OraQuick HIV Self-Test
Training Presentation
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Latam Business Development
CMLF Pilot Dec 2021

OraSure Infectious Disease of Products

OraSure has vast experience in developing rapid point-of-care testing for complex diagnostic problems such as HIV, HCV and Ebola, on a global scale.

- **OraQuick oral fluid products have tested over 76 million people worldwide** and is the most widely used HIV Self-Test

- OraQuick oral fluid products have been used in over 130 countries.

ORAQUICK HIV SELF-TEST

OraQuick Rapid Antibody Test HIV-1/2

OraQuick Rapid Antibody Test HCV

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OraSure Technologies

25+ Years of experience

Driving advances in oral fluid HIV testing

2002

First rapid HIV-1 test gains approval in the U.S. by the FDA

OraQuick Rapid HIV-1 Antibody Test

2003

CDC launches "Advancing HIV Prevention" initiative with OraQuick as cornerstone

2004

First FDA approved rapid HIV test utilizing oral fluid

OraQuick Rapid Antibody Test ADVANCE® HIV-1/2

OraSure receives **"2004 Best of What's New" award** for OraQuick from **Popular Science**

2009

OraQuick Rapid Antibody Test ADVANCE® HIV-1/2

Receives FDA-approval for raw materials updates to support production demand

2012

First and only FDA oral fluid rapid HIV test available OTC gains approval

ORAQUICK

Time Magazine names OraQuick **Invention of the Year**

2015

WHO recommends self-test for HIV screening programs, leveraging OraQuick studies

2016

FDA approves comparability performance to a 3rd generation EIA

OraQuick Rapid Antibody Test ADVANCE® HIV-1/2

2017

ORAQUICK HIV SELF-TEST

WHO prequalifies as first and only oral fluid rapid HIV self-test

2019

First WHO approved rapid HIV self-test for pediatrics

ORAQUICK HIV SELF-TEST

2020+ and beyond

CDC recommends HIV self-testing as one way to **end the HIV epidemic** in the U.S. by 2030

The Continuing HIV Challenge

Key population HIV testing remain a public health priority

- Key populations (MSM, transgender, injection drug users) and their sexual partners accounted for 88% of new HIV infections in 2018-2019
- Late diagnosis rates remain stubbornly high at 49% despite a reduction in diagnosis rates, wholesale adoption of ‘treatment as prevention’ policies and increased PrEP availability.

Barriers to uptake in HIV testing

- Unwillingness to attend sexual health or outreach clinic to discuss sexual behaviour with health professionals due to:
  - Perceived stigma
  - Concerns of over confidentiality
  - Time pressures
- Fear of needles
- Difficulty in obtaining appointments at convenient times

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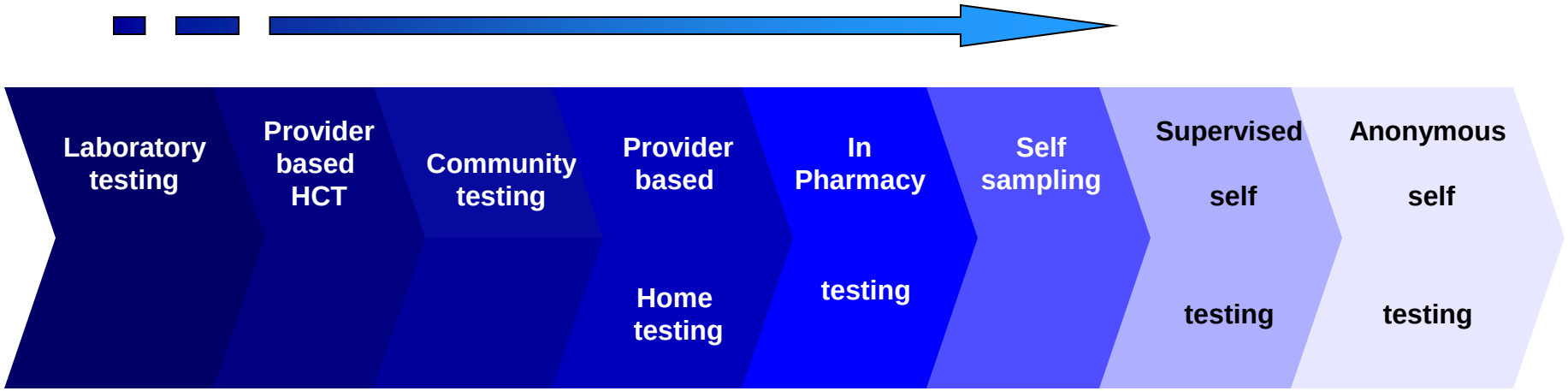
Reaching the unreachable – novel testing means



