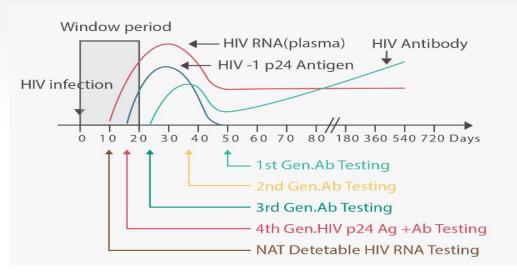


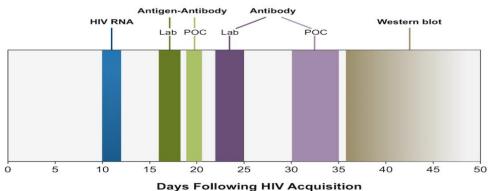
# Advancing Pediatric HIV Care: Introducing the Xpert HIV-1 Qual XC Test

Gwynn Stevens, PhD Director Medical Affairs



## **HIV Diagnostics**





	Antibody test 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> generation	Antigen (p24) + antibody 4 <sup>th</sup> generation	Nucleic acid tests (NAT)
Method	Serology	Serology	Molecular PCR
HIV targets	HIV1/2	HIV1/2	HIV-1 or HIV1/2
Tests detect	IgM, IgG antibodies	HIV p24 plus antigen IgM, IgG antibodies	HIV RNA or RNA/DNA
Age group	Adolescents & adults (post acute phase)	Adolescents & adults (post acute stage)	Early infant diagnosis adolescents & adults acute and later stages
Stage of detection <sup>2</sup>	23 to 90 days after exposure	18 to 90 days after exposure.	10 to 33 days after exposure
Lab test	Plasma, serum	Plasma, serum	Plasma, DBS
RAPID or POC tests	Venous or capillary whole blood, plasma serum or saliva	Venous or capillary whole blood, plasma serum or saliva	Venous or capillary whole blood DBS



HIV NAT tests detect infections earlier in the acute phase versus serology-based tests.

1. Image - https://www.mindray.com/content/xpace/en/media-center/blogs/raising-awareness-finding-hiv-infections-fast.html

Cepheid.

- Table https://www.cdc.gov/hiv/testing/laboratorytests.html
- Table https://www.hiv.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all#page-title



## **HIV Diagnosis**

#### **Adult & adolescents**

- Key populations are disproportionately affected by HIV, and in almost every setting have a higher prevalence and incidence than people outside of these groups
- Almost half of new HIV diagnosis are at the late stage's highlights the need to improve access to testing to diagnose people living with HIV at an earlier stage.<sup>2</sup>
- Early diagnosis and antiretroviral therapy can prevent transmission, benefitting public health as well as reducing the impact to affected individuals<sup>1</sup>
- HIV test and treat models of care in community settings enable Health care providers to reach key populations

#### **Early Infant Diagnosis**

- Trans-placentally transmitted maternal HIV antibody may persist in a child up to 18 months preventing the use of serological testing for diagnosis
- HIV infection in infants <18 months can be definitively confirmed only with HIV NAT (e.g. PCR) testing.
- HIV vertical transmission can occur during pregnancy, childbirth birth and breast feeding<sup>3</sup>
- WHO recommends that **point-of-care nucleic acid** testing should be used to diagnose HIV among infants below 18 months<sup>3</sup>

