OPEN ACCESS

Quality, acceptability and usability of self-sampling kits used by non-healthcare professionals for STI diagnosis in Spain: a single-blind study

Javier Gómez-Castellá ,[1,2] Marta Cobos Briz,[1] Néstor Nuño,[1] Asuncion Diaz,[3] Francisco Javier Bru-Gorraiz,[4] Alejandro Martín-Gorgojo,[4] Maria Concepción Almonacid-Garrido,[5] Anna Mir,[6] Mario Muñoz,[7] Julia Del Amo[1]

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/sextrans-2024-056124).

[1]Division for Control of HIV, STIs, Viral Hepatitis and Tuberculosis, Government of Spain Ministry of Health, Madrid, Spain
[2]University of Alcalá de Henares, Madrid, Spain
[3]National Centre for Epidemiology, CIBERINFEC, Institute of Health Carlos III (ISCIII), Madrid, Spain
[4]STI/Dermatology Department-Centro de Diagnóstico Médico, Madrid City Council, Madrid, Spain
[5]Clinic Laboratory Department-Centro de Diagnóstico Médico, Madrid City Council, Madrid, Spain
[6]Technical, RA, Quality & Environment Director, Deltalab Group, Barcelona, Spain
[7]Strategy & Business Development Director, Deltalab Group, Barcelona, Spain

Correspondence to
Dr Javier Gómez-Castellá; jgomezc@sanidad.gob.es

Received 26 January 2024
Accepted 9 June 2024
Published Online First 4 July 2024

To cite: Gómez-Castellá J, Cobos Briz M, Nuño N, *et al*. *Sex Transm Infect* 2024;**100**:405–410.

ABSTRACT

Objectives Sexually transmitted infections (STIs) have markedly increased over the last decade in Spain, calling for prevention and control innovative approaches. While there is evidence indicating the effectiveness of self-sampling for STI diagnosis, no kits for this purpose have been authorised in Spain.

Methods A prospective single-blind cross-sectional study carried out between November and December 2022 in an STI clinic in Madrid, Spain, to determine the validity, feasibility and acceptability of self-sampling kits used by non-healthcare professionals from vagina, pharynx, rectum and urethra to diagnose *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). Self-samples were compared with samples collected by healthcare professional (HC samples) and analysed by PCR. Frequency of CT and NG diagnosis by sample type was compared using McNemar's test for paired data. Sensitivity and specificity of self-samples for CT and NG diagnosis were also calculated.

Results 306 self-samples from 51 participants were analysed. 80% were men with median age of 33 (IQR: 28–38) years. Self-samples and HC samples showed no significant statistical differences in CT and NG diagnosis. Self-samples had a sensitivity of 81% for CT and 93% for NG, with a specificity of 97% for CT and 95% for NG. More than 90% of participants had no difficulty understanding the kit instructions and 71% expressed high levels of satisfaction with the self-sampling kit.

Conclusion Self-sampling kits for CT and NG diagnosis can be safely and effectively used by non-healthcare professionals in Spain. National strategies for STI prevention and control should prioritise self-sampling strategies.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The results of self-sampling for sexually transmitted infection (STI) diagnosis are comparable with those performed by healthcare professionals.

WHAT THIS STUDY ADDS

⇒ We provide data regarding usability and acceptability of self-sampling in a Spanish cohort of key population while complying with the European Union 2017/745 regulation on medical devices.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results of this study will help the health authorities in Spain to approve the self-sampling procedure for STI diagnosis according to European and Spanish regulations on medical devices.

