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## Point-of-care (POC)/Near POC virological technologies for HIV Early Infant Diagnosis (EID) and Viral Load (VL) monitoring

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### Background

It is estimated that by the end of 2017, about 1.8 million children were living with HIV worldwide, and approximately 110,000 of the same population have died from AIDS since the inception of HIV/AIDS epidemic.<sup>i</sup> World Health Organization recommends that HIV exposed infants receive a virological test within 6 weeks of birth, followed by antiretroviral treatment initiation for those who are infected.<sup>ii</sup> Regardless of these recommendations, it is estimated that from 2010-2017, only 50% of HIV exposed infants had a virological test by 8 weeks of age worldwide.<sup>iii</sup> Delayed HIV testing could lead to poor health outcomes of HIV infected infants. Early diagnosis and antiretroviral treatment initiation of HIV-infected infants could reduce the risk of AIDS related child mortality by 76%.<sup>iv</sup> Nevertheless, it is estimated that almost 50% of HIV-infected infants die before the age of two with no HIV treatment.<sup>v</sup> Guided by the Strategic Plan for 2018-2021 that aims to ensure that every child survives and thrives (Goal Area 1), UNICEF works with global, regional and country partners to deliver material resources, including point of care/near point of care virological detection technologies, for HIV/AIDS response, centering it on infants, children, adolescents, pregnant women, and mothers.

### Objective

The objective of this bulletin is to provide information on HIV Early Infant and Viral Load POC /near POC nucleic acid detection technologies available for procurement through UNICEF Supply Division.

### Product description

Point-of-care (POC)/Near POC virological technologies for HIV early infant diagnosis (EID) and viral load (VL) monitoring, are automated or semi-automated systems for nucleic acid detection. These systems are integrated and typically comprised of an instrument platform, protocol software, and disposable test cartridges. The cartridges contain all reagents and internal controls required for the assay in a stabilized form and as such each cartridge runs a single test. Samples are applied directly into the cartridges with no further sample processing required. The self-contained cartridges are specific to the platform and protocol software (closed systems). These technologies can reduce the turnaround time for results, detect multiple targets (polyvalent), facilitate decentralization of testing through placement at lower level facilities with limited laboratory infrastructure where it can be operated by a non-laboratory health worker after minimum training.

### Quality Assurance

In the interest of public safety, quality assurance and minimizing risks associated with procurement of In vitro diagnostics, WHO pre-qualification program prequalifies diagnostic tests for diseases which pose high individual and public health risk including HIV diagnostics which are suitable for use in resource limited settings. Therefore, UNICEF

Supply Division procures only WHO pre-qualified HIV diagnostic products which are also compliant with UNICEF Supply Division 2016 IVD technical provisions as well as quality assurance policy. UNICEF will follow WHO post-market surveillance procedures if HIV POC products procured by UNICEF are found to be faulty. Despite WHO pre-qualification, end users are still required to appropriately train personnel on the use of these point of care technologies, and develop and implement quality assurance processes which include, but are not limited to:

- Competence assessment of personnel
- Appropriate documentation of testing activities
- Lot verification testing for continuous quality improvement
- Proficiency assessment of testers
- Verification of performance in their setting following the national HIV testing guidelines

National HIV programs should implement continuous quality improvement and quality assurance processes to ensure the accuracy and precision of test results produced through POC diagnostic technologies.

## Product selection

- In-country product selection will be based on national HIV testing protocols, policies and guidelines.
- Detailed information on quality assurance, product and site selection can be accessed at the following links:
  - English: <http://www.childrenandaids.org/index.php/poc-toolkit-page>
  - French: <http://www.childrenandaids.org/manuel-poc>

## UNICEF Long Term Arrangement (LTAs) for EID and VL POC/near POC technologies

- UNICEF has established LTAs for EID/VL POC/Near POC technologies listed in table 1 using WHO prequalification as a pre-requisite for procurement.
- Table 2 represents a list of products for non-HIV assays which can be performed using the same GeneXpert analyser (material number S0002141 and/S0002142 in table 1) used for EID/VL and are available for procurement through UNICEF Supply Division

## UNICEF Supply Catalogue

- Please refer to UNICEF Supply Catalogue for updated prices and detailed technical information for EID /VL POC/near POC technologies available for procurement through UNICEF. UNICEF Supply Catalogue is available online <https://supply.unicef.org>

Table 1. EID and VL POC/Near POC technologies available for procurement through UNICEF supply division

