

Overview of self-testing/self-sampling devices and diagnostic technologies for HIV, STIs & viral Hepatitis

Irith De Baetselier

Institute of Tropical Medicine, Belgium

Clinical Reference Laboratory

Disclosures

- I received funding from the Flemish government to develop the Collect2Know device
- Otherwise no disclosures to report

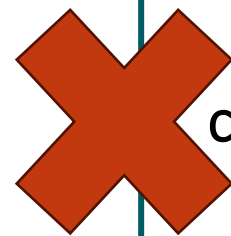


Content

- Focus on **online home-based self-sampling or self-testing methods**



- If you want to implement a remote online testing method, what factors do you need to consider in terms of the **diagnostic accuracy of the test and its feasibility in the laboratory?**





Public Health and User challenges and opportunities



Before we start...Let's get the definitions straight!

- **Online STI testing or internet-based testing service:** Use of digital technologies to deliver self-sampling or self-testing directly to health service users

	Self-sampling 	Self-testing 
Location	Various locations – home or clinic	Usually at home
Procedure	Collecting samples at home and sending them to a lab or clinic for testing.	Collecting samples and requiring a diagnostic test kit or device to perform the test.
Time to results	A few days	Immediately
Results	Delivered by healthcare professionals	Self-interpretation
Follow-up care	Through healthcare professionals when the individuals return for results and treatment.	May be difficult due to the lack of interaction with healthcare professionals.

Different kind of options for online HIV/STI testing

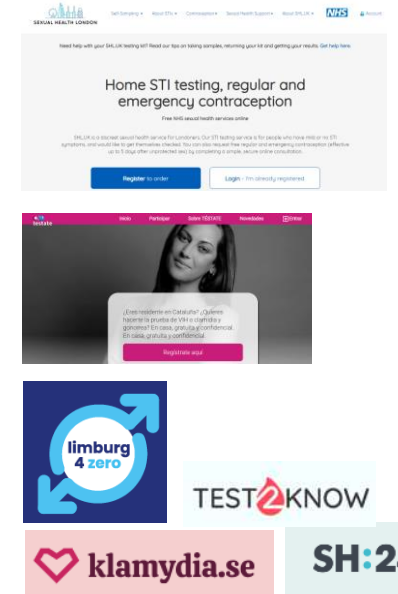


1. Take away: Mix between OPSS & physical consultation



- Quality of sample collection is guaranteed and no influence of shipment on sample quality
- Tested in a certified laboratory
- Results via phone or online platform

Different kind of options for online HIV/STI testing



2. Delivery: Online Postal Self-Sampling or OPSS and is the most often used option



- Samples taken by the individual itself
- Transport of the samples via courier or regular mail
- Samples are tested in certified laboratory
- Results via online platform or via phone



Challenges of Online Postal Self-Sampling HIV/STI services from a lab perspective

Factors affecting quality of laboratory results → principles of quality management in a certified laboratory



- Self-sampling devices should be CE certified and validated for self-sampling
- Validation of laboratory assays
- Temperature and transport conditions should be validated!
 - Differences between countries

**Include the laboratory
asap in your program
to guarantee the
results!!**




Self-sampling devices for HIV/STI

What is on the market?



Blood collection devices

Review



OPEN ACCESS

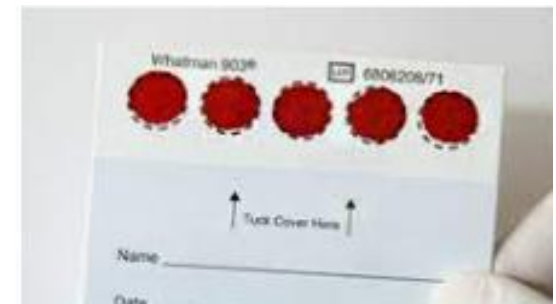
Access to, usage and clinic outcomes of, online postal sexually transmitted infection services: a scoping review