INTRODUCTION

Similar to other European countries, there has been a marked increase in sexually transmitted infections (STIs) in Spain over the last years. Between 2015 and 2021, the rates per 100 000 people increased for *Neisseria gonorrhoeae* (NG) (13.71 cases vs 32.41 cases), syphilis (7.26 cases vs 13.97 cases) and *Chlamydia trachomatis* (CT) (18.06 cases vs 48.36 cases). In 2021, NG and syphilis were most prevalent among men (25–34 years old), while the majority of CT cases were reported among young women (19–24 years old) and men (25–34 years old).[1]

The progressive increase in STI in Spain calls for innovative approaches to prevention and control of these diseases. Self-diagnosis of HIV has proven useful and effective in reducing HIV undiagnosed fraction.[2] Additionally, several studies have demonstrated that the results of self-sampling kits for STI diagnosis are comparable with those performed by healthcare professionals.[3 4] For this reason, international studies recommend the promotion of self-sampling as part of broad national strategies for STI prevention and control.[5 6] Taking into account the experience followed by HIV self-testing strategies as well as self-sampling for STI diagnosis in other countries, the Strategic Plan for the Prevention and Control of HIV and other Sexually Transmitted Infections in Spain 2021–2030 tries to enhance early diagnosis of HIV and STI through innovation on diagnosis, such as the implementation of self-diagnosis and self-sampling strategies among groups at higher risk of STI or with difficult access to healthcare services such as rural areas.[7]

However, according to the Spanish and European regulations on medical devices, swabs used for STI sampling in Spain are authorised for healthcare professionals use only.[8 9] To overcome this barrier, we carried out a study to assess the validity, feasibility and acceptability of self-collected samples

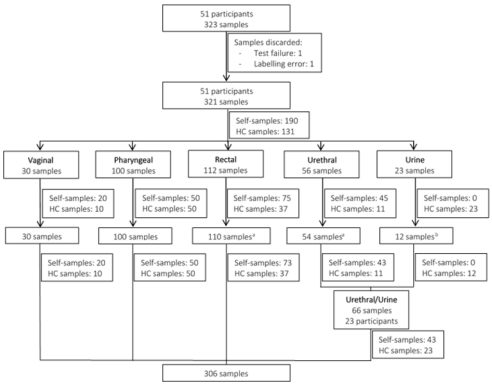

Figure 1 Study flow chart. The number of participants in each body location refers to those from whom samples were collected. [a]Two self-samples without HC sample were excluded. [b]11 HC samples without a counterpart self-sample were excluded. HC samples, healthcare professional-collected samples.

versus samples collected by trained professionals for the detection of CT and NG in real-life conditions. The secondary objective was to evaluate the usability and acceptability of the self-sampling devices.

METHODS

Study design and participants

We conducted a prospective single-blind cross-sectional study between November and December 2022 in an STI clinic in Madrid, Spain. The study was promoted by the Ministry of Health of Spain. To assess the validity, we measured the concordance between self-collected and healthcare professional-collected samples (henceforth referred to as 'HC samples'). All samples were analysed by PCR, which is the gold standard. The company Deltalab Group developed and manufactured the self-sampling kits for this study based on the clinical and laboratory standards institute guidelines.[10] Information on the characteristics of the self-sampling kits is described in online supplemental file 1. Vicum/Amies media were chosen to ensure broad compatibility with different PCR assays across the microbiology laboratories, ensure adequate preservation of specimens and mimic sample collection procedure in real-life settings. Any further information regarding the kits must be requested to Deltalab Group. Participants were selected through convenience sampling among people who attended the STI clinic. A convenience sample size of 51 individuals and approximately 300 samples were determined based on the capacity to manufacture self-sampling kits for the study. Inclusion criteria were: (1) being between 18 and 65 years of age; (2) being able to read and understand the self-sampling kit's instructions; and (3) having a symptomatic STI evidenced by either urethritis, cervicitis or proctitis without prior antibiotic treatment (symptomatic patients were specifically selected to maximise the number of positive diagnosis). During their day-to-day practice and without changing their usual clinical approach, the team's experienced dermatovenereologists determined from which of four anatomical locations samples should be collected: vagina, urethra, pharynx and rectum. The usability and acceptability of self-sampling were evaluated using a study-specific paper-based questionnaire. This questionnaire aimed to explore the user's experience, including their understanding of the instructions, acceptability and overall usability of the self-sampling process.