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ORAQUICK®

HIV SELF-TEST

Proven performance

- Sensitivity **99.4% ***
- Specificity **99.0%**

Easy to Use

- No blood required
- Painless *oral fluid test*
- Simple 3 step testing process
- Easy disposal of test after use; no biohazard container needed

Rapid-format test that detects HIV antibodies in **oral mucosal transudate ("oral fluid")**

- Oral fluid contains high concentration of early antibodies
- Oral Fluid HIV testing has demonstrated comparable performance to lab-based blood testing and is used by healthcare professionals around the globe.

*WHO PQ **self reported**

HIVST is highly acceptable to patients and grants individuals autonomy in “knowing their status”

HIVST is convenient, empowering, and does not lead to social harm

98%

- Chose HIVST over facility-based HTS
- Described the process as “easy” or “very easy”

Main benefits

- Noninvasiveness
- Ability to test oneself
- Being the first to know one’s status
- Privacy

Quotes

“I was given the chance to be the first person to see my results”

“It is easy to test oneslf, takes short time and is pain free”

WHO’s meta-analysis of HIVST use across settings suggests there have been zero reported incidents of social harm related to HIVST[1]

Key Source Overview:

- **Source:** Zerbe et al
- **Year:** 2015
- **Type:** Acceptability & feasibility study with surveys
- **Region/Country:** Lesotho
- **Population:** Household members of PLHIV

[1]Johnson et al

Pediatric Use , Rev WHO PQ 29-Nov-2019

2. Revision of the IFU from a double-sided single page to a single-sided single page. Added a limitation of the test in the IFU as follows

"This product has not been evaluated for use in self-testing for individuals younger than 12 years of age.

For children **ages 2-11,** testing must be performed by a trained health care worker".

Young Population , at high Risk had never been tested and prefer Self tests.

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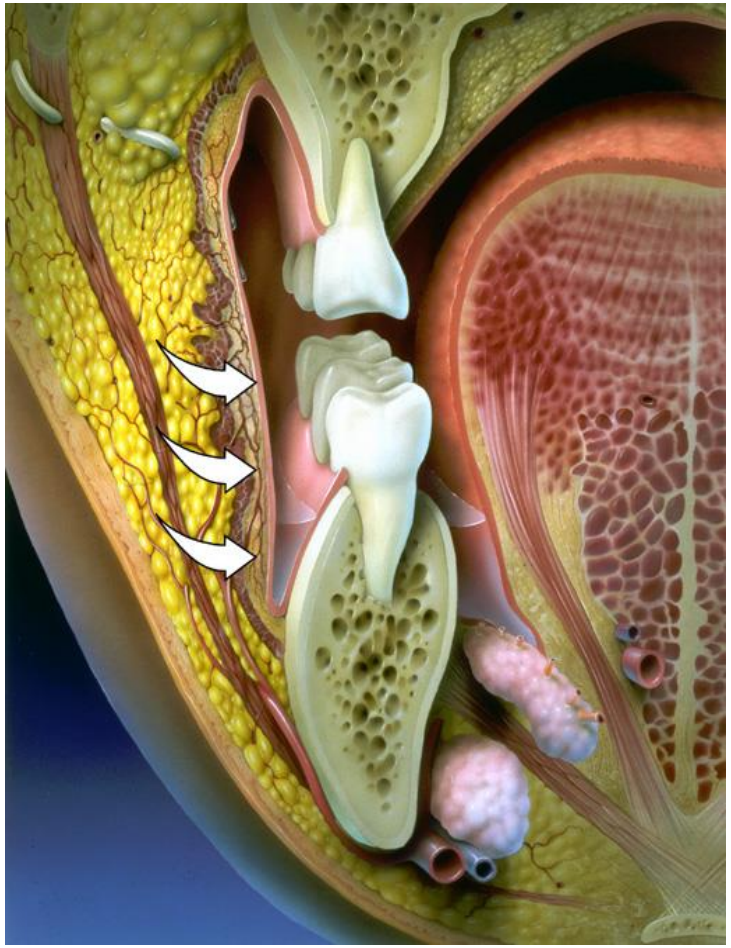
This is an Oral Fluid Test