Kirsi Sumray,¹ Karen C Lloyd ,² Claudia S Estcourt ,³ Fiona Burns ,⁴
Jo Gibbs ²

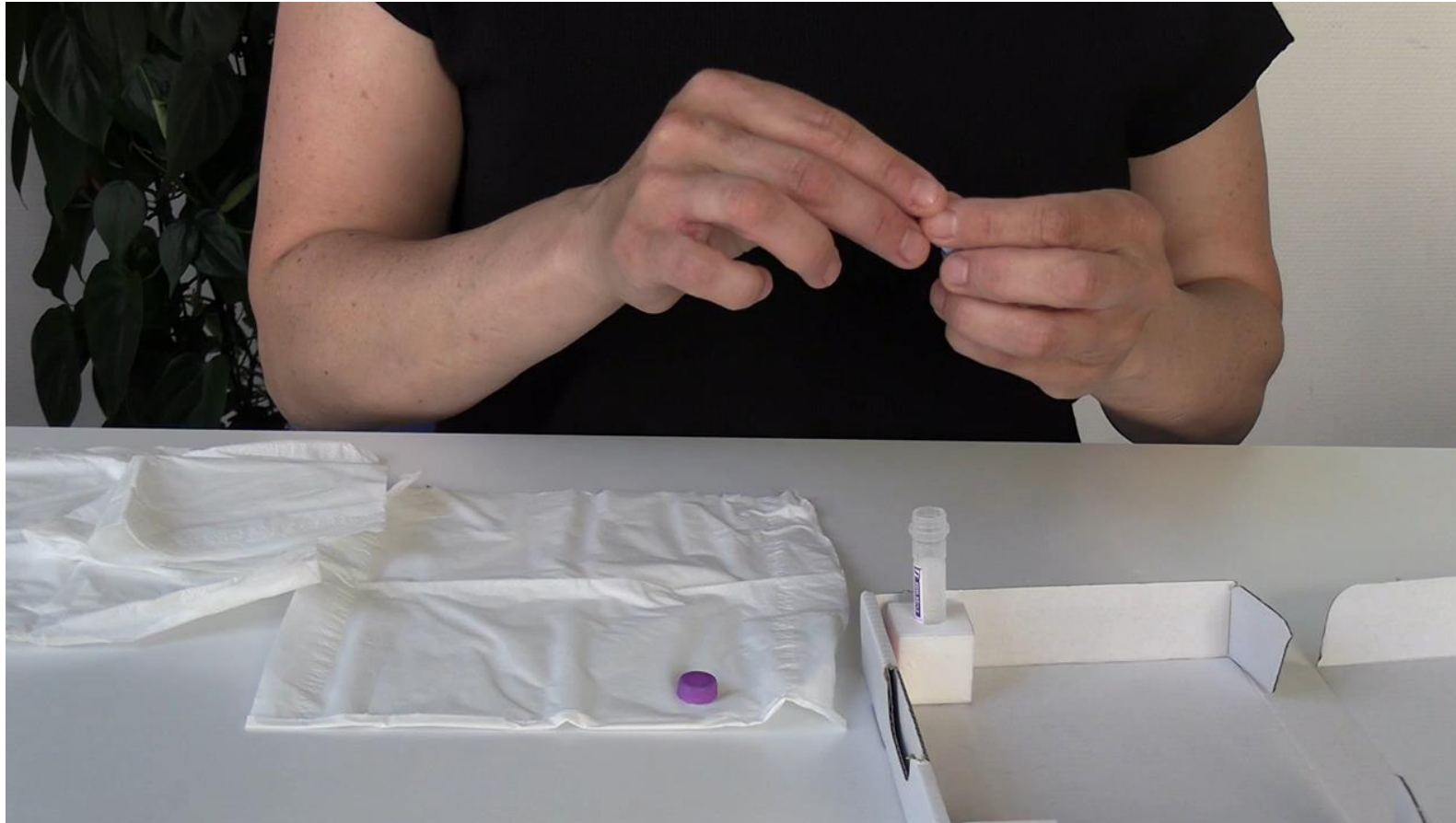
Blood sampling poses one of the biggest challenges for OPSS users

Most blood-based postal sampling kits use the following methodology:

- Standard lancet (addition of 2-3 in the package) and collection of blood via “free-fall” or via a capillary tube
- Microtainer
- Dried Blood Spots or DBS





Blood collection devices – microtainer



- Prone to errors
- Pricking not standardized
- Milking finger
- Unhygienic

Are all blood-based postal sampling kits the same? A comparative service evaluation of the performance of dried blood spot and mini tube sample collection systems for postal HIV and syphilis testing