Sample collection procedure

The project manager informed participants of the study's objectives and obtained their written informed consent. For the self-sampling procedure, an explanatory video of the procedure was also used in combination with the kit instructions for use. This kit provided detailed information for handwashing recommendations and collection of pharyngeal (swab), urethral (swab) and rectal (swab) self-samples in written and graphic form. Instructions for urine sample collection were also given by healthcare professionals. Self-samples were collected at the clinic facility by study participants from all previously defined anatomical locations according to dermatovenereologist criteria and immediately afterwards; HC samples were obtained by a trained professional. All samples were numbered and recorded by project personnel and sent to the laboratory at the same time after collection. It was not possible for the laboratory personnel

Table 1 Frequencies of CT and NG diagnoses by body location and sample type

	Self-samples		HC samples		Agreement	Kappa (κ)	P value*
	N	n (%)	N	n (%)			
Vaginal	20		20				
CT		5 (25.0)		6 (30.0)	95.0%	0.88	0.317
NG		1 (5.0)		2 (10.0)	95.0%	0.64	0.317
Pharyngeal	50		50				
CT		3 (6.0)		1 (2.0)	92.0%	−0.03	0.317
NG		9 (18.0)		9 (18.0)	92.0%	0.73	1.000
Rectal	73		73				
CT		13 (17.8)		14 (19.2)	93.2%	0.77	0.655
NG		22 (30.1)		19 (26.0)	95.9%	0.90	0.083
Urine/urethral	43		43				
CT		9 (20.9)		10 (23.3)	97.7%	0.93	0.317
NG		16 (37.2)		14 (32.6)	95.4%	0.90	0.157
Total	186		186				
CT		30 (16.1)		31 (16.7)	94.1%	0.78	0.763
NG		48 (25.8)		44 (23.7)	94.6%	0.86	0.206

*Calculated using the McNemar's statistical test for paired nominal data.
CT, *Chlamydia trachomatis*; HC samples, healthcare professional-collected samples; NG, *Neisseria gonorrhoeae*.

Table 2 Sensitivity and specificity analysis

Self-sample	HC sample		Sensitivity	Specificity	PPV	NPV
	N	N	%	%	%	%
Chlamydia trachomatis						
Vaginal	+	–				
+	5	0	83.3	100	100	93.3
–	1	14				
Pharyngeal	+	–				
+	0	3	0.0	93.9	0.0	97.9
–	1	46				
Rectal	+	–				
+	11	2	78.6	96.6	84.6	91.7
–	3	57				
Urine/urethral	+	–				
+	9	0	90.0	100	100	97.1
–	1	33				
Total	+	–				
+	25	5	80.6	96.8	83.3	96.2
–	6	150				
Neisseria gonorrhoeae						
Vaginal	+	–				
+	1	0	50.0	100	100	94.7
–	1	18				
Pharyngeal	+	–				
+	7	2	77.8	95.1	77.8	95.1
–	2	39				
Rectal	+	–				
+	19	3	100	94.4	86.4	100
–	0	51				
Urine/urethral	+	–				
+	14	2	100	93.1	87.5	100
–	0	27				
Total	+	–				
+	41	7	93.2	95.1	85.4	97.8
–	3	135				

HC sample, healthcare professional-collected sample; NPV, negative predictive value; PPV, positive predictive value.

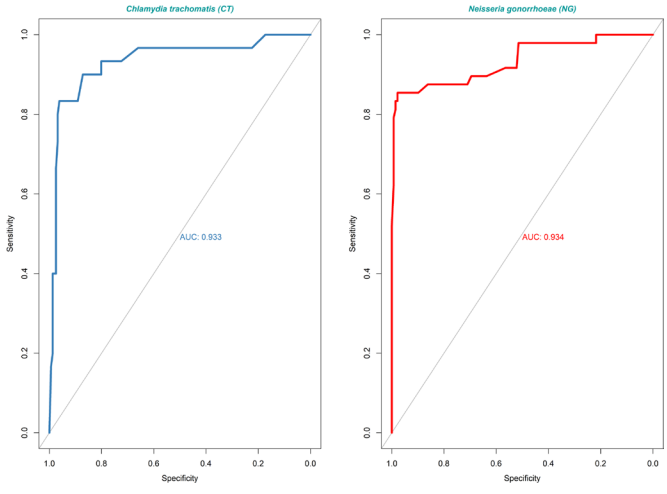

Figure 2 Receiver operating characteristic curves for the diagnosis of CT and NG and using self-samples. The areas under the curves (AUCs) represent the ability of self-samples to distinguish between positive and negative CT and NG cases correctly. CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*.