Rapid-format test that detects HIV antibodies in **oral mucosal transudate (OMT)**

OMT contains high concentration of IgG antibodies.

- **No Drinking , Smoking 15 min before sampling, Why?**
- **Eating/drinking potential false results (e.g. sugar) and rinsing away oral fluid.**
- **Oral fluid refreshes itself in about 10 mins hence the 15 min wait**
- **Toothpaste can contain mild bleaching agent hence the 30mins .**
- **Lipstick has no impact unless you cover the pad.**
- **Dentures covers the gums**

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OraQuick HIV Self-Test Product Review

Packaging and product specifications.

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Product Packaging Configuration

Designed for pharmacy retail, over the counter sales and pubic health distribution

- Same test used by health professionals
- QR code to access Instructional videos included

Product components
- Testing device
- Buffer
- Stand
- Disposal bag (Pharmacy)
- Instructions For Use (English)

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Taking the Test

Instructions for use and test interpretation.

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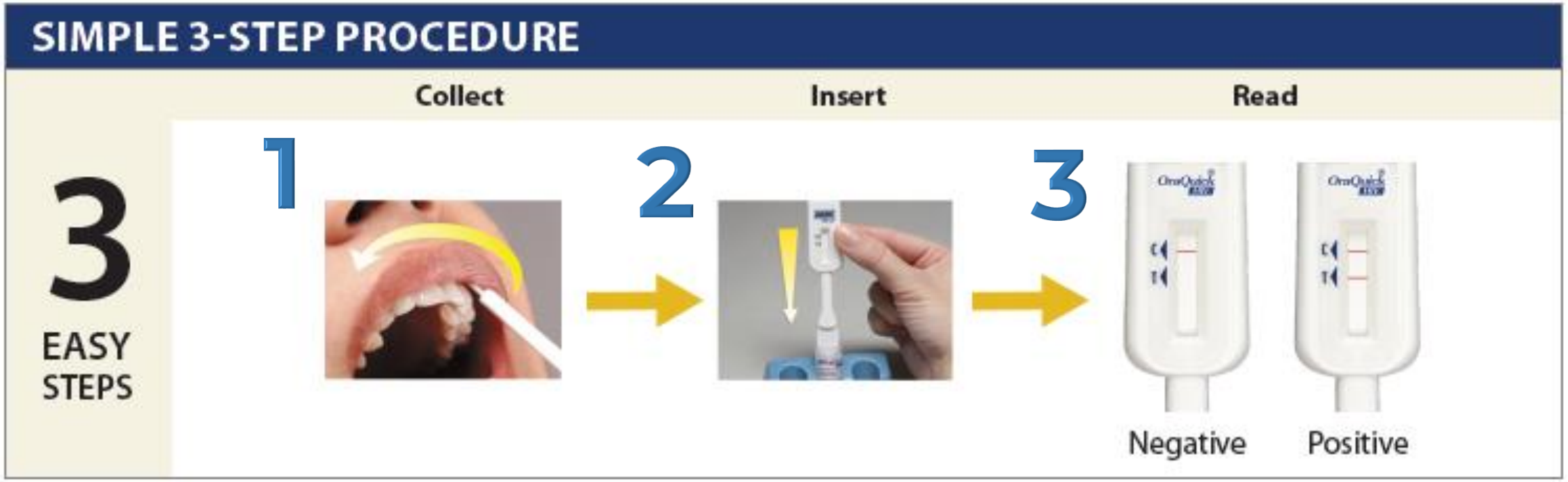
Procedure: Taking the Test



