn the system mechanics off, and then turn system mechanics on, use the following steps:

- 1. At the workspace, select **System Status**.
- 2. Select Turn System Mechanics Off.
- 3. Select Turn System Mechanics On.

Important Steps Prior to Changing the PHI Key with Active Records

If you need to change the PHI key at any time, be aware that any records (active or historical databases) have to be archived prior to changing the PHI key.

Deleting Master Curve Definitions and Calibrator Material Definitions

The system software has been enhanced so that you can now delete Master Curve definitions and Calibrator Material definitions. Ensure that there are no patient, QC, or calibrator results in the active database before you start to delete either the Master Curve definition or Calibrator Material definition. Make sure that all results have been moved to Historical before you start deletions.

To delete the Calibrator Material definition, go to the Calibration Definition screen, select the Calibration Material definition that you want to delete, and then select **Delete**.

To delete the Master Curve, first delete the associated Calibrator Material Definition, select the Master Curve you want to delete, and then select **Delete**. Then, reboot the workstation.

NOTE: There is a limit (300) to the number of calibration definitions that can be stored on the system. A minimum of one Master Curve for an assay must remain on the system because of the association to the Test Definition.

Scanning the Confirmatory Master Curve Card for HBsAg and HBsIIAg Assays

The system software has been enhanced so that you can now scan multiple 2-D barcodes for the Confirmatory reagent for the HBsAg and HBsIIAg assays.

Scan the barcode sets as follows:

- 1. Scan the first set of barcodes for RgtA (labelled 1, set of 3 barcodes), and then select **Save**.
- 2. Scan the next set of barcodes for RgtB (labelled 2, set of 2 barcodes), and then select **Save**.
- 3. Scan the remaining set of barcodes for Conf (labelled 3, set of 2 barcodes), and then select **Save**.

LAS Supports both Classic and Enhanced Protocol

The system software has been enhanced so that it supports both the original LAS Protocol (also known as "Classic") and the newer LAS Enhanced Protocol. This setting is performed by your technical support provider. The LAS Enhanced Protocol is automatically selected when the software is installed.

To select the Classic Protocol, select **Settings** > **LAS Configuration**. On the LAS Configuration screen, uncheck the LAS Enhanced Protocol checkbox.

Adding Calibrations to the Watchlist Tab on the Test Results Screen

The system software has been enhanced so that you can add currently running calibrations to the Watchlist tab. Under **Test Result > Dashboard: Patient and QC** screen, select the record, and then select **Start Watching...** The Watchlist tab opens. You can then view the watched records.

Improving System Performance for Archiving and Deleting Historical Calibrations

When performing the Archive and Delete Maintenance Task, the historical calibration orders archive and delete should be increased from the default value of 120 days to every 30 days to improve system performance.

To perform this improvement for historical calibration orders, from the Archive and Delete edit screen, select **Archive and Delete**, and then select **30**.

Improving System Performance in General

At least every week, perform a total system reboot to reduce the extraneous memory consumption. To facilitate this action, create a weekly maintenance task. In this way, the system generates a weekly reminder for this task.

Number of Characters for a Control ID is Increased

The system software has been enhanced so that the number of characters for QC control ID in the QC Definition screen is now 20 (previously 11).

Displaying Control Bracket Levels

The system software has been enhanced so that the control bracket levels display when ordering the EHIV QC from the Control Brackets tab for an EHIV test with a modified display name.

When defining Controls on the Add QC Definitions screen for kitted controls, in order to select the appropriate assay, select Kit from the Control Type field menu.

Ordering QC from the Reagent Screen

The system software has been enhanced so that you can quickly order QC. On the **Reagents > Status** tab, select the primary reagent pack, then select **Order QC**.

Exporting Patient Orders and Control Orders

Customers can export patient orders and control orders. The data that can be exported includes the following items:

- Replicate ID
- Replicate Result
- Replicate RLU
- Reagent Lot
- Reagent Pack ID
- Ancillary 1 Pack ID
- Ancillary 2 Pack ID

To export the data for patient orders and control orders, use the following steps:

- 1. Go to Test Results screen, and select Filter.
- 2. Select the sample type **Patient**.
- 3. To select control orders, select **Control**.
- 4. Select Apply.
- 5. Select **Export**.
- 6. On the Test Results Export window, check the Use Results Screen Selections and Filter option.
- 7. On the Test Results Export window, select Export.

These steps export all the patient orders. To export data for a specific date range, select the date range using the Order Date checkbox in the Test Results filter.

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