Table 3 Usability and acceptability of the self-sampling kits

	n (%)
Level of understanding (self-sampling process)	
Instructions	48 (94.1)
Use of the swabs	48 (94.1)
Swab introduction into the reagent	44 (86.3)
Identification of tubes	50 (98.0)
Misuse of the kit and its consequences*	48 (96.0)
Usability	
Understood the self-sampling process	51 (100)
Considered self-sampling provides reliable results	51 (100)
Saw the video provided by the QR code	25 (49.0)
Considered self-sampling process is simple	52 (100)
Considered instructions were clear	48 (94.1)
Level of acceptance	
Very unsatisfied	0 (0.0)
Unsatisfied	0 (0.0)
Neither satisfied nor unsatisfied	2 (3.9)
Satisfied	13 (25.5)
Very satisfied	36 (70.6)
Total	51 (100)

*Percentage over 50 responses.

to distinguish between self-samples and HC samples. A parallel nucleic acid amplification test was conducted to determine the presence of CT and NG infection within 12 hours of collection using the Cobas 4800 CT/NG system (Roche, Basel, Switzerland). HC samples were collected using Cobas PCR Media according to the manufacturer's specifications. For self-collected samples, the Deltalab flocked swabs initially discharged in Amies or ViCUM media were resuspended in 1 mL cobas PCR medium. Samples were then tested on the cobas 4800 system.[11–14] All samples were refrigerated at 4°C and destroyed after the end of the study. No adverse effects were observed due to the sample collection procedure during the study.

Data analysis

The database was created using Microsoft Excel (Microsoft, USA) and analysed using STATA V.15.0 (Stata Corporation, USA) and R V.3.4 (R, Foundation for Statistical Computing, Austria).

We used descriptive statistics (frequency tables for categorical variables and median and IQRs for numerical variables) to present the sociodemographic characteristics of participants and the usability and acceptability of self-sampling kits.

As the number of urethral HC samples was limited, we asked participants to collect urine samples, and both urine and urethral samples were considered complementary and grouped together (henceforth referred to 'urine/urethral samples') in the analysis. We calculated the frequency of CT and NG diagnoses by type of sample (ie, self-sample or HC sample) and body location (ie, vaginal, pharyngeal, rectal and urine/urethral). The agreement between self-sample and HC sample results was reported using the kappa statistic. Using the McNemar's test for paired data, we assessed differences in the frequencies of CT and NG by sample type. Furthermore, we calculated the sensitivity, specificity, positive predictive value and negative predictive value of self-samples using HC samples as a gold-standard reference.

The receiver operating characteristic (ROC) curves were calculated to assess the CT and NG diagnostic potential of self-samples.

RESULTS

Characteristics of participants

In total, 323 samples from 51 participants were collected. 99% (321) of the samples were valid. Two HC samples were discarded: one because of test failure and another because of a labelling error. Additionally, 11 urine samples without a urethral self-sample counterpart and 4 self-samples (2 rectal and 2 urethral) without a counterpart HC sample were excluded. The final analysis included 306 samples (figure 1).

Each participant produced a median of 3 (IQR: 3–5) self-samples. There was a balance in the type of culture media used by gender and sample type. The characteristics of all samples are described in online supplemental file 2.

The sociodemographic characteristics of the study participants are presented in online supplemental file 3. The majority of participants (80%) were males, with a median of 33 (IQR: 28–38) years. Regarding educational level, 53% of participants had a university degree. 47% of respondents had performed self-sampling in the past, and 24% had some medical or scientific training.

