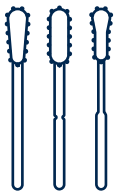
Self-collection

Defending sample quality in the intimacy of domestic walls

Better diagnostics begins
with a better sample collection.

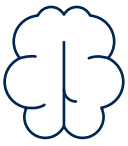
Copan
innovating together



Collection

Transport

Processing



Artificial Intelligence

Our comprehensive approach to preanalytics

Background

On self-awareness and self-collection

Self-collection. The meaning of this 2-word magic formula is clear: it's **the sampling of a biological specimen performed by the patient himself**, either at home or under supervision by a healthcare professional.
Even if logistic and cultural obstacles still have to be overcome and despite the idea of patients collecting their samples could scare most clinicians, **self-collection offers many advantages**, such as empowering people to take part in their own diagnostic path while simultaneously saving time and resources in hospitals and POCs.
Submitting self-collected specimens became already a common practice for many purposes, but simplifying the use of collection devices and ensuring their suitability for prolonged transport could promote self-collection expansion in many new medical fields to the **benefit of both healthcare professionals and patients themselves.**

What's the Copan solution for self-collection?

- ***Sexually transmitted infections***

  Self Vaginal FLOQSwabs® - Self UriSponge®

- ***Gastrointestinal diseases and gut microbiome***

  SMART eNAT®

- ***Respiratory diseases***

  Lollisponge™

Features and benefits

It's public health common sense!

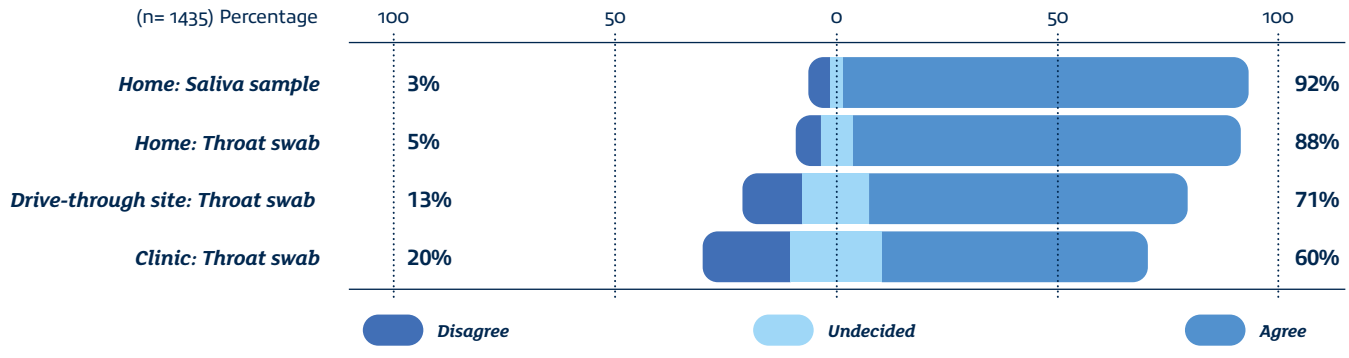
From a public health perspective, self-collection:

- Avoids close contact between patients in hospitals and emergency rooms.
- Improves healthcare professionals' safety.
- Done at home and mailed to the laboratory, saves patients and professionals time.
- Optimizes healthcare cost-effectiveness and reduce medical staff workload.

The enhanced intimacy of self-collection – compared to POC collection – is of great importance, especially when cultural barriers limit testing. Also, self-collected specimens at home facilitated telemedicine's implementation - crucial in the past years for remote areas and essential during COVID-19 pandemic – and **increased participation in clinical studies and screening programs**[1,2]. Two surveys conducted in 2020 found a strong preference for research studies and diagnostic testing that allowed home-based self-collection[3,4]. In both cases, most participants reported being more prone to participate in a study if they were able to collect their specimens at home.

Willingness to use specimen collection methods for diagnosis of COVID-19[4]

Willingness to seek laboratory testing for SARS-CoV-2 under different specimen collection scenarios.



Applications

Your health into your own hands

Applications

STI in males

The use of self-collected samples for the diagnosis of sexually transmitted infections (STIs) has been around for a long time. Still, as innovative programs are being developed, implemented, and found acceptable to participants, the options for getting tested for STIs are expected to increase.

Most of the studies involving self-collection are focused on women as participants; however, self-collection for STI screening for men can also be useful, since they are also adversely affected by a high STIs burden. **For males, self-collection has been reported to be highly sensitive for detecting multiple STIs**, and reported acceptable to most patients[5], while urine self-collected samples are used routinely for testing.