VIDEO

Read results after 20 minutes but *not more* than 40 minutes. Adequate lighting must be available

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When to get tested for HIV

- How often you test, depends on your circumstances.
- Test every three months if you engage in risky activities that can result in HIV infection.
- If you have been recently exposed to a risk event, your body may not be making these antibodies yet.
- If you are using this test earlier than 3 months since a risk event and your test is NEGATIVE, you should test again 3 months after the risk event

When should I NOT use this test

- If you are HIV positive and on HIV treatment (ARVs).
- If the box seal has been broken or if any of the package contents are missing, broken, or have been opened.
- If today is after the expiration date on the side of the box. (Expired Test)
- If you are age 11 or younger.

Prior to using OraQuick HIV Self-Test

- Do not eat, drink or smoke 15 minutes before using the test.
- Do not use oral care products (such as mouthwash, toothpaste or whitening strips) 30 minutes before starting this test.
- Remove dental products such as dentures or any other products that cover your gums.
- Find a quiet, well-lit place where you can be for at least 20 minutes.
- Read the instructions
- Video : QR Code Link in the Bag

Did you know

HIV <u>cannot</u> be transmitted by saliva.

This test works by detecting your body's natural defenders (antibodies) that help you fight infection. These "defenders" are present in the mouth, around the gumline, as well as in blood.

- If you are infected by HIV, OraQuick® will detect these "defenders" and your test will be POSITIVE

- If you are NOT infected by HIV these "defenders" will not be present and your test will be NEGATIVE

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How to use the test

You will need a way to time your test.

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How to use the test

The pouch contains a **test kit, test stand** and **instructions**.

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How to use the Test

The test kit contains **two pouches.**

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How to use the test

Remove the vial from the pouch

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How to use the test

Remove the cap.

Slide the tube into the stand.

DO NOT pour out the liquid

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How to use the test

Tear open pouch containing the **test device** and remove.

DO NOT touch the flat pad with your fingers.

Preservative THROW AWAY. Not needed for the test..

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How to use the Test

Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).

DO NOT swab the roof of the mouth, the inside of the cheek or the tongue.

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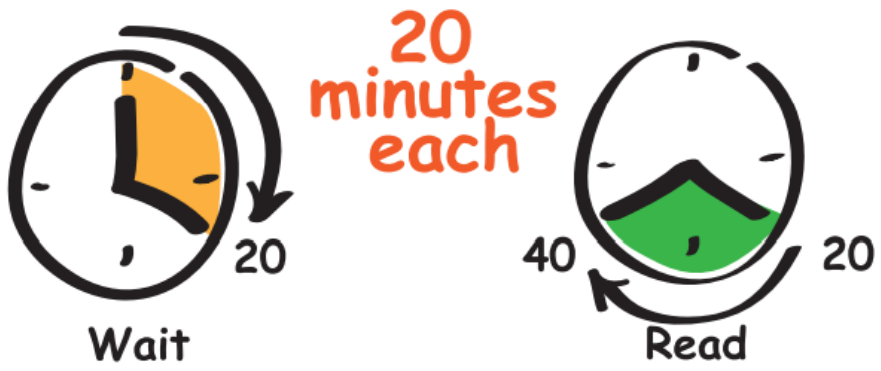
How to use the test

Put the **flat pad** all the way into the tube until it touches the bottom.