Frequency and agreement of CT and NG diagnoses

Table 1 presents the frequencies and agreement of CT and NG diagnoses by location and sample type. Overall, 16% of self-samples and 17% of HC samples tested positive for CT. Self-samples and HC samples showed 94% agreement (κ=0.78). 26% of self-samples and 24% of HC samples tested positive for NG. Self-samples and HC samples showed 95% agreement (κ=0.86). The highest CT frequency was observed in vaginal samples, with 25% in self-samples and 30% in HC-samples. Vaginal self-samples and HC samples showed 95% agreement (κ=0.88). The highest NG frequency was detected in urine/urethral samples, with 37% in self-samples and 33% in HC samples. Urine/urethral self-samples and HC samples showed 95% agreement (κ=0.90). No differences in CT and NG diagnoses were observed between self-samples and HC samples.

Sensitivity and specificity of self-samples

The analysis of the sensitivity and specificity of self-samples is presented in table 2. There was a sensitivity of 83% for CT in vaginal self-samples, of 78% for NG in pharyngeal self-samples, of 79% for CT and 100% for NG in rectal self-samples, and of 90% for CT and 100% for NG in urine/urethral self-samples. The lowest sensitivity was observed in the pharynx for CT (0%) and vagina for NG (50%). The low frequency of diagnoses found in these body locations (6% and 5%, respectively) may have contributed to this result. Specificity levels were over 93% for both CT and NG in all body locations. Overall, self-samples had a sensitivity of 81% for CT and 93% for NG, and a specificity of 97% for CT and 95% for NG. Percentages of positive and negative predicted values are also presented in table 2.

ROC curves adjusted by gender and age for CT and NG self-sampling diagnosis are presented in figure 2. Overall, self-samples distinguished between cases with and without CT and NG diagnoses with a 93% accuracy rate.

Usability and acceptability of self-sampling kits

Table 3 describes the acceptability and usability results of the self-sampling kit. The large majority of participants reported understanding the self-sampling process and found self-sampling kits to be easy to use. Likewise, the level of acceptance of the self-sampling kit was high. 99% of participants were satisfied or very satisfied with the self-sampling kits.

DISCUSSION

We conducted a single-blind cross-sectional study to assess the validity, acceptability and usability of self-sampling kits to diagnose CT and NG in patients with symptoms compatible with an STI in an STI clinic in Madrid, Spain. Self-samples and HC samples showed no statistically significant differences in CT and NG diagnosis. Self-samples had a sensitivity of 81% for CT and 93% for NG, with a specificity of 97% for CT and 95% for NG. These levels are consistent with the results of a recent systematic review and meta-analysis.[15] The accuracy rate of self-samples to distinguish between positive and negative CT and NG cases was 93%. We have observed, however, low sensitivity for CT detection in pharyngeal specimens. Regarding the usability of the self-sampling kits, our study shows that the vast majority of participants had no difficulty understanding the kit instructions and considered self-sampling procedure was simple. The large majority of participants also expressed satisfaction with the self-sampling kit.

This is one of the first studies, and the first of its kind in Spain, to evaluate the validity of self-sampling kits for STI diagnosis in accordance with the new European Regulation 745/2017 on medical devices. This regulation specifies that public administrations can only approve new diagnostic procedures based on usability, safety and efficacy.[8] Therefore, this study represents a significant step towards standardising the promotion of self-sampling for STI diagnosis outside healthcare facilities in Spain. Our study did not examine the cost-savings associated with self-sampling. However, other studies indicate that access to self-sampling kits can significantly reduce health spending while improving access to these services, particularly for the most vulnerable populations.[16 17]