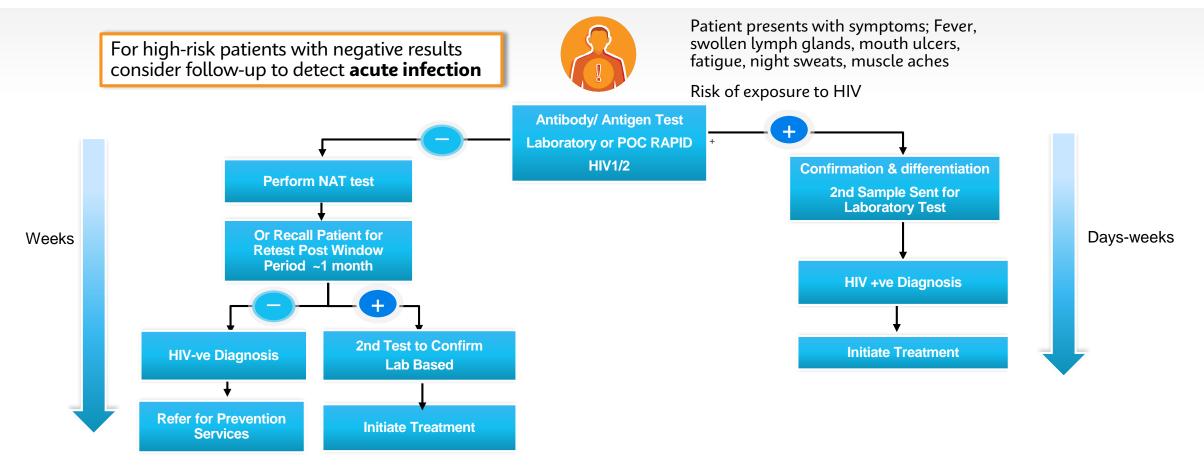




## Near patient testing enables early diagnosis and linkage to care for key & priority populations

1.https://www.ecdc.europa.eu/sites/default/files/documents/HIV-AIDS\_surveillance\_in\_Europe\_2023\_%28\_2022\_data\_%29\_0.pdf
2.Cohen MS, Shaw GM, McMichael AJ, Haynes BF (2011) Acute HIV-1 infection. N Engl J Med 364: 1943–1954. doi: 10.1056/NEJMra1011874 PMID: 21591946 https://www.ncbi.nlm.nih.gov/books/NBK563020
3. Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring https://www.who.int/publications/i/item/9789240022232

## Patient Pathway Adult Adults





Multiple steps in testing process increases time to diagnosis and treatment.



#### HIV in children

- 2.58 million children (≤18 years) are infected with HIV in 2022.
- In 2017, only 51% of all HIV-exposed infants were tested for HIV
- Without testing and treatment, 30% will die before age 1 and >50% will die before age 2.
- A child's likelihood of dying from an AIDS related illness declines by 75% if given antiretroviral treatment within the first 12 weeks of life.

UNICEF. Point-of-care for HIV early infant diagnosis - technical bulletin. Accessed December 2020. <a href="https://www.unicef.org/supply/documents/point-care-hiv-early-infant-diagnosis-technical-bulletin">https://www.unicef.org/supply/documents/point-care-hiv-early-infant-diagnosis-technical-bulletin</a>

Source: UNAIDS 2023 epidemiological estimates..

https://www.unaids.org/sites/default/files/media asset/UNAIDS FactSheet en.pdf https://www.unaids.org/sites/default/files/media asset/FactSheet Children en.pdf https://data.unicef.org/topic/hivaids/global-regional-trends/



https://www.unaids.org/en/resources/presscentre/featurestories/2017/december/20171207\_i nfant-diagnosis

## **Early Infant Diagnosis**

Only Half of HIV-Exposed Babies Are Tested for HIV Before 8 Weeks<sup>1</sup>

8 weeks 50% tested



8 weeks

50% receive results & are treated



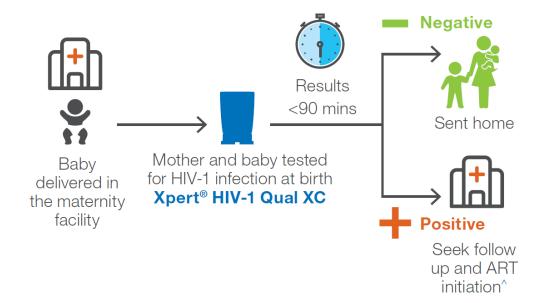
Without treatment, one third of HIV-infected infants will die before their first birthday, and more than 50% will die before reaching two vears old old.<sup>3</sup>