LEAVE IT THERE for 20 MINUTES before reading the results. DO NOT read the result after 40 minutes.



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Recap: Reading and Interpreting a Reactive Test

A test is **REACTIVE** if:

- A reddish-purple line appears next to the triangle labeled “C” **and** a reddish-purple line appears next to the triangle labeled “T”. Lines may vary in intensity.

- **NOTE:** The test is reactive if a complete reddish-purple line appears next to the “T” triangle **and** next to the “C” triangle, no matter how faint.

A Reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen.

The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.

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Recap: Reading and Interpreting a Non-Reactive Test

A test is **NON-REACTIVE** if:

- A reddish-purple line appears next to the triangle labeled “C” **and** no line appears next to the triangle labeled “T”.

A Non-Reactive test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen.

The test result is interpreted as NEGATIVE for HIV-1 and HIV-2 antibodies.

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Reading an Invalid Test

A test is INVALID if:

- No reddish-purple lines appears next to the triangle labeled “C” (see picture a and b), or
- A red background in the Results Window makes it difficult to read the result after 20 minutes (picture c), or
- If any of the lines are NOT inside the “C” or “T” triangle areas (picture d or e).
- If any of the lines are partially developed on either side of the “C” or “T” zones (pictures f and g)

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Interpreting an Invalid Test

An Invalid test result means that there was a problem running the test, either related to the specimen or to the Device.

IT CANNOT BE INTERPRETED.

Repeat test

Incorrect sampling could be an issue but if the lines are not in the triangle marks it is likely a manufacturing issue. Our manufacturing error rate is very low >0.01%

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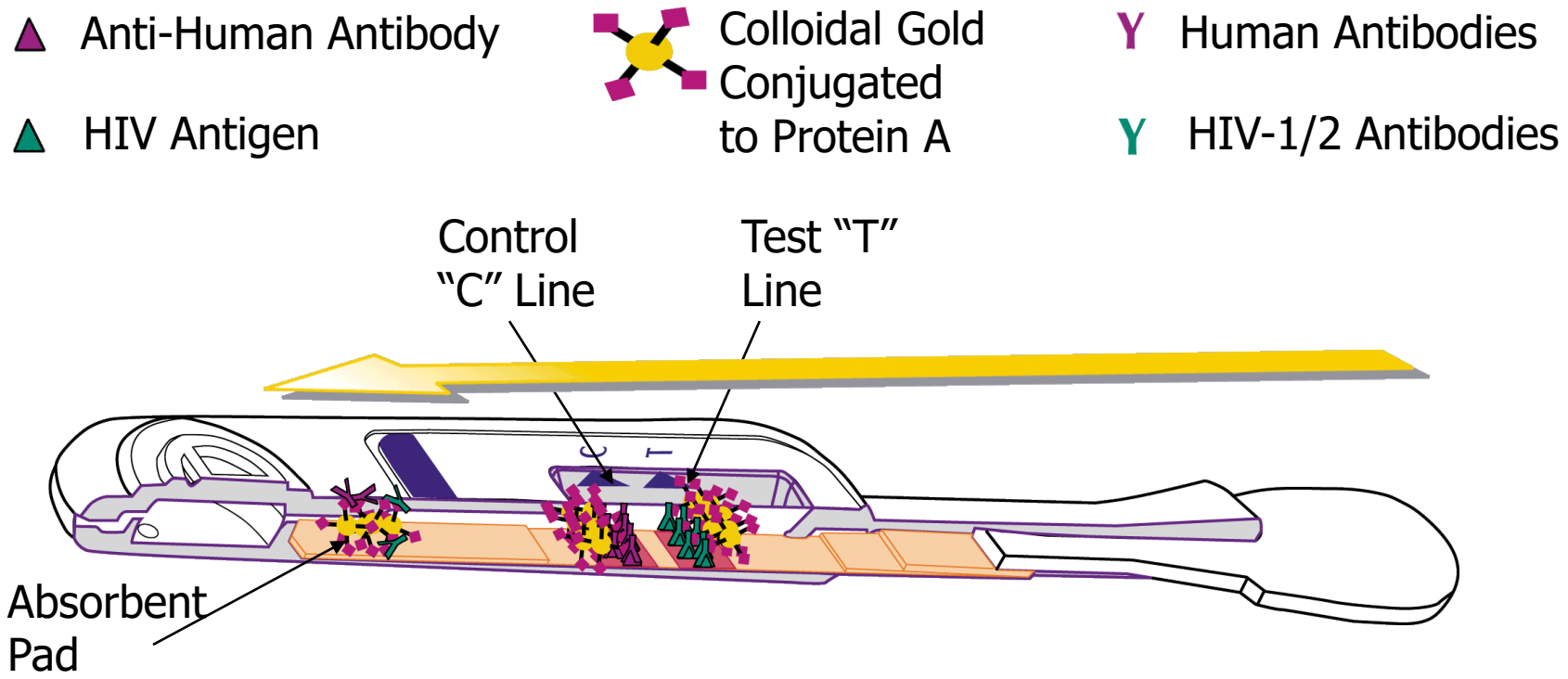
OraQuick® Clinical Features Operating Principle