Our results are similar to other studies evaluating self-sampling kits for STI diagnosis. A systematic review and meta-analysis of 21 studies showed that both vaginal self-samples for CT diagnosis and urine samples for NG diagnosis had a sensitivity and specificity above 90%.[3] Another study in Germany found that the sensitivity of self-samples for CT and NG diagnosis was 93% and 90%, respectively.[18] These results are consistent with those obtained in studies among women and gay, bisexual and other men who have sex with men.[5 6 19] Several studies on the acceptability and usability of self-sampling kits for STI have been conducted in various countries and suggest self-sampling kits are well accepted by target populations.[3 20–24] In addition, since the COVID-19 pandemic, self-sampling and self-testing procedures have become very popular among the general population, increasing awareness of this method, although several challenges arise.[25–27] The low sensitivity for CT detection in pharyngeal specimens could be due to different reasons, including quality of samples taken by both HC professional and self-collected samples or due to the performance of the PCR assay. Several studies with different PCR assays suggest there are differences in sensitivity of pharyngeal CT detection depending on the technique used.[13 28 29] It is unlikely that the transport media used played a role since we did not find statistically significant differences when comparing samples, as some studies suggest.[14] However, further compatibility studies across molecular assays should be performed by manufacturers in the future.

Our study has some limitations. First, since the study was conducted in an STI clinic, the results regarding acceptability and usability may be overestimated. There is a possibility that participants were more familiar with self-sampling kits if they were frequent users of STI clinics. Second, we could only enrol 51 participants due to logistical and time constraints, leading to fewer female participants. We conducted various self-samples for each participant to overcome this limitation and obtain precise estimates. We acknowledge that randomising the order of HC samples and self-samples would have given more validity to our study. However, we had to adapt our study to the daily operating environment of the STI care service. Third, the use of different transport media combined with the manufacturer's medium in our sample collection procedure is an off-label indication of the molecular assay for CT/NG diagnosis. As previously mentioned, further studies of compatibility with different molecular assays should be performed by the manufacturers in order to change the indications of use in the future. Finally, we observed limitations with the collection of urethral samples since male participants found them uncomfortable. For this reason, we analysed both urine and urethral samples together. This decision was made to avoid excluding HC samples without corresponding self-samples in this anatomical location. There is evidence that urine and urethral samples can be consistently compared in men.[30]

In summary, the results of this study indicate that self-sampling kits for CT and NG diagnosis are acceptable and can be effectively used by lay users for STI diagnosis in Spain. In March 2023, these results were submitted to the Spanish Agency for Medicines and Medical Devices (Notified Body O318) in order to request approval for the use of self-sampling kits for STI diagnosis. Our study will contribute to improve STI diagnosis within the framework of national STI prevention and control strategies in Spain and we believe it could inspire other countries to benefit from this strategy.

Handling editor Irith De Baetselier

Contributors JGC conceived and designed the study, contributed to the development of the self-sampling kit and is responsible for the overall content as guarantor. MCB carried out the study, under supervision of FJB-G. FJB-G and AM-G participated in patient selection and sample collection. MCA-G carried out simple analysis in the laboratory. NN and JGC contributed to the statistical analysis of the data. AM and MM developed and provided the self-sampling kits for the study. AD and JDA contributed to the final version of the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests This study is the result of an agreement between the Spanish Ministry of Health of Spain, the City Council of Madrid and Deltalab Group. Deltalab Group was responsible for the development and provision of the self-sampling kits used in this study.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. Ethical approval was obtained from the ethics committee of La Princesa University Hospital (reference number: 4,857). All participants signed an informed consent form prior to participation. The information obtained from the study was treated confidentially, according to European and Spanish data protection regulations. All information was anonymised to ensure compliance with the ethical principles of research. The Spanish Agency for Medicines and Medical Devices (AEMPS), the Spanish National Commission for the Coordination and Monitoring of STI and HIV Programs and the Spanish National Commission for Public Health were informed about the purpose of the study. Self-sampling kits were manufactured thanks to a partnership between the Spanish Ministry of Health, the Madrid Regional Health Department and the company Deltalab Group (Spanish official state bulletin, reference A-2023-10554).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information.

