

Xpert® HIV-1 Viral Load Product Comparison

Datasheet — CE-IVD

| | Xpert® HIV-1 Viral Load | Xpert® HIV-1 Viral Load XC |
|----------------------------|--|--|
| Catalog Number | GXHIV-VL-CE-10 | GXHIV-VL-XC-CE-10 |
| Technology | Reverse Transcription Polymerase Chain Reaction (RT-PCR) | |
| HIV-1 Targets | Single target: included in the LTR (Long Terminal Repeat) region | Dual target: target included in the LTR region and addition of POL (polymerase gene) |
| Inclusivity | HIV-1 Group M subtypes: A, B, C, D, CRF01_AE, F, G, H, CRF03_AB, CRF02_AG, J, K; Group N and Group O | HIV-1 Group M: A-D, F-H, J,K, CRF-A/B, CRF-A/E, CRF-A/G, CRF-B/C; Group O, Group N and Group P |
| Test Run Time | Approximately 90 minutes | Approximately 91 minutes |
| CE-IVD Claims | Viral Load monitoring | Viral Load monitoring |
| Collection Media | K2 EDTA or ACD tubes or PPT™ Plasma Preparation Tubes | K2 EDTA and PPT™ Plasma Preparation Tubes |
| Sample Storage | <p>Whole Blood K2 EDTA: RT: 15–30 °C up to 8h; Refrigerate: 2–8 °C up to 3 days</p> <p>Plasma: RT: 15–30 °C up to 24h; Refrigerate: 2–8 °C up to 6 days; Frozen: ≤ -18 °C and ≤ -70 °C for up to 6 weeks</p> | <p>Whole Blood K2 EDTA: RT/Refrigerate: 2–30 °C up to 24h</p> <p>Plasma: RT: 2–35 °C up to 24hr; Refrigerate: 2–8 °C up to 7 days; Frozen: -18 °C and <-70 °C up to 6 weeks</p> |
| Quality Control | <p>Sample Volume Adequacy (SVA)</p> <p>High and Low Internal Quantification Standards (IQS-H/IQS-L)</p> <p>Probe Check Control (PCC)</p> | <p>Sample Volume Adequacy (SVA)</p> <p>High and Low Internal Quantification Standards (IQS-H/IQS-L)</p> <p>Probe Check Control (PCC)</p> <p>Lot Specific Parameters (LSP) for Quantitation</p> |
| Sensitivity | <p>LoD WHO* reference material: 18.3 cp/mL</p> <p>LoD VQA reference material: 15.3 cp/mL</p> <p>HIV-1 Subtype B</p> | <p>LoD: 20 cp/mL</p> <p>LoD WHO# (group M subtype B): 13.6 cp/mL</p> |
| Sample Types | 1mL plasma (K2 EDTA) | |
| Sample Extraction | Automated/Integrated | |
| Precision Pipetting | Single use disposable pipette provided | |
| Quantitative Range | 40 to 10,000,000 cp/mL | |
| Kit Storage | 2–28 °C | |
| Batch or On-Demand | Both | |
| Minimum Batch Size | 1 | |
| Commercial Controls | Contact Cepheid Technical Support for reference to commercially available control material | |
| GX Systems | GeneXpert Dx and Infinity | |
| GX Systems Software | GX Dx software v4.7b and Xpertise software v6.4b or higher | |

* WHO 3rd HIV-1 International Standard (NIBSC code: 10/152)

WHO 4th International Standard for HIV-1 (NIBSC code: 16/194)

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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