UNICEF number	Product description	Product code	Kit contents	Specimen type	Site level	Additional Information	Performance characteristics (%)	Indicative price (In USD)
S0002141	GeneXpert IV analyzer with starter kit- Desktop	GXIV-4-D	1x GeneXpert GXIV analyzer, GX4.0SWKIT: warranty 2 years 1x Desktop PC Startup kit, including: 2x Filters 1x PCR slot cleaning brush 2x Tools 1x Dust cover 1x Instructional DVD 1x Quick reference guide 1x Startup guide 1x Connecting cable 1x Instructions for use in English, French, Spanish, Portuguese, Italian, German, Russian and Mandarin Training and Installation included	NA	Near POC	2 years standard warranty included in the product price; 3-years extended warranty (U484650) available at \$7,902/system.	N/A	17,000.00
S0002142	GeneXpert IV analyser with starter kit- Laptop	GXIV-4-L	1x GeneXpert GXIV analyser , and GX4.0SWKIT : warranty 2 years, 1x Laptop PC Startup kit, including: 2 x Filters 1 x PCR slot cleaning brush 2 x Tools 1x Dust cover 1x Training program 1x Instructional DVD 1x Quick reference guide 1x Startup guide	NA	Near POC	2 years standard warranty included; 3-years extended warranty (U484650) available at \$7,902/system.	N/A	17,500.00

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			1x Connecting cables 1x Instructions for use in English, French, Spanish, Portuguese, Italian, German, Russian and Mandarin Training and Installation included					
S0002145	GeneXpert IV, UPS	ABCE 800-22	Uninterrupted Power Supply Unit 2 years warranty 1 x Material safety data sheet 1 x Instruction for use	NA	Near POC	Dedicated UPS to use with item S0002141 GeneXpert IV with starter kit- desktop or with item S0002142 GeneXpert IV with starter kit- laptop.		790.00
S0002144	R2 Hard Case for GeneXpert Diagnosis System	301-0177	R2 Hard Case for GeneXpert Diagnosis System	NA	NA	Dedicated travel case to use with item S0002141 GeneXpert IV with starter kit- desktop or with item S0002142 GeneXpert IV with starter kit- laptop.	N/A	900.00
S0002143	Xpert HIV-1 Viral Load Assay	GX-HIV1-VL-CE-10	Xpert HIV-1 Viral Load Cartridges with integrated reaction tubes - kit 10 tests 10 x Disposable 1ml transfer pipette 1 x CD (instruction for use)  Material Safety Data Sheet (MSDS) and Guideline on safe disposal of cartridges - to be supplied with each order	Plasma	Near POC	Blood collection kits are not included in the kit and must be ordered additionally, in adequate quantity. Suggested material: S0001572 Blood, collection, neonates, set, box/100  A centrifuge might be required for plasma separation <b>Note: The cartridge contains guanidinium thiocyanate as the lysis reagent. This chemical is highly toxic, and all care should be taken</b>	Sensitivity for virological failure at 1000 copies/ml: 94.14 Specificity for virological failure at 1000 copies/ml: 98.5	149.00

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						<b>when using the cartridges in case of spills etc. Please note that as this chemical is also highly toxic to aquatic life, it should be disposed of by incineration above 1000°C. No liquids from the cartridge should be released into the environment.</b>		
S0002147	Xpert HIV-1 Qual Assay	GX-HIV1-QA-CE-10	Xpert HIV-1 Qual Assay cartridges with integrated reaction tubes - kit 10 tests 10 x Qual Assay Sample reagent set 10 x Disposable 1ml transfer pipettes 10 x Disposable 100 µl Transfer Micropipettes 1x CD (Instruction for use) Material Safety Data Sheet (MSDS) and Guideline on safe disposal of cartridges - to be supplied with each order	Whole Blood (WB), Dried Blood Spot (DBS)	Near POC	Blood collection kits are not included in the kit and must be ordered additionally, in adequate quantity. Suggested materials  WB: S0001573 Set, neonate, EDTA 0.2 ml w/capil, box/100  DBS: S0001531 Set, EID, DBS collection, unit, kit/20 The following materials are required for DBS sample processing but are not included in the kit; S0001591 Thermoblock, S0001592 Thermomixer	Sensitivity infants (WB): 98.69 Specificity infants (WB): 100  Sensitivity infants (DBS): 99.34 Specificity infants (DBS): 100  Sensitivity adults: 96 Specificity adults: 100	149.00
S0002130	Alere Q analyzer with starter kit	27030002	Alere q complete - product code 270300002 Containing: 1 x Alere q -product code 270300001 1 x Alere USB printer- product code 270400007 1 x Alere Power Drum- product code 270400004	NA	POC	1-year service and maintenance contract (S0002133) available at \$ 2,500/analyser.	N/A	15,000.00