12 months





#### **Xpert** HIV-1 Qual XC Testing Pathway



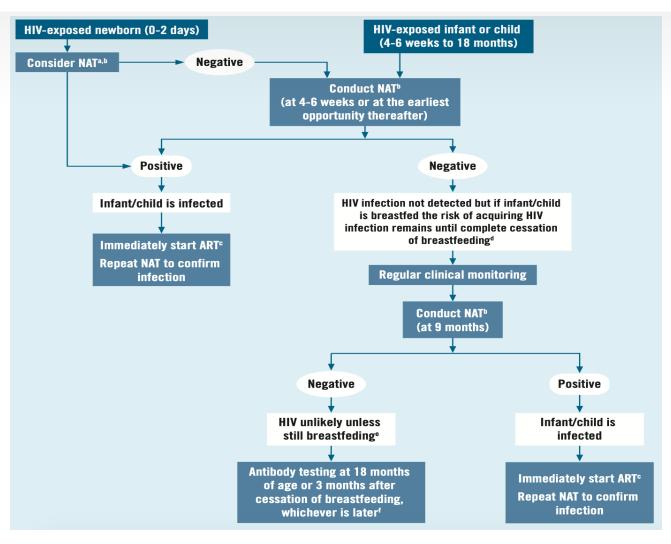


<sup>^</sup> ART: Anti retroviral therapy

<sup>1.</sup> Only half of HIV-exposed babies are tested for HIV. https://www.unaids.org/en/resources/presscentre/featurestories/2019/march/20190325\_gow\_babies

<sup>2.</sup> Lallemant M, et al. Paediatric HIV- A neglected disease? N Engl J Med 2011; 365(7):581-583

## **Early Infant Diagnosis** *Early Infants Diagnosis* < 18 months



## EID testing recommended at multiple timepoints

- Birth (where of value)
- 6 weeks old
- 9 months old
- Any time HIV exposed infants present sick
- Diagnosis is not completed without "final diagnosis" at the end of the period of risk for transmission

#### Notes:

- a. Based on 2016 WHO Consolidated ARV Guidelines, addition of NAT at birth to the existing testing algorithm can be considered.
- b. POC NAT can be used to diagnose HIV infection as well as to confirm positive results.
- c. Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase: retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.
- d. For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.
- e. The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.
- f. If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

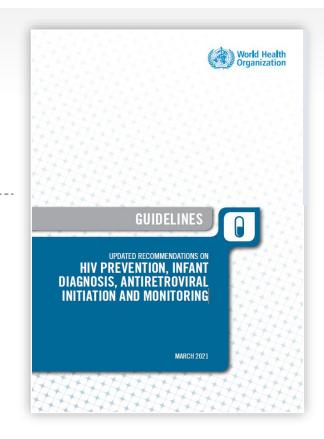
#### WHO Guidelines 2021

#### Point-of-care infant diagnosis recommendation

#### **WHO Recommendation**

Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age (strong recommendation; high-certainty evidence)

- Decentralization of ART or strengthening of referral systems for ART initiation remain of critical importance to ensure impact on infant outcomes.
- Point-of-care infant diagnosis technologies should be considered and used within the current infant diagnosis algorithm at any point when a NAT is required.
- Access to high-quality diagnostic testing should be continually expanded across HIV and other molecular testing needs.
- Ensure adequate human resources, training, service and maintenance and quality assurance.







## 3. Product Overview



## Product Overview: Xpert® HIV-1 Qual XC



#### **Intended Use**

The **Xpert**® **HIV-1 Qual XC** is an in vitro nucleic acid amplification test for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) **total nucleic acids**, on the automated GeneXpert® System.

The test is used to detect HIV-1 in human dried blood spots (DBS) and EDTA capillary or venous whole blood(WB) specimens from individuals suspected of HIV-1 infection. Xpert HIV-1 Qual XC is intended to aid in the diagnosis of HIV-1 infection in infant, adolescent, and adult populations.

The test is intended to be used by laboratory professionals, trained healthcare professionals, or other healthcare workers. This test may be used in laboratory or **near-patient testing environments**.