HIV antibodies bind to the HIV antigen "T" line (TEST LINE) forming a visible red band.

Human antibodies bind to the Anti-Human Antibodies "C" line (CONTROL LINE) forming a visible red band.

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Disposal

- Remove the test stick, put the cap on the test tube and throw away all contents in the regular trash bin.
- You may use the disposal bag included in the test to dispose of the components for privacy

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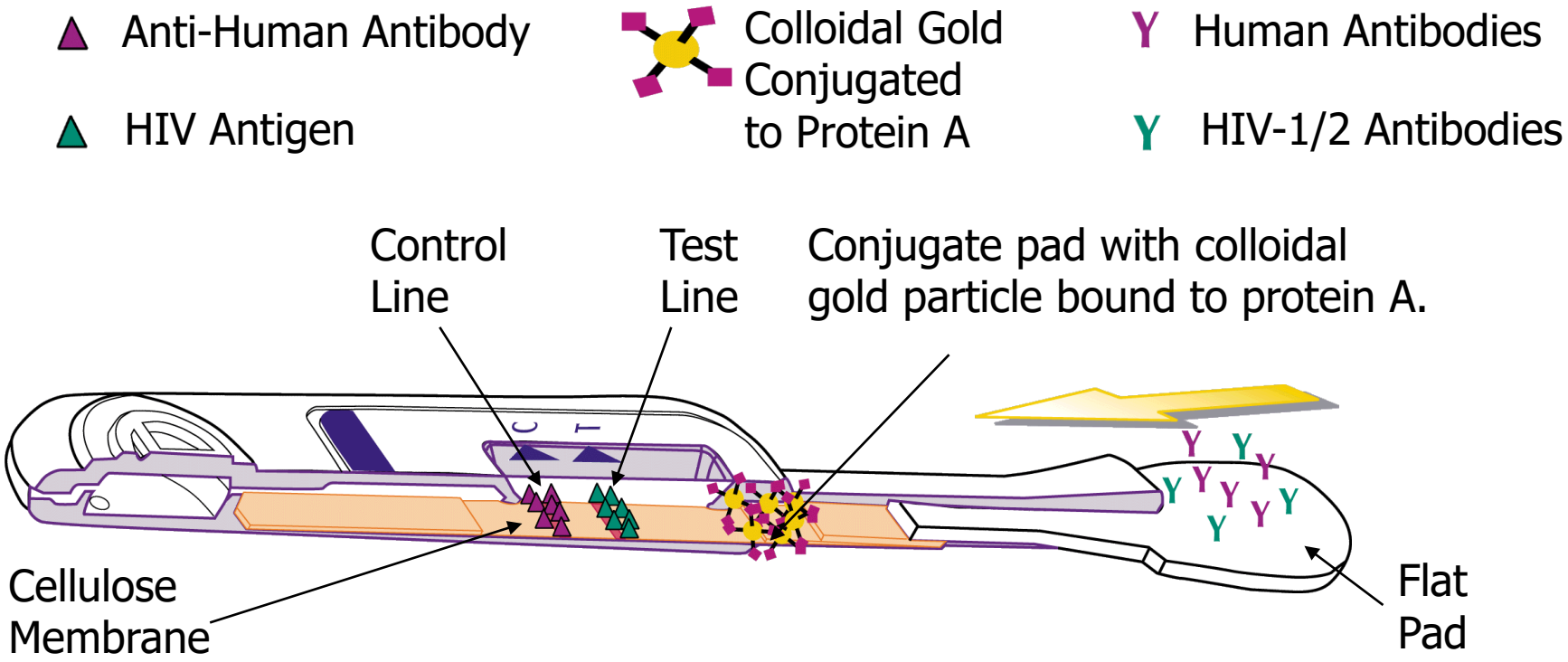
OraQuick® Clinical Features Operating Principle



