STIs and HPV

Easy STI testing, for everybody

Better diagnostics begins
with a better sample collection.

Copan
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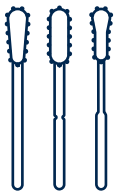
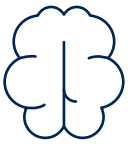


Collection

Transport

Processing



Artificial Intelligence

Our comprehensive approach to preanalytics

Background

Caring about sexual health

Although most Sexually Transmitted Infections have no or only mild symptoms, **the morbidity resulting from untreated cases leads to a worldwide medical expense burden and a health emergency**.
In this context, the steady testing rate – remaining low despite the prevalence and incidence of STIs having risen significantly year-on-year[1,2,3] – is alarming.
Inadequate STIs testing may result from several factors, including the stigma associated with these diseases, lack of screening programs, limited access to testing, and scarce resources[4]. **International screening guidelines and programs have been developed to identify and treat STIs** to limit their transmission and complications.[1]

What's the Copan solution for Sexually transmitted Infections?

- ***Professional sampling***

  FLOQSwabs® - MSwab® - eSwab® - eNAT® - UTM®

- ***Self-collection***

  Self Vaginal FLOQSwabs® - Self UriSponge® - MSwab®

- ***Sample preparation***

  UniVerse®

Etiology

A multifaceted threat

In 2018, an estimated 1 in 5 adults had an STI in the US[3], but this high prevalence is heterogeneous: populations with higher risk include people younger than 25 years, sexual, racial, and ethnic minorities. **Over 30 different types of microorganisms can cause an STI[5],** but to date, healthcare professionals' attention focuses mainly on four pathogens:

- ***Chlamydia trachomatis (CT)***, a bacteria which causes an infection that can be cured but can induce serious health complications and permanent damage to the women's reproductive system if left untreated.
- ***Neisseria gonorrhoeae (NG)***, also known as gonococcus, a bacterial agent that causes a serious STI. NG has a high risk of coinfection with other STIs, and the antibiotic resistance developed in the last decades increased its morbidity and mortality.
- ***Human papillomavirus (HPV)***, which infection is the most significant risk factor for developing cervical cancer.
- ***Treponema pallidum (TP)***, the bacteria responsible for syphilis. Efficient systems are already in place to screen and treat pregnant women to eliminate congenital syphilis, but as for NG, the insurgence of antibiotic-resistant strains is challenging control programs.

Consequences

Body, mind, and pocket

Untreated STIs may have severe physical, psychological, and social long-term consequences, compromising the quality of life of those infected, their partners, and their children. These **consequences impose a substantial strain on the budgets of households and national health systems and have adverse effects on the lives of individuals of any age**, for example:

- ***Cervical cancer*** – HPV is responsible for an estimated 570.000 cases of cervical cancer worldwide in 2018[6];
- ***Infertility*** – sexually transmitted infections, such as CT and NG, are important causes of infertility worldwide[7];
- ***Fetal and neonatal deaths*** – Syphilis during pregnancy leads to over 200.000 fetal and neonatal deaths each year[8];
- ***HIV*** – the presence of an STI such as NG, syphilis, or herpes simplex virus (HSV) dramatically increases the risk of getting or transmitting HIV infection[9].

HPV

Preempt cervical cancer

Cervical cancer is the **fourth most common type of cancer and the fourth leading cause of tumor death among women worldwide**, with 604.000 cases and 342.000 deaths annually[10]; **more than 95% of cervical cancer cases are due to an HPV infection.**

In 2018, the WHO announced a call to action to eliminate cervical cancer as a public health problem, leading to a global strategy that includes the scale-up of HPV vaccination, screening, precancer treatment, and invasive cancer treatment globally[11]. According to modeling studies, the successful implementation of this strategy would reduce cervical cancer mortality by 98.6% by 2120[12].

The WHO vision

Ending STIs as a public health concern

Not only HPV: the WHO has a clear vision for all Sexually Transmitted Infections: **ending them as a major public health concern** by *"ensuring zero new infections, zero sexually transmitted infection-related complications and deaths, and zero discrimination in a world where everybody has free and easy access to sexually transmitted infection prevention and treatment services, resulting in people able to live long and healthy lives[13]"*.

Most of the tools required for reaching this ambitious target by 2030 are already available; nevertheless, using them efficiently will require **focusing the most effective programs on populations and geographical locations where the need is greatest.**

Copan and STIs' prevention

Testing, testing, testing!

On top of awareness and safe sex, **STIs' effective prevention and treatment pass through testing:** people with high-risk sexual behavior need to be screened, and individuals with symptoms need to be tested, to prevent further transmission and severe health consequences.
While traditional methods such as serology and cytology remain the gold-standard methods to diagnose some STIs[14], high-sensitivity NAATs are nowadays used to diagnose many others, such as Gonorrhea and Chlamydia. Even cervical cancer screening has evolved from a simple Pap smear to innovative techniques, including highly sensitive molecular testing[15].

These improved methodologies would lead to earlier and more accurate diagnosis and strengthen patient monitoring, but to ensure the broadest access to these services, simple and accessible sample collection methods must be readily taken to scale. The **reliability of the whole sample workflow must also not be underestimated**, as no top-notch diagnostic platform could retrieve what you lost during a poor sampling, nor wide-approach screening could be effective with a defective sample transport and handling.

