



Xpert® HIV-1 Viral Load and Xpert® HIV-1 Qual Integration on Existing GeneXpert® Systems

Frequently Asked Questions

Q: Is the Xpert HIV-1 Viral Load assay WHO Pre-qualified?

A: Yes.

Q: Can the Xpert HIV-1 Qual test be used for Early Infant Diagnosis (EID)?

A: Yes, the Xpert HIV-1 Qual test can be used for EID and detection of acute HIV infection. This test is CE-IVD registered and WHO prequalified (WHO PQ) for this purpose.

Q: Are there verification protocols for Xpert HIV-1 Viral Load and Xpert HIV-1 Qual?

A: Yes, these have been developed by the Cepheid Field Applications Support team. Please contact the Cepheid Technical Support Team for more details.

Q: What are the validated sample types for Xpert HIV-1 Qual?

A: The approved sample types for Xpert HIV-1 Qual are Dried Blood Spots (DBS) and Whole Blood (WB).

Q: What are the validated sample types for Xpert HIV-1 Viral Load?

A: The approved sample type for Xpert HIV-1 Viral Load is only plasma derived from whole blood collected in EDTA, EDTA-PPT, or ACD collection tubes.

Q: Can Xpert HIV-1 Viral Load and Xpert HIV-1 Qual tests be processed on existing GeneXpert Systems?

A: Yes.

Q: Do the existing GeneXpert Systems need a hardware upgrade before the Xpert HIV-1 Viral Load and Xpert HIV-1 Qual tests can be processed?

A: No, existing GeneXpert Systems do not need a hardware upgrade.

Q: Do the existing GeneXpert Systems need software upgrades before the Xpert HIV-1 Viral Load and Xpert HIV-1 Qual tests can be processed?

A: Yes, existing GeneXpert Systems need software upgrades to version 4.7b or higher. The Assay Definition Files (ADFs) of Xpert HIV-1 Viral Load and Xpert HIV-1 Qual should be loaded before use.

Q: How much do the software upgrades and Xpert HIV-1 Viral Load and Xpert HIV-1 Qual ADFs cost?

A: The software upgrades and ADFs are provided free of charge by Cepheid and our Authorized Service Providers (ASP).

Q: On a GeneXpert System with 2 or more modules, can Xpert HIV-1 Viral Load or Xpert HIV-1 Qual tests be processed at the same time as a Xpert MTB/RIF test?

A: Yes, Xpert HIV-1 Viral Load or Xpert HIV-1 Qual tests can be processed at the same time as an Xpert MTB/RIF test because the GeneXpert System is a true polyvalent and random access platform with modules that operate independently.

Q: Do existing GeneXpert users require special training to be able to process Xpert HIV-1 Viral Load and Xpert HIV-1 Qual tests?

A: Yes, existing GeneXpert users need to be trained to ensure proper sample preparation, processing and results interpretation/reporting. However, this training is simple and can be provided online/remotely. Please contact your nearest Cepheid representative to get more information.

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