Matthew Page ^{1,2}, Sowsan Atabani,³ Joseph Arumainayagam,⁴ Steven Wilson,³ Daniel Hartland,⁵ Stephen Taylor ^{1,2}

Blood collection devices

- 5670 STI postal kit requests reviewed (2016-2019)
 - Successful processing rates
 - DBS: 94,6%
 - Microtainer: 54,4%
 - False-positive rates

Blood collection system	STI tested	Reactive tests, n (%)	Confirmed reactive tests, n (%)	False positive, n (%)
MT	HIV	35/561 (6.2)	1/30* (3.3)	29/556* (5.2)
DBS	HIV	13/2583 (0.5)	1/11* (9.1)	10/2582* (0.4)
<i>p</i> value	–	<0.001	0.470	<0.001
Percentage difference (95% CI)		–5.7 (–7.8 to –3.7)	5.8 (n/a)	–4.8 (–6.7 to –3.0)
MT	STS	6/544 (1.1)	4/6 (66.7)	2/544 (0.4)
DBS	STS	17/2579 (0.7)	16/16* (100.0)	0/2578* (0.0)
<i>p</i> value	--	0.271	0.065	0.030
Percentage difference (95% CI)		–0.4 (–1.4 to 0.5)	33.3(n/a)	–0.4 (n/a)

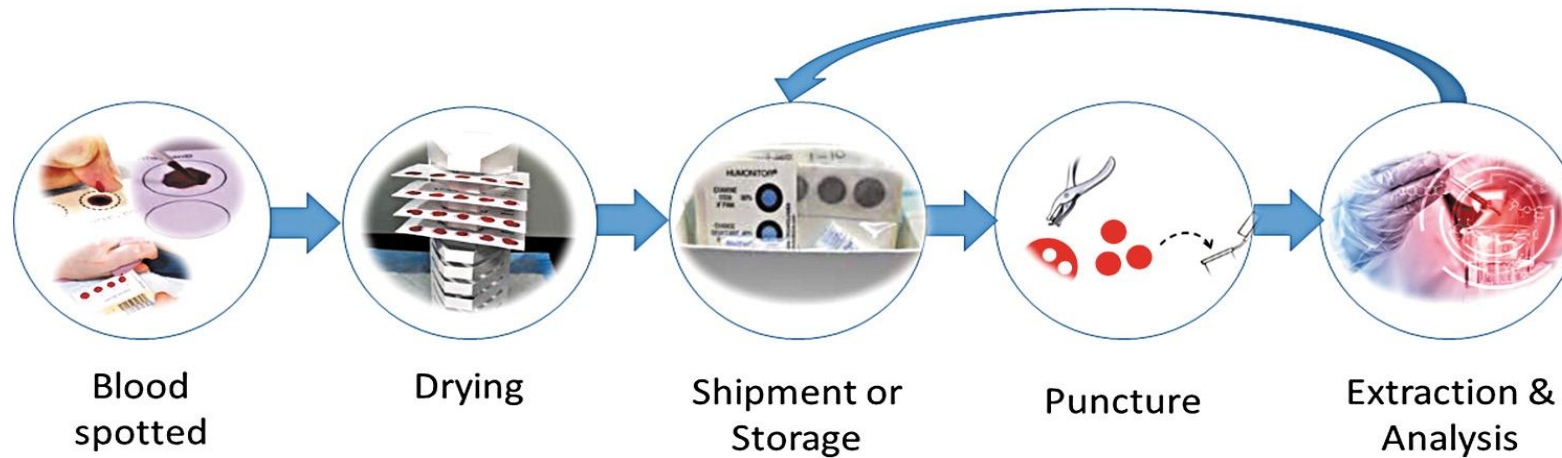
MT: Microtainer, STS: Syphilis treponemal serology