ORCID iD

Javier Gómez-Castellá http://orcid.org/0000-0003-4025-7372

REFERENCES

1 Unidad de vigilanciade VIH, ITS y hepatitis B y C. Vigilancia Epidemiológica de las infecciones de transmisión sexual. In: *Centro Nacional de Epidemiología, Instituto de Salud Carlos III/División de Control de VIH, ITS, hepatitis virales y tuberculosis, Dirección General de Salud Pública*. 2023.
2 Galli RA, Lo Hog Tian JM, Sumner-Williams M, *et al*. An observed, prospective field study to evaluate the performance and acceptance of a blood-based HIV self-test in Canada. *BMC Public Health* 2021;21:1421.
3 Lunny C, Taylor D, Hoang L, *et al*. Self-collected versus clinician-collected sampling for chlamydia and gonorrhea screening: a systemic review and meta-analysis. *PLoS One* 2015;10:e0132776.
4 Chinnock B, Yore M, Mason J, *et al*. Self-obtained vaginal Swabs are not inferior to provider-performed endocervical sampling for emergency department diagnosis of neisseria gonorrhoeae and chlamydia trachomatis. *Acad Emerg Med* 2021;28:612–20.
5 Rahib D, Delagreverie H, Gabassi A, *et al*. Online self-sampling kits to screen multipartner MSM for HIV and other stis: participant characteristics and factors associated with kit use in the first 3 months of the memodepistages programme. *Sex Transm Infect* 2021;97:134–40.
6 Rahib D, Bercot B, Delagreverie H, *et al*. Online self-sampling kits for human immunodeficiency virus and other sexually transmitted infections: feasibility, positivity rates, and factors associated with infections in France. *Int J STD AIDS* 2022;33:355–62.
7 Division for Control of HIV, STIs, Viral Hepatitis, and Tuberculosis. Ministry of health of Spain. strategic plan for the prevention and control of HIV and other sexually transmitted infections in Spain. 2021. Available: https://www.sanidad.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/planNalSida/PLAN_FOR_THE_PREVENTION_AND_CONTROL_OF_HIV_AND_OTHER_SEXUALLY_TRANSMITTED_INFECTIONS_IN_SPAIN.pdf
8 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April342 2017 on medical devices, amending directive 2001/83/EC, regulation (EC) No343 178/2002 and regulation (EC) no 1223/2009 and repealing Council Directives344 90/385/EEC and 93/42/EEC (text with EEA relevance.). 2017. Available: http://data.europa.eu/eli/reg/2017/745/oj
9 Real Decreto Legislativo 1/2015, de 24 de julio. Por El que se Aprueba El Texto Refundido de la Ley de Garantías Y USO Racional de Los Medicamentos Y Productos Sanitarios. spaña: Ministerio de Sanidad. n.d. Available: https://www.boe.es/eli/es/rdlg/2015/07/24/1/con
10 CLSI. Quality control of Microbiological transport systems; approved standard-second edition. In: *CLSI document*. 2014: M40–A2.
11 Le Roy C, Papaxanthos A, Liesenfeld O, *et al*. Swabs (dry or collected in universal transport medium) and semen can be used for the detection of chlamydia trachomatis using the cobas 4800 system. *J Med Microbiol* 2013;62:217–22.
12 VanACastryck H, Lontie M. Validation of the Roche Cobas® 4800 CT/NG assay on eSwab samples. 2013.
13 Pflüger LS, Nörz D, Grunwald M, *et al*. Analytical and clinical validation of a multiplex PCR assay for detection of neisseria gonorrhoeae and chlamydia trachomatis including simultaneous LGV serotyping on an automated high-throughput PCR system. *Microbiol Spectr* 2024;12.
14 Fernando JA, Krysiak M, Prestedge J, *et al*. Evaluating preanalytical sample storage parameters for nucleic acid-based detection of. *Sex Transm Infect 1 de Febrero De* 2024;100:48.
15 Vialard F, Anand A, Leung Soo C, *et al*. Self-sampling strategies (with/without Digital innovations) in populations at risk of chlamydia trachomatis and neisseria gonorrhoeae: a systematic review and meta-analyses. *Sex Transm Infect* 2023;99:420–8.
16 Wilson JD, Wallace HE, Loftus-Keeling M, *et al*. Swab-yourself trial with economic monitoring and testing for infections collectively (SYSTEMATIC): part 1. a diagnostic

