**Unitaid/EGPAF Point-of-Care EID Project: Side-by-Side Analysis of Quality Assured POC EID Products**

Updated: 27 June 2018

|  | **Cepheid GeneXpert****Xpert® HIV-1 Qual Assay (EID)** | **Alere Q****HIV-1/2 Detect (EID)** | **Diagnostics for the Real World (DRW)** **Samba II HIV-1 Qual (EID)** |
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| **Cartridge shelf life**: | Currently 12 months from manufacture.  | Currently 9 months from manufacture, working towards longer shelf life | Currently 9 months from manufacture, guaranteeing 6 month from delivery.  |
| **Max throughput**: | 20 tests/day | 8 tests/day | 4 test/day using one Assay module. Possibility to add up another assays module control by the same tablet. |
| **Routine maintenance**: | Daily and monthly cleaning procedures are crucial | Nothing specific | TBD |
| **Storage temperature:** | Shipping at 2-8C, storage at 2-28C. Manufacturers have agreed to ship from point of origin to country ports cold chain.  | Shipping and storage 4-30C | 2-37C for long term storage, -10C to 55C shipping stability (up to 1 month) |
| **Environment for running of tests:** | 15-30C | 10-40C | 10-38C; Rel. humidity: ≤80% @ ≤31ºC, decreasing linearly to 50% RH @ 40ºC (can’t be used in very hot and very humid environment) |
| **Power requirements:** | Requires good and stable power supply, thus would need an external gel battery with each platform | Comes with a built in battery, thus stable power at the testing facility is not required | Requires good and stable power supply, thus we would need to purchase an external gel battery with each platform |
| **Connectivity solution** | TBD | Includes routers, SIM cards, data and transfer, shipping/customs, and support | TBD |
| **Portable**? | No. However, a highly-portable, battery-operated version called the Omni is expected to be released in Q3 2017.  | Yes. (7.8 kg) This means it could be “shared” between multiple sites | No because of power requirement. |
| **Polyvalent capacity***(ie: Can the platform conduct other assay types?):* | Yes, there is potential to use this platform for TB and other viral testing. One consideration here is if there are currently underutilized platforms that are being used for TB, there is potential to add EID to optimize these existing platforms | Currently only HIV-1/2. HIV viral load is in development with planned accelerated WHO PQ submission in Q4 2017. Other viral testing, including filovirus testing (e.g. ebola) in development. | Currently HIV qualitative and HIV viral load semi-quantitative. Dev. stage: Chlamydia and gonorrhea Duplex test, Flu A/B Duplex test |
| **Tests for:** | HIV 1 only | HIV 1 and HIV-2 | HIV 1 only |
| **Type of sample:** | DBS or 100µl of whole blood EDTA (capillary or venous). Note that testing with DBS will require extra time, a warmer, and extra steps to prepare the sample for testing. Due to the power requirements the warmer requires, it is unlikely to be able to be placed at a decentralized facility.  | 25µl of Whole blood EDTA (capillary or venous) | 100µl of Whole blood (capillary or venous) |
| **Time to result:**  | 92 minutes per test. Up to 4 individual tests can be run concurrently. | 52 minutes per test, to be run one test at a time | 120 minutes per test, to be run one test at a time on each Assay module |
| **Waste management:** | Cartridges contain guanidinium thiocyanate, a harmful chemical if release in drainage system and which requires high temperature incineration (TBC). Facilities using this product need access to an incinerator on-site, or regular waste transportation to an incinerator. | TBD, most likely a simple burner is ok. | MSDS not available yet. TBD |
| **Pricing:\*** | GeneXpert-IV platform: $USD 17,500 incl. laptop, (includes a 2-year warranty)Cartridge: $USD 17.95Cost of gel battery (required): $2,500 - $4,000Service and Maintenance:* Two-year warranty included in the purchase price
* $2,900 per year to extend the warranty beyond 2 years, if purchased with the instrument; or
* $6,840 to extend the warranty for 3 additional years, for a total of 5 years, if purchased with instrument; or
* $7,900 to extend the warranty for 3 additional years, for a total of 5 years, if purchased after the instrument is installed.
 | Platform: $USD 25,000, includes battery, modem and printer (includes 1-year warranty)Cartridge: $25.00Service and Maintenance:* One-year warranty included in the purchase price
* $2,500 per year to extend the warranty beyond 1 year, if purchased with the instrument.
* $9,000 to extend the warranty for 4 additional years, for a total of 5 years, if purchased with instrument
 | Platform: Assay Module= $26,750 including tablet, security system, printer & paper (includes 1-year warranty)Cartridges; $37.40 + 10-15% distribution marginHeel prick capillary blood collection kits with EDTA transport microtube included in the cartridge kit.Cost of battery and charger-inverter: TBDService and Maintenance:* One-year warranty included in the purchase price
* $3,250 to extend the warranty for 1 additional year (2 years total)
* $6,500 to extend the warranty for 2 additional years (3 years total)
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| **Recommended testing setting:**  | More suitable for larger, more centralized facilities with increased HR capacity, higher testing volumes, good electricity grid, or possibility to install alternative power backup system, and access to incinerator (TBC) | More suitable for decentralized settings (battery pack, lower throughput) | More suitable for larger, more centralized facilities with increased HR capacity, not too high volumes, but good electricity grid, or possibility to install alternative power |
| **Stringent Regulatory Authority (SRA) approval:** | Cepheid Xpert® HIV-1 Qual Assay (EID):* WHO Prequalified (<http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160613PQPublicReport_0259-0700-00_XpertQualHIV_v2.pdf?ua=1>)
* CE-IVD Mark

(<http://ir.cepheid.com/releasedetail.cfm?releaseid=906875>)  | Alere™ q HIV-1/2 Detect (EID):* WHO Prequalified (<http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160902_amended_public_report_0226_032_00_alere_hiv_detect_v3.pdf?ua=1>)
* CE-IVD Mark

(<http://news.alere.com/~/media/Files/A/Alere-Newsroom-V2/press-release/Alere_q_Detect_CE_IVD_Mark_3_2_2015_FINAL4.pdf>)  | Samba II HIV-1 Qual (EID):* CE-IVD Mark
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\*Note: All platforms procured by EGPAF will include an extended warranty that ensures service and maintenance coverage of the instrument by the manufacturer for five (5) years from the date of installation of the platform. Please contact Esther Turunga for information about the terms of the service and maintenance agreements (eturunga@pedaids.org).

**For more information, please contact Jeff Lemaire, Diagnostic Advisor, EGPAF, Geneva (****jlemaire@pedaids.org****)**