→ Need for confirmation assays



Blood collection devices – Dried blood spots

Dry Blood Spot Card Usual Workflow



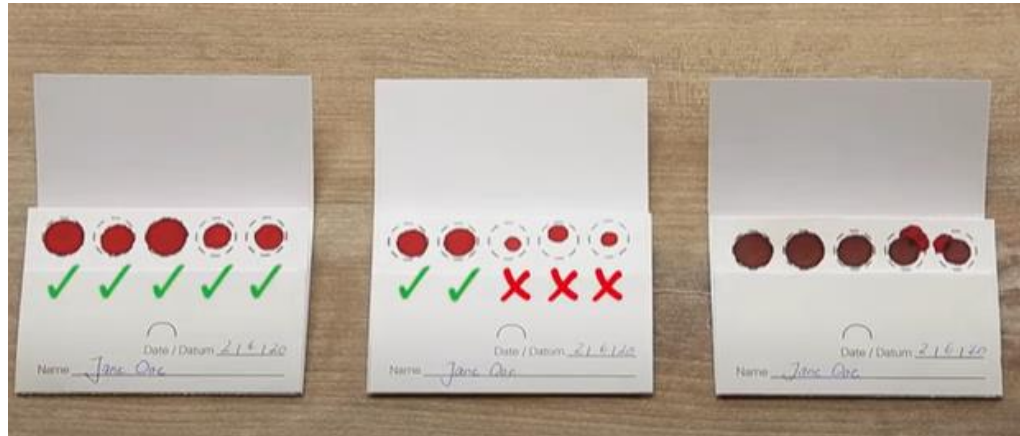
- Additional processing in lab – time consuming
- Not for all assays (for syphilis non-treponemal confirmation assay such as RPR)

But also has some advantages!

- Stability during transportation in high temperatures



Blood collection devices –dried blood spots



Blood volumes not standardized –
one spot contains 15-50 μL of
whole blood

Volumetric microsampling methods ($\leq 50 \mu\text{L}$)



Insufficient blood for HIV, syphilis
& HCV testing + processing

Capitainer $\rightarrow 2 * 50 \mu\text{L}$
Capitainer AB, Solna, Sweden

Mitra $\rightarrow 2 * 50 \mu\text{L}$
Neoteryx, Trajan Scientific Americas Inc.

Blood collection devices – push-button systems

To be placed on your upper arm. Blood is collected from capillaries under vacuum pressure.

Self-collection of capillary blood using an innovative device for HIV, Syphilis testing among PrEP-using MSM
Limburg4Zero
CJD (Hanneke) Goense
 ✉ hanneke.goense@ggdzi.nl



“This innovative blood collection device was highly acceptable and feasible among PrEP-using MSM”