The perfect match

FLOQSwabs® Inside

The combination of any transport media with our patented FLOQSwabs® expands testing possibilities by ensuring an unmatched specimen collection in many anatomical collection sites. Discover why we call them "the perfect collection device" on the dedicated brochure.

Self Vaginal FLOQSwabs®

The FLOQSwabs® version designed for vaginal home-collection

With their soft and small tip, ergonomic shaft, insertion length mark, and clear instructions, Self Vaginal FLOQSwabs® will make every woman forget unpleasant tests. Also, being dry translates into cost-effective transport without any liquid-related safety issues! **Dry FLOQSwabs® self-collection performance resulted comparable to professional collection**[16,17,18] and wet sampling systems[19,20]. Numerous HPV and cervical cancer screening programs already used self vaginal FLOQSwabs®, improving overall participation[21,22,23].

MSwab®

Specimen Collection and Preservation Optimized for Molecular and Culture Applications

MSwab® offers the possibility to **collect, transport, and elute the sample in the same tube** without the need for further manipulation; it is suitable for crude rapid direct nucleic acid heat extraction and culture backup of selected bacteria and viruses.MSwab® represents a **non-flammable alternative to HPV testing alcohol-based media**[24], safe to transport and economically convenient. A true **all-around pre-analytical device designed for optimized compatibility with molecular platforms**, MSwab® is available in bulk, paired with Self Vaginal FLOQSwabs®, or as a 500ml bottle for use with UniVerse®.

eNAT ®

Nucleic acid collection and preservation medium

eNat® is our medium designed for **viral and bacterial nucleic acids collection and preservation**[25]. Containing guanidine-thiocyanate, **eNat® lyses cells and virus particles, removing the sample's infectivity and bacterial proliferation and preserving RNA and DNA integrity**. eNat® allows long-term sample storage for up to four weeks at RT or six months at -20°C by denaturing proteins - including nucleases - in only 30 minutes. eNat has been used successfully for molecular testing of Chlamydia, NG, and HPV infection in women [26, 27, 28] also at Point-Of-Care (POC)[29].

UTM®

Collection, transport, and virus storage medium

UTM® is our Universal collection and Transport Medium **suitable for collection, transport, and long-term freeze storage** of viruses, chlamydia, mycoplasma, and ureaplasma. Preserving viability for 48 hours at room temperature, **UTM® is compatible with viral culture, antigen detection, and molecular assays.** This versatility made UTM® one of our most popular products.

UniVerse®

The answer to lab challenges and bottlenecks

UniVerse® is our flexible solution for sample preparation, of which any minor improvement is the quickest and easiest way to optimize the efficiency and reliability of every methodology. Designed to streamline sample handling, elution, and pre-analitic manipulation before any molecular biology analysis, **UniVerse® is compatible with our Liquid-Based Microbiology collection and transport devices and a rapidly expanding set of modules guarantees compatibility with third-party tubes** (such as Thin-Prep vials) **and various downstream molecular platform consumables.**

ID scan

Media dispensing

Vortexing

Decapping

Aliquoting

Recapping

Labelling

Expedite your workflow

Flexible and open solution for molecular testing sample preparation

UniVerse® completely automates samples' preparation for molecular testing, as tube decapping and recapping, the addition of an elution media, barcode identification, and liquid transfer to secondary tubes or 96-well plates. With its four operational modes and three independent robotic arms, UniVerse® handles 130 tubes/hour or 220 96-well plate samples/hour, **integrating impeccably into your molecular biology lab's workflow.**

Self-Collection

Your health into your own hands

Flexibility, enhanced intimacy, and cost-effectiveness made **self-collection valid and acceptable for many STIs**, especially when cultural or geographical barriers limit testing. Evidence from various studies showed that **self-collection increases participation in STIs screening programs in remote or low-resource settings** by enabling testing in multiple locations such as home, POC, and workplaces[30, 31, 32]. To cite, two surveys conducted in 2020 found a strong preference for research studies and diagnostic testing that allowed home-based self-collection[33, 34]. In both cases, most participants reported being more prone to participate in a program if they could collect their specimens at home.

Self UriSponge™

Innovative sponge system for urine self-collection

Self UriSponge™ is our **safe and easy-to-use device to collect urine samples at home**. The sponge absorbs the correct amount of first-void urine sample without risk and discomfort [35], while the leak-proof tube ensures safe handling and shipment. Thanks to the preservatives and its dry formula, Self UriSponge™ allows the **shipment of urine samples from remote areas without affecting the results**[35, 36]. Fitting the main molecular platforms, the performance of the UriSponge™ is comparable with the testing of neat first-catch urine specimens[36] and **reduces the cost per infection detected compared to clinic testing**[35].

eSwab®

For traditional bacteriology culture and molecular assays

If you plan to perform other assays besides culture, you should opt for eSwab®. eSwab® medium preserves the viability of aerobes, anaerobes, and fastidious bacteria from swab specimens for bacterial culture purposes and can be used to maintain antigens and nucleic acids from STIs bacteria and viruses[37,38,39,40,41]. There is no need to say: eSwab® is compatible with WASP® automated processing.

Conclusions

A bright future

Creating awareness on consequences and prevention is fundamental in mitigating the increasing STIs rates affecting today's population. On top of that, **testing plays an essential role in limiting their transmission and spreading**. With Copan, you will cover all the aspects of STIs and HPV preanalytics, from collection to diagnostics. **One sole provider to ensure quality, standardization, and efficacy for all your STI testing needs.**

Scientific references

All the independent studies we cited in this product focus are listed here.

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