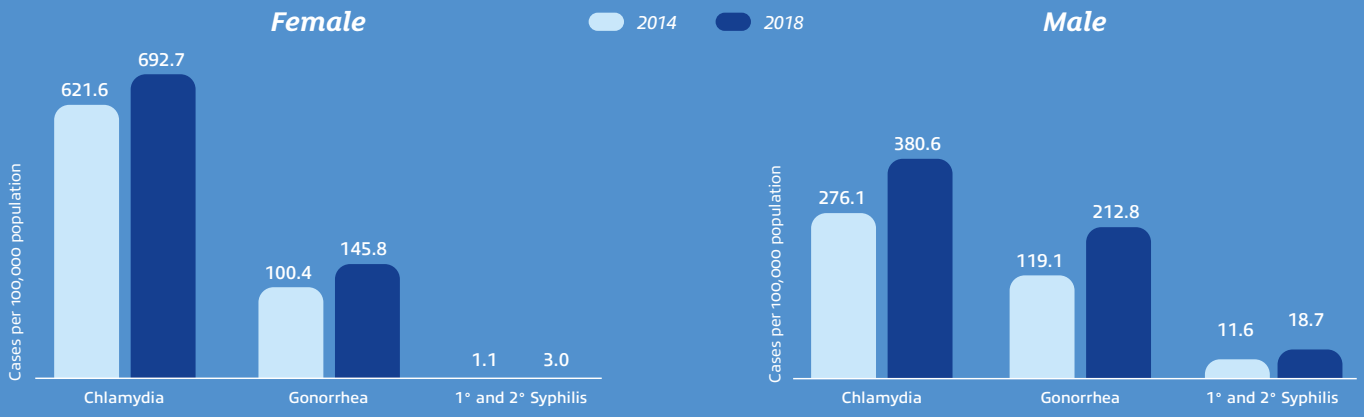
Self UriSponge™

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[6], 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[6,7]**. Fitting the main molecular platform ts, the performance of the UriSponge™ is comparable with the testing of neat first-catch urine specimens[7] and reduces the cost per infection detected compared to clinic testing[6].

Rates of sexually transmitted infections by sex from 2014 to 2018

While women still account for the highest reported cases of STIs, men saw greater increases in rates of syphilis, chlamydia, and gonorrhea in recent years (data from a KFF 2020 poll).



Applications

STIs & cervical cancer

Human Papilloma Virus (HPV) cervical cancer is a severe public health problem, to the point that WHO promoted a call to eliminate it by 2120[8]. **The primary issue regarding cervical cancer prevention is the women's adherence to screening programs;** that's why HPV is one of the main applications of STIs self-sampling.

In fact, most cervical cancer cases are reported in low and middle-income countries[9], and even within high-income countries, most cases occur in women who are never or under-screened[7].

The flexibility of self-collection – enabling screening in various settings such as healthcare facilities, workplaces, and homes – **increases participation in cervical screening in remote or low resource settings,** as shown already by many studies [1,2,11]. Other studies have also evaluated the results of self-collected vaginal swabs versus physician-collected swabs for detection of HPV[12,13], establishing comparable performances of self-collected vaginal samples across several investigations[14].

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**[14,15,16] and wet sampling systems[17,18]. Numerous HPV and cervical cancer screening programs already used self vaginal FLOQSwabs®, improving overall participation[19,20,21].

Applications

Respiratory diseases

As for STIs, self-collection of respiratory secretions would increase access to testing. Several studies – such as a 2019 meta-analysis on influenza[22] – have already demonstrated that self-collection can be used for many common upper respiratory pathogens, with high levels of agreement with HCP-collected samples[23,24]. The need for safe and timely methods for collecting upper respiratory specimens became evident in 2020, with the rapid spread of Covid-19 pandemic. **In the case of a dangerous infection as SARS-CoV-2, self-collection has the potential to limit the spread of the pathology to healthcare professionals or other patients[25].**

LolliSponge™

The sponge-made device for saliva collection

LolliSponge™ can be used to collect saliva when professional assistance is not available. After the sampling – performed just by keeping the dry sponge stick in the mouth for a few minutes – the sponge is placed in the tube and transported to the lab, where it can be centrifuged and tested with molecular diagnostic assays. Of note, **saliva demonstrated to preserve viral RNA stability for prolonged periods** - at 4°C, RT, and even 30°C - as shown for SARS-CoV-2 [26]

Applications

Gastrointestinal infections and gut microbiome

In some situations, it may not be feasible or practical for patients to access a POC and deliver a fresh stool sample on demand, or even deliver a sample in transport medium to a laboratory during the active phase of the disease. That's why **self-collection of fecal material is already standard practice for many diseases**, and for various stool pathogens and microbiome analyses, transport media preservation for later laboratory testing is also suitable[27]. Also, self-collection for enteric infections makes sense, especially given NAAT enteric pathogen panels' ability to analyze preserved samples without the need for culture.