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			1 x Alere connectivity Pack II- product code 260400016 1x Printer Paper I/10 - product code 260400009 1 x Connectivity pack user guide 1 x Alere q user guide 1 x Alere q detect for EID user guide 1 x Alere q HIV 1/2 EID animation 1 year warranty Training and Installation included					
S0001694	Alere Q analyzer with starter kit	270 300 003	Alere q complete - product code 270300003 Containing : 1 x Alere q -product code 270300001 1 x Alere USB printer- product code 270400007 1 x Alere Power Drum- product code 270400004 1 x Alere connectivity Pack I- product code 260400015 1x Printer Paper I/10 - product code 260400009 1 x Connectivity pack user guide 1 x Alere q user guide 1 x Alere q detect for EID user guide 1 x Alere q HIV 1/2 EID animation 2 years warranty Training and Installation included	NA	POC	2-years standard warranty included; Training and Installation included; 1-year service and maintenance contract (S0002133) available at \$ 2,500/analyser.	N/A	15,000.00
S0002131	Alere Q HIV 1/2 Detect-cartridges kit of 50 tests	270 110 050	Alere q HIV-1/2 Detect Cartridge kit of 50 1 x user guide	WB, plasma	POC	Blood collection kits are not included in the kit and must be ordered additionally, in adequate quantities. Suggested material S0002132 Alere neonatal sample collection kit/100	Sensitivity infants (WB): 98.69 Specificity infants (WB): 100  Sensitivity adults: 94	1,250.00

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							Specificity adults: 100	
S0001695	Alere q HIV 1/2 Detect cartridge kit of 10 tests	270 110 010	Alere q HIV 1/2 detect Cartridge kit of 10 1 x user guide	WB, plasma	POC	Blood collection kits are not included in the kit and must be ordered additionally, in adequate quantities. Suggested material S0002132 Alere neonatal sample collection kit/100	Sensitivity infants (WB): 98.69 Specificity infants (WB): 100  Sensitivity adults: 94 Specificity adults: 100	250.00
S0003316	m-PIMA HIV-1/2 VL cartridge kit of 50 tests	27015- W50	50 x m-PIMA HIV-1/2 VL individual pouched cartridge kit of 50 tests 1 x user guide 60 x individually wrapped disposable 50µl sample transfer tools	Plasma	POC	Blood collection kits are not included in the kit and must be ordered additionally, in adequate quantity. Suggested material: S0001572 Blood, collection, neonates, set, box/100, A centrifuge might be required for plasma separation	Sensitivity for virological failure at 1000 copies/ml: 95.1  Specificity for virological failure at 1000 copies/ml:99.4	1,250.00
S0001234	Alere printer paper, 10 rolls	260 400 009	Printer paper 1, 10 rolls	NA	POC	To be used with Alere SMS printer.	N/A	32.00

S0002132	Alere Neonatal sample collection kit of 100	270 400 200	Neonatal Sample collection kit of 100	NA	POC	Single-use neonatal sample collection kit.	N/A	120.00
S0001698	Alere SMS Printer	GT6000	USB/SMS Printer	NA	POC		N/A	240.00
S0001697	Alere Power Drum	270 400 004	Power Drum	NA	POC	The Alere Power Drum is intended to be used as an external rechargeable backup battery for the Alere Q analyzers (S0002130 and S0001694).	N/A	2,600.00
S0001692	Alere Connectivity Pack I	260 400 015	Connectivity Pack I	NA	POC	Compatible with: Alere Q analyser with starter kit (S0001694)	N/A	550.00
S0001693	Alere Connectivity Pack II	260 400 016	Connectivity Pack II	NA	POC	Compatible with: Alere Q analyser with starter kit (S0002130)	N/A	600.00
S0002133	Alere Q extended warranty, 1 year	N/A	1-year Extended Warranty for Alere q complete	NA	POC		N/A	2,500.00



Table 2. List of products for non-HIV assays which can be performed using the same GeneXpert analyzer (material number S0002141 or S0002142 in table 1 above) used for EID/VL assays and are available for procurement through UNICEF supply division. WHO prequalification was a pre-requisite for selection of HCV cartridges and selection of other cartridges were based on compliance with UNICEF supply division 2016 technical provisions on procurement of in vitro diagnostics and/UNICEF quality assurance policy on procurement of in vitro diagnostics.

UNICEF number	Product description	Product code	Kit contents	Specimen type	Additional Information	Performance characteristics (%)	Indicative price (In USD)
S0002148	Xpert HCV Viral Load Assay	GXHCV-VL-CE-10	Xpert HCV -1 Viral Load Cartridges with integrated reaction tubes - kit 10 test 10 x Disposable 1ml transfer pipette 1 x CD (instruction for use) Material Safety Data Sheet (MSDS)and Guideline on safe disposal of cartridges - to be supplied with each order	Plasma /Serum	Specimen collection consumables not included  Centrifuge might be required for serum/plasma separation. <b>Note: The cartridge contains guanidinium thiocyanate as the lysis reagent. This chemical is highly toxic, and all care should be taken when using the cartridges in case of spills etc. Please note that as this chemical is also highly toxic to aquatic life, it should be disposed of by incineration above 1000°C. No liquids from the cartridge should be released into the environment.</b>	Sensitivity:100% Specificity: 100%	149.00
S0002149	Xpert HPV Assay	GXHPV-CE-10	Xpert HPV assay Cartridges with integrated reaction tubes - kit 10 tests 10 x Disposable 1 ml transfer pipettes x CD with assay definition file and instructions for use  Material Safety Data Sheet (MSDS)and Guideline on safe disposal of	1 Cervical /Endocervical specimen	Specimen collection material required but not included in the kit: PreservCyt® Solution, Broom-like device or an endocervical brush/spatula	Positive percent agreement %: 88.51 Negative percent	149.00