accuracy and cost-effectiveness study comparing clinician-taken vs self-taken rectal and pharyngeal samples for the diagnosis of gonorrhea and chlamydia. *Clinical Infectious Diseases* 2021;73:e3172–80.
17 Wilson JD, Wallace HE, Loftus-Keeling M, *et al*. Swab-yourself trial with economic monitoring and testing for infections collectively (SYSTEMATIC): part 2. a diagnostic accuracy and cost-effectiveness study comparing rectal, pharyngeal, and urogenital samples analyzed individually, versus as a pooled specimen, for the diagnosis of gonorrhea and chlamydia. *Clinical Infectious Diseases* 2021;73:e3183–93.
18 Weidlich S, Schellberg S, Scholten S, *et al*. Evaluation of self-collected versus health care professional (HCP)-performed sampling and the potential impact on the diagnostic results of asymptomatic sexually transmitted infections (stis) in high-risk individuals. *Infect Dis Rep* 2023;15:470–7.
19 Sallabank G, Stephenson R, Gandhi M, *et al*. Lessons learned from the implementation of a pilot study on self-collected specimen return by sexual minority men (project caboodle!): qualitative exploration. *JMIR Form Res* 2023;7:e43539.
20 Ogale Y, Yeh PT, Kennedy CE, *et al*. Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis. *BMJ Glob Health* 2019;4:e001349.
21 De Baetselier I, Smet H, Abdellati S, *et al*. 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. *BMJ Open* 2019;9:e028145.
22 McCartney DJ, Pinheiro TF, Gomez JL, *et al*. Acceptability of self-sampling for etiological diagnosis of mucosal sexually transmitted infections (stis) among transgender women in a longitudinal cohort study in São Paulo. *Braz J Infect Dis* 2022;26:102356.
23 Vahabi M, Mishra G, Pimple S, *et al*. n.d. Effectiveness of family-centred sexual health education and HPV self-sampling in promoting cervical cancer screening among hard-to-reach Indian women in rural and tribal areas: a community-based pilot study. *BMC Public Health*23:671.
24 Leenen J, Hoebe CJPA, Ackens RP, *et al*. Pilot implementation of a home-care programme with chlamydia, gonorrhoea, hepatitis B, and syphilis self-sampling in HIV-positive men who have sex with men. *BMC Infect Dis* 2020;20:925.
25 Manabe YC. The impact of COVID-19 pandemic on technologic and process innovation in point-of-care diagnostics for sexually transmitted infections. *Clin Biochem* 2023;117:75–83.
26 Goggolidou P, Hodges-Mameletzis I, Purewal S, *et al*. Self-testing as an invaluable tool in fighting the COVID-19 pandemic. *J Prim Care Community Health* 2021;12.
27 Kersh EN, Shukla M, Raphael BH, *et al*. At-home specimen self-collection and self-testing for sexually transmitted infection screening demand accelerated by the COVID-19 pandemic: a review of laboratory implementation issues. *J Clin Microbiol* 2021;59.
28 Ota KV, Tamari IE, Smieja M, *et al*. Detection of neisseria gonorrhoeae and chlamydia trachomatis. *Sex Transm Infect* 2009;85:182.
29 Harkins AL, Munson E. Molecular diagnosis of sexually transmitted chlamydia trachomatis in the United States. *ISRN Obstet Gynecol* 2011;2011:279149.
30 Shafer MA, Moncada J, Boyer CB, *et al*. Comparing first-void urine specimens, self-collected vaginal swabs, and endocervical specimens to detect chlamydia trachomatis and neisseria gonorrhoeae by a nucleic acid amplification test. *J Clin Microbiol* 2003;41:4395–9.