SMART eNAT®

High-performance and intuitive device for nucleic acids self-sampling

SMART-eNAT® brings eNAT® performances to self-collection, combining it with FLOQSwabs® and with a unique SMART push & turn activation and delivery system. **SMART-eNAT® makes sample collection an easy process** – guarding against spillage or unwanted contact – and provides a safe and efficient nucleic acid collection and transport for prolonged periods.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self
LolliSponge™

A worldwide success

SCoPE, Australia

Australia already transitioned its national programs from cytology to HPV as the primary screening test and included self-collection. The SCoPE study compared the sensitivity of self-collected vs. practitioner collected cervical specimens in the context of the Australian National Cervical Screening Program (NCSP). More than 300 women took their own sample using FLOQSwabs® and then had a practitioner-collected specimen taken at colposcopy. All samples were tested at a single laboratory on the six PCR-based HPV assays utilized in the NCSP. The results showed that **self-collection for HPV-based cervical screening shows good concordance and relative sensitivity compared to practitioner collected samples** across assays in the NCSP[28].

YouScreen, UK

Since January 2021, many London General practitioners have been taking part in the YouScreen study, offering HPV self-sampling to non-attenders within the NHS Cervical Screening Programme. YouScreen will integrate self-sampling into the program for the first time, providing general practitioners an exciting opportunity to increase their practice's coverage. **The study aims to test the implementation of self-sampling for non-attenders within the NHS cervical screening program** and provide evidence that self-sampling can improve cervical screening coverage and increase the detection and treatment of high-grade cervical intraepithelial neoplasia[29].

ROSE, Malaysia

ROSE (Removing Obstacles to cervical ScrEening) Foundation has the ambitious goal of making Malaysia one of the first Asian nations free of cervical cancer. To achieve this, the Foundation launched in 2019 the Pilot Project ROSE, **aiming to create a cheaper and more efficient screening, assessing the acceptability, feasibility, and reach of a novel cervical screening strategy that utilized self-sampling**. Instead of the conventional pap smear conducted by a healthcare professional, Program ROSE offered women the choice to use a self-FLOQSwab® followed by molecular tests and prompt delivery of results straight to women's mobile phones. Preliminary results of the pilot study are excellent, with 94% of the women saying they preferred it to Pap smear screening because it was simple (96%), quick (87%), self-performed (89%), and provided fast results (82%)[30].

Downstream Applications

Designed with diagnostic assays in mind

Our self-collection products offer excellent performances for many downstream molecular assays. Discover below how professionals used them internationally!

PCR - Vaginal

The performance of Self-collection with dry self-vaginal FLOQSwabs has been compared - after a week-long storage - with practitioner-collected samples for HPV diagnosis with 6 of the most diffused PCR-based HPV assays. The results? A high agreement between self- and practitioner-collected samples on all assays! [28]
Indeed, Self-collection using dry swabs is sensitive for detecting LSIL+ and less expensive than FTA cartridge or physician collection using a swab and liquid-based medium[12]. PCR-based HPV test was also used to assess the population impact of the HPV vaccination program and to monitoring HPV prevalence among women and men. Self-vaginal FLOQSwabs have also been used in a study analyzing genital HPV positivity from 2009 to 2017 among women, heterosexual men, and unvaccinated women using Poisson generalized estimating equation models[31].

PCR - Urine

UriSponge allows transport of urine for Chlamydia trachomatis (CT), Mycoplasma genitalium (MG) and Neisseria gonorrhoeae (NG) nucleic acid detection regardless of storage time or temperature, suggesting that CT and NG are stable for up to 16 days, while MG up to 10 days. Also, results derived from VERSANT CT/GC DNA assay kit and Roche Cobas 4800 CT/NG assay were comparable with the testing of neat first-catch urine specimens for both CTand NG[7,32].

Future directions and opportunities

It's a game of give and take

It is clear that self-collection represents an excellent opportunity for the future of medicine; its implementation in new clinical specialties and for other biological specimens is highly desirable.

The low global awareness on the topic and patients' concerns about getting the correct diagnosis when collecting
their own specimens are self-collection main challenges. If, for the first obstacle, awareness campaigns are necessary, the second hurdle would be overcome by optimizing and guiding specimen collection to enhance the tests' value no matter where, how, and by whom the sample is collected. Also, developing high-quality and easily accessible clinical laboratory testing, along with easy-to-use self-collection devices for various biological specimens, is crucial. Here is where Copan takes the field, with its never-ending research towards safe and reliable devices designed specifically for the home-based collection.

Concluding, the conjunct efforts of medical companies, public healthcare providers, and private organizations will benefit individual patients but also these entities themselves – which may exploit self-collection to give an increasingly timely and effcient service while at the same time reducing operational workload costs and risks.

Scientific references

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

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