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			cartridges			agreement %: 98.68	
S0001690	Xpert MTB/Rif Ultra Assay	GXMTB/RIF- ULTRA-50	Xpert MTB/Rif Ultra Assay (GXMTB/RIF-ULTRA-50) contains: 50 x Reaction Tubes 50 x Sample Reagent Bottles 60 x Disposable Transfer Pipettes 1 x CD (instruction for use)	Sputum	Screw-cap sterile specimen containers and specimen transfer pipette not included and should be procured separately	Sensitivity: smear- positive/culture- positive: 99.5% smear- negative/culture -positive: 73.3%  Specificity: 95%	499.00
S0001686	Xpert CT/NG 120 Assay	GXCT/NG- CE-120	Xpert CT/NG Assay kit (GXCT/NG-CE-120) contains: 120 x Xpert CT/NG Assay Cartridges with Integrated Reaction Tubes 125 x Disposable Transfer Pipettes 1 x CD (instruction for use)	Vaginal swab Endocervical swab Urine	Specimen collection kits (CT/NGSWAB-50, (CT/NGURINE-50, URINE/A-50) are not included in the kit and must be ordered additionally.	Patient Collected Vaginal Swabs: CT Sensitivity 99.5%, NG Sensitivity 100%, CT Specificity 99.1%. NG specificity 99.9% Endocervical Swabs: CT Sensitivity 96.0%. NG Sensitivity 100%. CT Specificity	1,944.00

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						99.6%. NG specificity >99.9% Male Urine: Sensitivity CT 98.5% Sensitivity NG 98.3% Specificity CT 99.8% Specificity NG 99.9%	
S0001685	Xpert CT/NG 10 Assay	GXCT/NG-CE-10	Xpert CT/NG Assay kit (GXCT/NG-CE-10) contains: 10 x Xpert CT/NG Assay Cartridges with Integrated Reaction Tubes 10 x Disposable Transfer Pipettes 1 x CD (instruction for use)	Vaginal swab Endocervical swab Urine	Specimen collection kits (CT/NGSWAB-10, SWAB/A-10 CT/NGURINE-10, URINE/A-10) are not included in the kit and must be ordered additionally.	Patient Collected Vaginal Swabs: CT Sensitivity 99.5%, NG Sensitivity 100% CT Specificity 99.1%. NG specificity 99.9% Endocervical Swabs: CT Sensitivity 96.0%. NG Sensitivity 100%. CT Specificity 99.6%. NG specificity >99.9%	162.00

						<p>Female Urine: Sensitivity CT 98.1% Sensitivity NG 94.4% Specificity CT 99.8% Specificity NG &gt;99.9% Male Urine: Sensitivity CT 98.5% Sensitivity NG 98.3% Specificity CT 99.8%, Specificity NG 99.9%</p>	
S0001691	Xpert TV Assay, kit/10	GXTV-CE-10	Xpert TV Assay, kit/10 (GXTV-CE-10) contains: 10 x Xpert TV assay 1 x CD (instruction for use)	Vaginal /Endocervical swab Urine	Specimen Collection Kits (SWAB/A-50, URINE/A-50) are not included in the kit and must be ordered additionally.	<p>Endocervical swab: Sensitivity 98.9%. Specificity 98.9% Patient-collected vaginal swab Sensitivity 96.4%. Specificity 99.6% Female urine: Sensitivity 98.4%,</p>	190.00

							Specificity 99.7% Male urine: Sensitivity 89.6%, Specificity 99.3%
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- i. [https://www.aidsdatahub.org/sites/default/files/publication/UNAIDS\\_Data\\_2018.pdf](https://www.aidsdatahub.org/sites/default/files/publication/UNAIDS_Data_2018.pdf)
- ii. [https://apps.who.int/iris/bitstream/handle/10665/44275/9789241599085\\_eng.pdf;sequence=1](https://apps.who.int/iris/bitstream/handle/10665/44275/9789241599085_eng.pdf;sequence=1)
- iii. [http://www.unaids.org/sites/default/files/media\\_asset/miles-to-go\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/miles-to-go_en.pdf)
- iv. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258281/#CR1>