Refer to most current package insert for Xpert® HIV-1 Qual XC 302-3767

#### **Xpert® HIV-1 Qual XC**

Targets	LTR and POL region of the HIV-1 genome	
Sample Types	100ul K2 EDTA capillary or venous WB; 1x DBS	
Time to Result	WB: 79 min, DBS: 91 min (EAT* WB: 63 min, DBS: 76 min)	
Workflow	Sample added directly to cartridge	
CE-IVD Part Number	GXHIV-QA-XC-CE-10	
Software Version	GeneXpert Dx–Version 4.7b or higher GeneXpert Infinity – Xpertise™ 6.4b or higher	
Onboard Internal Controls	Sample Adequacy Control (SAC) Sample Processing Control (SPC) Probe Check Control (PCC)	



<sup>\*</sup>Early Assay Termination

<sup>•</sup> CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States © 2024 Cepheid.

## **Key Features & Performance Specifications**

	Xpert® HIV-1 Qual XC	00045678901245	
Technology	Real-time RT-PCR	Constraint.	
Intended Use	<b>The Xpert® HIV-1 Qual XC</b> is an in vitro nucleic acid amplification test for the qualitative detection of HIV-1 total nucleic acids in human dried blood spots (DBS) and EDTA capillary or venous whole blood(WB) specimens from individuals suspected of HIV-1 infection.		
Claim	Diagnostic and near patient test for infant, adolescent and adult populations		
Targets	LTR and POL region of the HIV-1 genome		
Inclusivity	HIV-1 Group M subtypes A, D, F, G, H, K, Circulating recombinant forms CRF-A/E, CRF-A/G, CRF-B/C, CRF06 and HIV-1 Group O		
LOD	161 copies/ml for WB, 706 copies/ml for DBS, Depending on HIV-1 group and subtype*		
Sample Type	nple Type 100ul K2 EDTA capillary or venous WB; 1x DBS		
Time to Result	to Result WB: 79 min, DBS: 91 min (EAT WB: 63 min, DBS: 76 min)		
Catalog Numbers: CE-IVD	Numbers: CE-IVD GXHIV-QA-XC-CE-10		
WHO Pre-qualified	Pre-qualified January 2024		

Refer to most current package insert for Xpert® HIV-1 Qual XC 302-3767



<sup>•</sup> CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States

## **Xpert** HIV-1 Qual XC Improved Performance





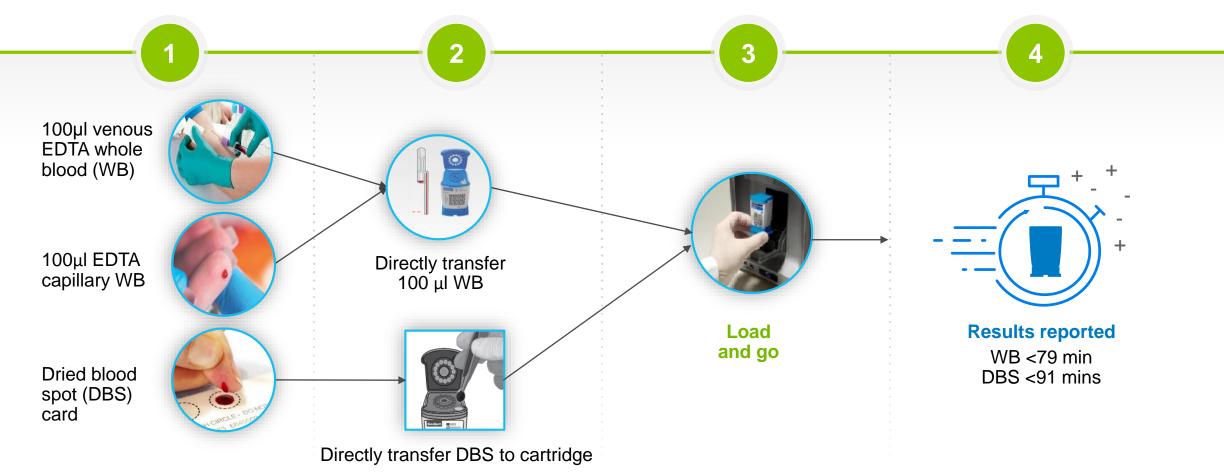
Refer to most current package insert for Xpert® HIV-1 Qual XC 302-3767

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



## Xpert HIV-1 Qual XC1

Simple Workflow, Flexible Throughput, and Fast Results





Fast, simple process with no need for pretreatment of DBS or whole blood.