TAP II
2019 - Current



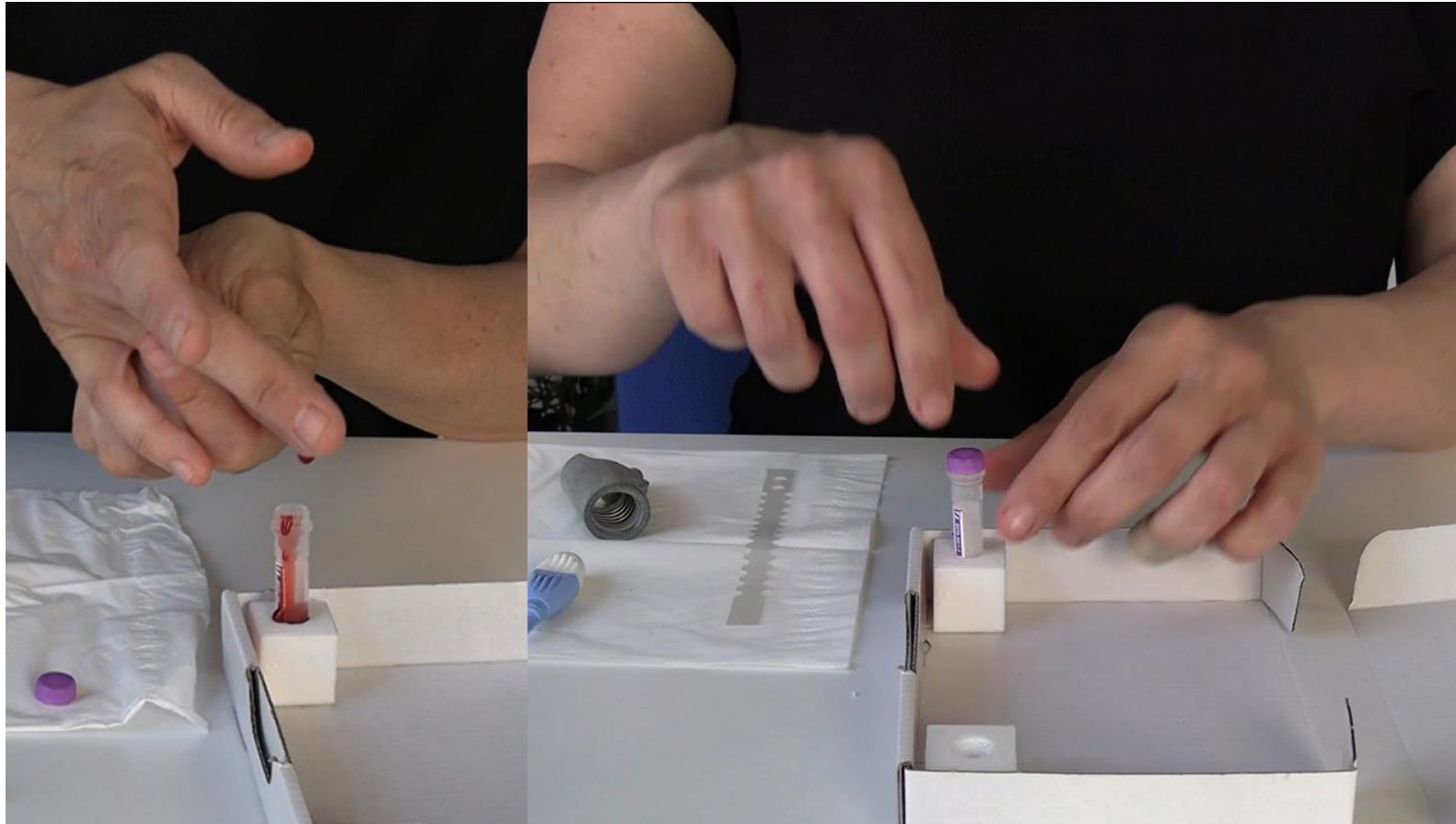
Onedraw



Dr. Tom Platteau

TASSO most famous device. Now also available in combination with DBS.

Collect2Know device



- Standardized pricking location
- User-friendly
- Hygienic
- Minimal discomfort
- Can be re-used

Very early, no CE mark, but...interested? Please come by!!

Oral Fluid for HIV testing



Oral fluid is possible for HIV serology however **confirmation testing** is needed and **false reactive results** are possible **in low prevalence settings**

Example: Swab2Know in Belgium and TESTATE in Spain 😊

Urine collection devices for Chlamydia/Gonorrhea testing



Urine collection methods or simply ask a clean cup and transfer to a specific transport tube

Also other devices are available specialized in collecting first-void urine!



Urine collection devices for Chlamydia/Gonorrhoea testing



Comparative Study > [BMJ Open](#). 2019 Apr 3;9(4):e028145. doi: 10.1136/bmjopen-2018-028145.

Evaluation of the 'Colli-Pee', a first-void urine collection device for self-sampling at home for the detection of sexually transmitted infections, versus a routine clinic-based urine collection in a one-to-one comparison study design: efficacy and acceptability among MSM in Belgium

Irith De Baetselier ¹, Hilde Smet ¹, Said Abdellati ¹, Bénédicte De Deken ¹, Vicky Cuylaerts ¹, Thijs Reyniers ², Bea Vuylsteke ², Tania Crucitti ¹

> [Int J STD AIDS](#). 2013 Jun;24(6):477-80. doi: 10.1177/0956462412472834. Epub 2013 Jul 19.

