GeneXpert® Dx 6.5a Software Release Notes

This document contains new information, known limitations, and clarifications not described in the *GeneXpert Dx System Operator Manual*.

Installation and Operation Information

Please refer to the following documents for installation and operation guidance for software version 6.5a:

- GeneXpert Dx Install Instructions, version 6.5, Rev. D (Document No. 302-4071)
- GeneXpert Dx Operator Manual, version 6.5, Rev. C (Document No. 303-3411) for IVD
- GeneXpert Dx Operator Manual, version 6.5, Rev. E (Document No. 302-8378) for CE-IVD
- Windows 11 GeneXpert Dx Multilanguage Flyer (Document No. 303-5234)

The existing version 6.5 documents also apply to version 6.5a, as no changes were made to the instructions from version 6.5.

1. New Features

This patch release includes the following updates:

- Upgraded to the latest version of OpenJDK 8 to incorporate important security enhancements
- The software can now be installed on Windows 11 systems

2. Resolved Issues

The latest release corrects known issues in previous revisions of the software:

- Remote users are now required to enter a password when logging in with LDAP enabled

3. Known Issues

3.1. Create Test

Caution:

Cepheid recommends to always confirm that LIS uploaded results match GeneXpert test results after any changes to the GeneXpert or Host system, including (but not limited to) changes to the following:

- GeneXpert software version
- GeneXpert Assay Definition version
- GeneXpert Host Communication Settings
- Host middleware software or configuration changes
- LIS software or configuration changes

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3.2. Create Test

3.2.1.   Do not scan a barcode into the Patient ID or Sample ID fields in the Create Test dialog box if you have already typed in the field. Scanning a barcode after typing into the field will cause invalid characters to be scanned. To update the Patient ID or Sample ID field, close the Create Test dialog box, select Create Test again, and scan the ID barcode.

3.2.2.   GX Dx 4.6 and higher does not support a combination of BA 4-Plex and BG Duplex Assays.

3.3. Database Conversion

3.3.1.   Database migration issues can be mitigated by performing the following actions:

3.3.1.1.   Run the installer and select custom install
3.3.1.2.   On custom install screen select clean database
3.3.1.3.   Follow on screen instructions to complete the installation of the software
3.3.1.4.   Contact Cepheid Technical Support to convert and restore database

3.4. Localization

3.4.1.   When the GeneXpert software is run in the Russian configuration, file selection dialogs display some text in English instead of being translated into Russian. The affected dialogs are the **Save** dialog during Archive Test, **Open** dialog during Retrieve Test, Database Backup dialog, and **Select File** dialog during Database Restore.

The missing translations are:
"Look In" - "Найти в"
"File Name" - "Имя файла"
"Files of Type" - "Тип файлов"
"Cancel" - "Отменить"
"Open" -"Открыть

3.5. Software License Agreement

3.5.1. During installation, the user may not be able to print the Software license agreement on Windows 11. The user can set the default application for .rtf files to Apache Open Office if it is installed on the system to enable printing before installation. Alternatively, the agreement can be printed after installation by opening the PDF version of the License Agreement from the About Screen within the Dx application.