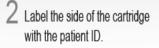
1. Package insert for Xpert® HIV-1 Qual XC 302-3767



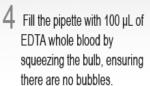
## Workflow-Xpert® HIV-1 Qual XC

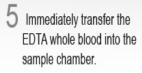
#### Whole blood





3 Open the cartridge lid.







Start the test within 4 hours.















© 2021 Cepheid. All rights reserved.



( | IVD | In Vitro Diagnostic Use In vitro medical diagnostic device. May not be available in all countries.

302-6884 Rev. A June 2021



## Workflow-Xpert® HIV-1 Qual XC

#### Dried blood Spot

Label the side of the cartridge with the sample ID. 2 Open the cartidge lid.

3 Using sterilized scissors, cut out one DBS from the filter paper card following the dashed line. If the dashed line is perforated, use tweezers to detach the DBS.

4 Using tweezers, insert the DBS into the sample chamber.

5 Push DBS down until it reaches the bottom of the chamber with tweezers.

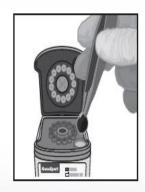
6 Close the cartridge lid.

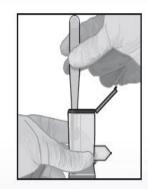
Start the test within 4 hours after adding the sample.



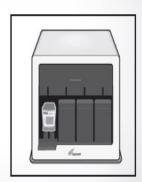












© 2021 Cepheid. All rights reserved.



vitro Diagnostic Use In vitro medical diagnostic device. May not be available in all countries.

302-6884 Rev. A June 2021





6. Key References



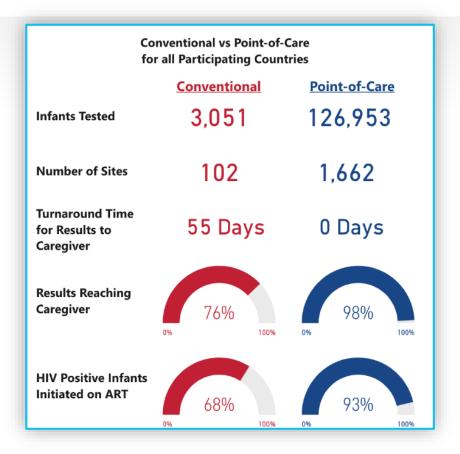
## The Impact of Near-Patient Testing for Early Infant Diagnosis

**EGPAF study in 9 African countries** tested 130,000 HIV-exposed infants and linked positives to early treatment

 Côte d'Ivoire, Cameroon, Kenya, Rwanda, Zambia, Zimbabwe, Mozambique, Eswatini, Lesotho

## Compared POC EID to conventional centralised EID testing

- Access to POC EID increased >six-fold while containing costs and ensuring operator proficiency
- 98% results were returned to the care giver in the same-day and 93% of infants initiated on ART





With POC EID 93% of HIV-infected infants initiated on HIV compared with just 43% using centralized lab-based testing.<sup>1,2</sup>



<sup>1.</sup> https://www.pedaids.org/our-expertise/prevention-of-mother-to-child-hiv-transmission/point-of-care-diagnostics Accessed 04 June 2021 2. https://www.pedaids.org/wp-content/uploads/2020/12/Screen-Shot-2020-12-21-at-3.50.49-PM.png Accessed 04 June 2021

## Performance of Xpert HIV-1 Qual XC

Diagnostic Accuracy Study



#### Next-generation point-of-care testing in pediatric human immunodeficiency virus infection facilitates diagnosis and monitoring of treatment