Use of the UriSwab collection device for testing of Chlamydia trachomatis and Neisseria gonorrhoeae: implications for a postal testing service

J McNicol ¹, J Debattista



Chlamydia / Gonorrhoea testing in anorectum and oropharynx



Self-sampling strategies (with/without digital innovations) in populations at risk of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: a systematic review and meta-analyses

Fiorella Vialard ^{1,2}, Apoorva Anand ¹, Cindy Leung Soo ², Anna de Waal ¹,
Madison McGuire ¹, Sergio Carmona ³, Marta Fernández-Suárez ³, Alice Anne Zwerling ⁴,
Nitika Pant Pai ^{1,5}



We conclude that extragenital self-sampling followed by NAAT for CT/NG detection is as accurate as conventional testing regardless of sampling site for MSM and women in high income countries



- Either dry swabs provided for collection or swabs with transport medium
- Instructions of use or very important

Chlamydia / Gonorrhoea testing in oropharynx

**Self-sampling with oral rinse to detect oropharyngeal
Neisseria gonorrhoeae among men who have sex with men
(SSONG study)**

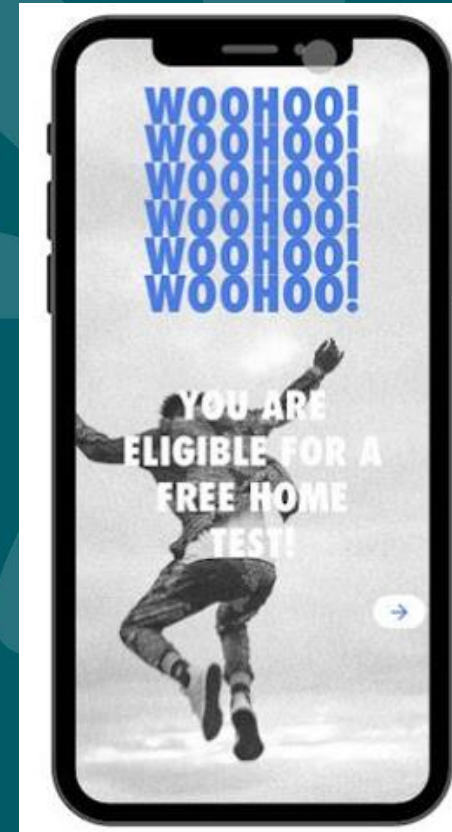
11h15 Room Doblon (AS4/04)

Thibaut Vanbaelen M.D.
Institute of Tropical Medicine, Antwerp, Belgium




Online HIV/STI self- testing

E.g. Take me Home programme from US.



Online HIV/STI self-testing

<p>WHO RECOMMENDS HIV SELF-TESTING – EVIDENCE UPDATE AND CONSIDERATIONS FOR SUCCESS</p> <p>NOVEMBER 2019</p>	<p>RECOMMENDATIONS AND GUIDANCE ON</p> <p>HEPATITIS C VIRUS SELF-TESTING</p> <p>JULY 2021</p>
---------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------

	Self-testing 
Location	Usually at home
Procedure	Collecting samples and requiring a diagnostic test kit or device to perform the test.
Time to results	Immediately
Results	Self-interpretation
Follow-up care	May be difficult due to the lack of interaction with healthcare professionals.

Need to be CE marked for self-testing!!

Box 3. NEW WHO recommendation on hepatitis C virus self-testing (HCVST)

HCV self-testing should be offered as an additional approach to HCV testing services (*strong recommendation, moderate-certainty evidence*).

Remarks

- HCVST **needs to be followed by linkage to appropriate post-test services**, including confirmation of viraemic infection, treatment, care and referral services, according to national standards.
- It is desirable to adapt HCVST service delivery and support options to the national and local context, which includes community preferences.
- Communities, including networks of key and vulnerable populations and peer-led organizations, need to be meaningfully and effectively engaged in developing, adapting, implementing and monitoring HCVST programmes.



HIV self-tests – CE marked or prequalified by WHO



Autotest VIH
AAZ-LMB



OraQuick In-Home HIV Test.
Orasure



INSTI HIV Self Test
BioLytical

Other HIV self-tests on WHO list

Wonfo HIV Self-Test, Guangzhou Wondfo Biotech Co., Ltd

CheckNOW HIV SELF TEST, Abbott Rapid Diagnostics Jena GmbH

SURE CHECK HIV Self-Test, Chembio Diagnostic Systems, Inc = Autotest VIH

Mylan HIV Self Test, Atomo Diagnostics Pvt. Ltd = Atomo HIV Self-Test

HCV self-testing

No approved rapid diagnostic test for self-testing however progress is being made!