As a lateral flow process, the specimen wicks up by the flat pad of the device.

Human antibodies and HIV antibodies (if present) bind to the colloidal gold particles.

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Is QC needed for the test?

- Our control Line C is an Anti Human IGG so that checks the sample is taken properly.

- There are No Oral Fluid Controls , but we have a separate control pack (serum HIV 1 -2 & Neg) that the MOH could use to check stocks, but an individual is not going to run controls.

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Oral fluid HIVST Usability Checklist _:A cross-sectional study | South African Journal of Science

Orasure (*n*=900)			
1. Did the participant read/use the IFU?	900 (100.0)	0 (0.0)	100.0
2. Was it difficult for the study participant to remove the contents of the test pack?	25(2.8)	875(97.2)	97.2
3. Was the study participant able to find the test tube packet?	900 (100.0)	0 (0.0)	100.0
4. Did the study participant remove the cap from the test tube?	900 (100.0)	0 (0.0)	100.0
5. Did the study participant place the test tube into the holder?	873 (97.0)	27 (3.0)	97.0
6. Did the study participant have any difficulty with the test tube?	40 (4.5)	860 (95.5)	95.5

Usability checklists	Yes *n* (%)	No *n* (%)	Usability index (%)
7. Was the study participant able to find the test stick packet?	891 (99.0)	9(1.0)	99.0
8. Did the study participant remove the test stick from the packet?	899 (99.9)	1 (0.1)	99.9
9. Did the study participant touch the flat pad?	112 (12.5)	788 (87.5)	87.5
10. Did the study participant collect the sample correctly?	840 (93.3)	60 (6.7)	93.3
11. Did the study participant place the test stick in the test tube correctly?	885(98.3)	15 (1.7)	98.3
12. Did the participant quit the process at any point? If Yes, explain	4 (0.5)	896 (99.5)	99.5
13. Did participant continue the process despite a missed or incorrect step?	896 (99.5)	4 (0.5)	99.5
Total usability index			**97.4**

Performance assessment of four HIV self-test devices in South Africa: A cross-sectional study | South African Journal of Science (sajs.co.za)

https://www.sajs.co.za/article/view/7738#:~:text=/-,VOL.%20117%20NO.%201/2%20(2021),-/

OraQuick HIV Self-Test Key Take-Aways

1. OraQuick HIV Self-Test, with oral fluid, is an **easy alternative to blood-based testing in hands of lay users**; easy to scale and easy integration into current HIV testing workflows.
2. **The preferred HIV self-testing solution by millions around the world**.
3. **Utilization of oral fluid HIV testing enables agency** within hard to reach and marginalized communities.
4. **OraQuick HIV Self-Test, using oral fluid, is a flexible alternative to clinic-based testing providing options during and after COVID.**
5. OraQuick is the mostly widely available HIV self test, **the only product approved by U.S. FDA, CE and WHO.**

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End