Nomonde Bengu, MDa,b, Noxolo Mchunu, BSc Honsa,c, Sijabulile Mokhethi, BAa,d, Rowena Fillis, MBChB, FCPaedc, Gabriela Cromhout, MBChB, MSc, TMIH, DTM&Ha,\* D Jeroen van Lobenstein, MBChB, FCPaed<sup>d</sup>, Yeney Graza, MD<sup>d,</sup>Constant Kapongo, FCPaed<sup>b</sup>, Kogielambal Chinniah, FCPaedse, Roopesh Bhoola, MBChB, FCPaedse, Emily Adland, PhDf, Mari C. Puertas, PhD<sup>9</sup>, Thumbi Ndung'u, PhD<sup>a,h,i,j</sup>, Javier Martinez-Picado, PhD<sup>g,k,l,m</sup>, Moherndran Archary, MBChB, FCPaeds, PhDn, Philip J. R Goulder, MBChB, FRCPCH, PhDaf

No discrepancies were observed using 2 Xpert tests or the SoC test in the 224 neonates studied, but only 95% of the SoC test results were generated compared with 100% of the PoC test results (P = .0009)..

The cycle threshold values for the research use only (RUO) assay were the lowest of the 3 assays (P < .0001 in each case).

A field evaluation of a new PoC test (Cepheid Xpert<sup>®</sup> HIV-1 Qual XC RUO) to determine whether this test improves EID and assists the management of children living with human immunodeficiency virus (HIV) infection.

Detection of HIV using the Xpert® HIV-1 Qual XC RUO and Xpert® HIV-1 Qual tests were compared in 224 infants with the SoC DBS Roche COBAS® HIV-1/HIV-2 test. The same 2 PoC tests were also evaluated in 35 older children who had initiated cART before 21 days of age and maintained undetectable plasma viremia for a mean of 25 months.



The Xpert HIV-1 Qual XC assay outperforms Xpert HIV-1 Qual in detecting HIV-1 infection.



#### Performance and Useability of Xpert HIV Qual XC

Near patient setting versus in centralised

Usability of HIV-1 Assay Using DBS for Early Infant Diagnosis in Field Settings in Kenya

Gloria Wandera, Priska Bwana, A,\* and Matilu Mwau

#### IMPACT STATEMENT

Dried blood spots taken for early diagnosis of HIV in infants require transportation to distant reference laboratories for testing. Transportation is costly and unreliable. Long test-to-result turnaround times worsen outcomes for the infants. The Xpert HIV-1 Qual assay is an accurate point-of-care test that runs on the GeneXpert platform using dried blood spots. In this study, we show that its usability characteristics are excellent. If rolled out, it could significantly reduce test-to-result turnaround time and improve the management of HIV-exposed infants.

Performance and useability comparison of Xpert HIV Qual XC in near patient setting versus Roche CAP/CTM HIV-1 Qual in centralised

- 263 DBS samples
- 100% corelation of Xpert HIV-1 Qual XC with Roche CAP/CTM
- Same day results versus ~ 16 days with centralised
- All users reported that the machine was easy to use, the workflow was simple, and the test results were easy to read and interpret.
- The improved Xpert HIV-1 Qual XC assay is highly accurate, has a simple workflow, and is easy to use and easy to interpret.

Wandera et al 2022 J Appl Lab Med. 2022 Sep 1;7(5):1120-1130. doi: 10.1093/jalm/jfac026.

#### Xpert HIV-1 Qual XC

#### Improved Workflow, Flexible Throughput, and Fast Results





Fast, simple process with no need for pretreatment of DBS or whole blood.

Refer to most current package insert for Xpert® HIV-1 Qual XC 302-3767

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





Articles & Issues ♥ Collections For Authors ♥ Journal Info ♥

SUPPLEMENT ARTICLE

#### Strengthening Existing Laboratory-Based Systems vs. Investing in Point-of-Care Assays for Early Infant Diagnosis of HIV: A Model-Based Cost-Effectiveness Analysis

McCann, Nicole C. BA<sup>a</sup>; Cohn, Jennifer MD, MPH<sup>b,c</sup>; Flanagan, Clare MPH<sup>a</sup>; Sacks, Emma PhD<sup>a</sup>; Mukherjee, Sushant MBA<sup>d</sup>; Walensky, Rochelle P. MD, MPH<sup>a,c,f,g</sup>; Adetunji, Oluwarantimi MS<sup>d</sup>; Maeka, Kenneth K. SDMLT (Virology), MComPM<sup>b</sup>; Panella, Christopher BA<sup>a</sup>; Chadambuka, Addmore MPH<sup>b</sup>; Mafaune, Haurovi MPH<sup>b</sup>; Odhiambo, Collins PhD<sup>b</sup>; Freedberg, Kenneth A. MD, MSC<sup>a,c,f,g</sup>; Ciaranello, Andrea L. MD, MPH<sup>a,c,f,g</sup>