Meeting the 2030 targets for hepatitis depends on improving access to diagnosis. Everyone living with the infection has a right to know their status so that they can be linked to care.

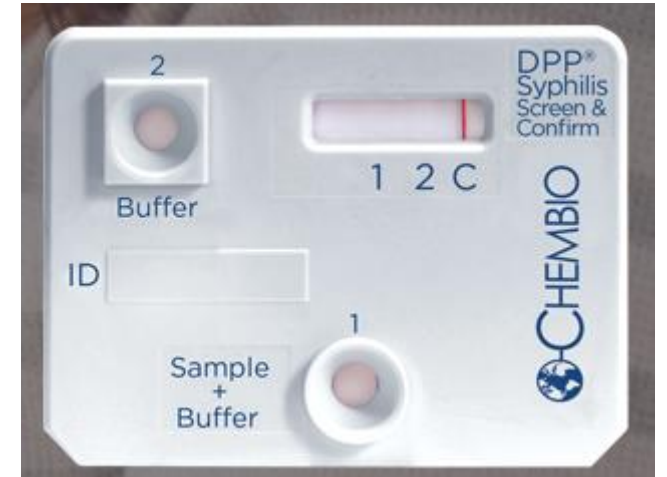


Cassandra Kelly-Cirino
Vice President, Programmes

FIND

Syphilis self-test

- To my knowledge none CE marked for self-testing
- Syphilis is **difficult to interpret**.
- Treponemal antibodies cannot distinguish between past and current syphilis infections
- **Combination of treponemal and non-treponemal antibodies needed in some high-risk populations, but might require more education**
- **Rapid diagnostic tests with HIV & syphilis are available**



Self-tests for Chlamydia/Gonorrhea??

- Very bad performance.
- Please do not buy!! 😊
- Except for this one



> Sex Transm Infect. 2016 Sep;92(6):430-2. doi: 10.1136/sextrans-2015-052202. Epub 2015 Oct 16.

Evaluation of an enzymatic *Chlamydia trachomatis* point-of-care rapid assay in Rwanda: the BioChekSwab Rapid Test

Irith De Baetselier¹, Lambert Mwambarangwe², Vicky Cuylaerts¹, Viateur Musengamana², Stephen Agaba², Evelyne Kestelyn³, Janneke van de Wijert³, Tania Crucitti¹



Very good overview of possible tests, point of care assays for STIs



What does the future bring?



HIV & syphilis
(treponemal and
non-treponemal
assay)



Chlamydia/Gonorrhea testing at home with reader



Besides online –
vending machines!

Wearable digital devices



MSHC
MELBOURNE SEXUAL HEALTH CENTRE
Part of AlfredHealth



- The British condoms i-Con Smart Condom Ring
 - Announced in 2017 and ~90,000 people pre-ordered (£59.99 or AU\$ 118)
- Like a FitBit but for your penis
 - Using nano-chip and Bluetooth technology to relay the data to a smartphone app
 - Can track frequency and duration of intercourse, calories burned, number and speed of thrusts
- Able detect STIs such as chlamydia and syphilis
 - Antibodies filter needs to be changed each month
 - Alert sent to smartphone app when proteins or antigens which are found in STIs are detected
- All data will be kept anonymous but users “will have the option to share their recent data with friends, or, indeed the world”.



Thanks to Eric Chow → IUSTI 2023

X @EricPFChow @MSHCRResearch

Source: <https://www.thesun.co.uk/tech/5024824/smart-condom-penis-size-stis-rate-sexual-performance/>
<https://www.nottinghampost.com/news/uk-world-news/would-you-buy-smart-condom-851278>


Lessons learned

- Always include your laboratory BEFORE starting a program. They have critical information!
- Online self-sampling programs are the future
- HIV self-tests available
- HCV or syphilis self-test will be available soon
- Watch out with self-tests for chlamydia/gonorrhea



Thank you

Fien Vanroye
Dorien Van den Bossche
Tom Platteau
Corinne Herrijgers
Birgit Baudry
Vicky Cuylaerts
Hilde Smet
Yolien de Caluwe
Saïd Abdellati
Wendy Thys

 ITGITMantwerp
 @itmantwerp
 @institute-of-tropical-medicine
 @ITMantwerp @TropischITG