Author Information ©

JAIDS Journal of Acquired Immune Deficiency Syndromes 84():p S12-S21, July 1, 2020. | DOI: 10.1097/QAI.000000000002384



SUPPLEMENT ARTICLE

#### Estimating the Cost of Point-of-Care Early Infant Diagnosis in a Program Setting: A Case Study Using Abbott m-PIMA and Cepheid GeneXpert IV in Zimbabwe

Mukherjee, Sushant MA, MBA<sup>a</sup>; Cohn, Jennifer MD, MPH<sup>a</sup>; Ciaranello, Andrea L. MD, MPH<sup>cd</sup>; Sacks, Emma PhD<sup>a</sup>; Adetunji, Oluwarantimi MS<sup>a</sup>; Chadambuka, Addmore MPH<sup>e</sup>; Mafaune, Haurovi MPH<sup>e</sup>; Makayi, McMillan MBA<sup>e</sup>; McCann, Nicole BA<sup>cd</sup>; Turunga, Esther MBA<sup>b</sup>
Author Information ⊗

JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

rticles & Issues 🗸 Collections For Authors 🗸 Journal Info 🗸

SUPPLEMENT ARTICLE

#### Strengthening Existing Laboratory-Based Systems vs. Investing in Point-of-Care Assays for Early Infant Diagnosis of HIV: A Model-Based Cost-Effectiveness Analysis

McCann, Nicole C. Ba<sup>A</sup>; Cohn, Jennifer MD, MPH<sup>A</sup>C. Flanagan, Clare MPH<sup>A</sup>; Sacks, Emma PhD<sup>A</sup>; Mukherjee, Sushant MBA<sup>A</sup>; Walensky, Rochelle P. MMD, MPH<sup>A-C,E</sup>; Adetunji, Oluwarantimi MS<sup>A</sup>; Maeka, Kenneth K. SDMLT (Virology), McComPM<sup>h</sup>; Panella, Christopher BA<sup>A</sup>; Chadambuka, Addmore MPH; Mafaune, Haurovi MPH; Odhiambo, Collins PhD; Freedberg, Kenneth A. MD, MSC-A<sup>A-C,E</sup>, Giranello, Andrea L. MD, MPH<sup>A-C,E</sup>

Author Information ⊙

> BMC Public Health. 2019 Jun 11;19(1):731. doi: 10.1186/s12889-019-6990-z.

#### Point-of-care HIV testing best practice for early infant diagnosis: an implementation study

Elizabeth Spooner  $^1$  , Kerusha Govender  $^2$  , Tarylee Reddy  $^3$  , Gita Ramjee  $^4$  , Noxolo Mbadi  $^5$  , Swaran Singh  $^5$  , Anna Coutsoudis  $^6$ 

Affiliations + expand

PMID: 31185962 PMCID: PMC6560857 DOI: 10.1186/s12889-019-6990-z



EPIDEMIOLOGY AND SOCIA

#### Modeling the cost-effectiveness of point-of-care platforms for infant diagnosis of HIV in sub-Saharan African countries

Salvatore, Phillip P.\*; de Broucker, Gatien<sup>b</sup>; Vojnov, Lara<sup>c</sup>; Moss, William J.\*.<sup>a,b</sup>; Dowdy, David W.\*.<sup>a,b</sup>; Sutcliffe, Catherine G.\*.<sup>b</sup>
Author Information ⊗

AIDS 35(2):p 287-297, February 2, 2021. | DOI: 10.1097/QAD.000000000002739

> Lancet HIV. 2019 Mar;6(3):e182-e190. doi: 10.1016/S2352-3018(18)30328-X. Epub 2019 Feb 5.

#### Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study

Simone C Frank <sup>1</sup>, Jennifer Cohn <sup>2</sup>, Lorna Dunning <sup>3</sup>, Emma Sacks <sup>4</sup>, Rochelle P Walensky <sup>5</sup>, Sushant Mukherjee <sup>4</sup>, Caitlin M Dugdale <sup>5</sup>, Esther Turunga <sup>6</sup>, Kenneth A Freedberg <sup>7</sup>, Andrea L Ciaranello <sup>8</sup>

Affiliations + expand



SUPPLEMENT ARTICLE

#### The Cascade of Care From Routine Point-of-Care HIV Testing at Birth: Results From an 18-Months Pilot Program in Eswatini

Khumalo, Philisiwe Ntombenhle PGDipPH<sup>a</sup>; Sacks, Emma PhD<sup>b</sup>; Chouraya, Caspian MBChB, MSC<sup>c</sup>; Tsabedze, Bhekisisa MPH<sup>a</sup>; Masuku, Thembie MSC<sup>c</sup>; Nyoni, Gcinile BSN<sup>c</sup>; Zikalala, Tandzile BMLT<sup>c</sup>; Nhlabatsi, Bonisile MPH<sup>a</sup>; Mthethwa, Nobuhle MCUR<sup>c</sup>; Cohn, Jennifer MD, MPH<sup>a</sup>

JAIDS Journal of Acquired Immune Deficiency Syndromes 84():p \$22-\$27, July 1, 2020. | DOI: 10.1097/QAI.000000000002380

> Lancet HIV. 2019 Jun;6(6):e373-e381. doi: 10.1016/S2352-3018(19)30033-5. Epub 2019 Apr 12.

#### Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries

Flavia Bianchi <sup>1</sup>, Jennifer Cohn <sup>2</sup>, Emma Sacks <sup>3</sup>, Rebecca Bailey <sup>2</sup>, Jean-Francois Lemaire <sup>2</sup>, Rhoderick Machekano <sup>3</sup>; EGPAF POC EID Study Team



Articles & Issues ♥ Collections For Authors ♥ Journal Info ♥

#### SUPPLEMENT ARTICLE

#### Impact of Routine Point-of-Care Versus Laboratory Testing for Early Infant Diagnosis of HIV: Results From a Multicountry Stepped-Wedge Cluster-Randomized Controlled Trial

Sacks, Emma PhD<sup>Ab\*</sup>; Cohn, Jennifer MD, MPH<sup>c\*</sup>; Ochika, Bernard MPH<sup>c</sup>; Mafaune, Haurovi MPH<sup>c</sup>; Chadambuka, Addmore PhD<sup>c</sup>; Odhiambo, Collins PhD<sup>d</sup>; Masaba, Rose MD<sup>c</sup>; Githuka, George MBChB<sup>c</sup>; Mahomva, Agnes MBChB, MPH<sup>b</sup>; Mushavi, Angela MBChB, MMed<sup>h</sup>; Lemaire, Jean-Francio MSC<sup>c</sup>; Bianchi, Flavia MSC<sup>c</sup>; Machekano. Rhoderick PhD. MPH<sup>b</sup>

Author Information @

JAIDS Journal of Acquired Immune Deficiency Syndromes 84():p S5-S11, July 1, 2020. | DOI: 10.1097/QAI.0000000000002383

#### SUPPLEMENT ARTICLE

#### Challenges in the Early Infant HIV Diagnosis and Treatment Cascade

Lynne M. Mofenson, MD, a Jennifer Cohn, MD, bc and Emma Sacks, PhDa





Research Article 🙃 Open Access 🙃 👣

Point-of-care testing can achieve same-day diagnosis for infants and rapid ART initiation: results from government programmes across six African countries

Caroline E Boeke 🔀 Jessica Joseph 🔀 Melody Wang 🔀 Zelalem M Abate 🛣 Charles Atem 🔀 Khady Diatou Coulibaly 🛣 Adisu Kebede 🕱 Brianán Kiernan 🛣 ... See all authors 🗸

First published: 21 March 2021 | https://doi.org/10.1002/jia2.25677 | Citations: 7





## In Closing