

CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX A

THE GOODS AND/OR SERVICES

REQUIREMENT (including Specification as published in the ITT)

1. Population Needs

1.1 National/Local Context and Evidence Base

Sexual health is an important area of public health. Most of the adult population in England are sexually active and access to good quality sexual health services improves the health and wellbeing of both individuals and populations. The Government has set out its ambitions for improving sexual health in its publication, A Framework for Sexual Health Improvement in England¹. Sexual ill-health is not equally distributed within the population. Some groups are at higher risk of poor sexual health and may face stigma and discrimination, which can restrict their ability to access services.

1.2 HIV

In the UK there are an estimated 101,600 people living with HIV of whom an estimated 7,800 (8%) are unaware of their infection². The two populations affected by HIV infection in the UK are men who have sex with men (MSM) and black African heterosexuals.

Gay, bisexual and other MSM are advised to test for HIV at least annually and every three months if having sex without condoms with new or casual partners. Black African men and women are advised to have an HIV test and repeat this every year if having unprotected sex with new or casual partners from countries where HIV is common. Despite recent declines in the numbers of new diagnoses in England late diagnosis remains a challenge. In 2017 43% of all HIV diagnoses were made at a late stage of infection².

In order to achieve the ultimate goal of the elimination of HIV transmission in England, HIV testing, including frequent testing of key populations is an important component of the combination prevention approach required. Providing a range of testing options and approaches in a variety of settings, including online will be key to maximising rates of HIV testing.

1.3 The National HIV Self-Sampling Service

In November 2015, based on the success of two national pilots, Public Health England and local authorities co-commissioned and launched a nation-wide HIV Self-Sampling Service for most at-risk populations for HIV acquisition. The current framework 3173_15 has shown that the demand for HIV Self-Sampling Service is relatively constant, but high numbers of kits are ordered during national campaign periods e.g. the weeks immediately before and after National HIV Testing Week. By April 2019, more than 150,000 kits have been ordered, with just under 86,000 returned for testing (56%). In 2018, quarterly return rates rose to between 62-64%. The Service Provider will be expected to maintain the quarterly return rate at at least 60%, and work towards improving upon this. During periods of normal activity the estimated number of kits requested is approximately 2,000 per month. This compares to periods around national campaigns, particularly between October and December when kit orders peak at around 12,000 in November.

The Service has been successful at engaging key populations including those who have never tested for HIV before³. The current Framework Agreement comes to an end on 29 October 2019 and following a review, the multi-disciplinary Steering Group has decided to proceed with procuring a new Framework Service Provider.

A single Service Provider will be appointed to provide a remote HIV Self-Sampling Service to the most at risk adult populations across England. As already outlined in the introduction to this document, the Service will be procured and performance managed by Eastern Shires Purchasing Organisation (ESPO), acting on behalf of Public Health England and the individual Customers. It is recognised that the Service Provider will need to work collaboratively across a number of national, regional and local providers as well as organisations responsible for both commissioning and delivery of different elements of the HIV clinical pathway.

2. Key Service Outcomes

2.1 The Service Provider will support delivery against one of three main sexual health Public Health Outcomes Framework indicators:

- People presenting with HIV at a late stage of infection
- In addition it will deliver the following outcomes to improve the sexual health in the populations as a whole:

2.1.1 Direct Outcomes:

- Improved access to HIV Self-Sampling Service for those most affected by sexual ill health

¹ Department of Health (2013). A Framework for Sexual Health Improvement in England.

<https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england>

² PHE (2018). Progress towards ending the HIV epidemic in the United Kingdom

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759408/HIV_annual_report_2018.pdf

³ PHE (2018). National HIV Self-Sampling Service Two year service report.

<https://www.gov.uk/government/publications/national-hiv-self-sampling-service>

- Increased uptake of HIV testing with particular emphasis on those who have not accessed other sexual health services in the last year, first time Service Users, and repeat testing of those that remain at risk
- Reduced sexual health inequalities amongst communities most at risk of HIV infection including black Africans, MSM, sex workers, drug users and trans communities
- Reduced number of undiagnosed cases of HIV
- Reduced late diagnoses of HIV

2.1.2. Indirect Outcomes:

- Increased number of those newly diagnosed routinely accessing treatment and care
- Reduced onward transmission of HIV and other sexual transmitted infections
- Improved health and wellbeing of people living with HIV
- Increased development of evidence-based practice
- Increased knowledge and awareness of HIV

3. Scope

3.1 Aims and Objectives of Service

The aim of this Service is to provide a cost effective and clinically robust remote HIV Self- Sampling Service for sexually active individuals aged 16 years and over. Emphasis will be placed on increasing testing for HIV amongst most key populations including MSM and black African populations. The Service will operate at no financial expense to the Service User and will run independently from all other STI home/remote sampling services.

Service objectives include but are not limited to:

- Access to free remote sampling services that allows people to self-sample independently with limited clinical involvement unless considered necessary.
- Appropriate onward referral for treatment and care following diagnosis with timely initiation of treatment when clinically indicated⁴.
- Rapid referral and signposting to free services for the prevention, detection and management (treatment and partner notification) of HIV, BBVs and other STIs to reduce population prevalence and onward transmission.

appropriate sexual health and Service information is provided to all Service Users including those not eligible to access the Service and following non-reactive result.

- Ensuring services are acceptable and accessible to people disproportionately affected by sexual ill health.
- Engaging national prevention bodies and non-governmental organisations to facilitate promotion, Service delivery and development
- Supporting evidence-based practice in sexual health including participation in audits and external Service evaluations and may include research.

3.2 Service Description/Pathway

The Service will be provided exclusively to sexually active individuals aged 16 years and over residing in the localities as specified by the Customers (or Public Health England during times of national campaign such as National HIV Testing Week during which times Service Users can reside anywhere in England).

The Service is characterised by the following:

User Interface and Access

- Designing, hosting, managing and maintaining a secure and accessible⁵ user- friendly interface that facilitates remote online ordering of an HIV self-sampling kit without the need to see a healthcare practitioner. The security, accessibility and user experience will be assessed by the steering group.
- In partnership with Public Health England the Service Provider will develop a brand for the platform using branding guidelines supplied by Public Health England.
- Public Health England will own the brand developed for the Service but not the platform through which the Service is delivered. www.freetesting.hiv will be the URL used to access the Service.
- Signposting individuals residing outside of the local authorities that are co-investing in the Service to obtain an HIV test from an alternative provider – this should include signposting to sexual and reproductive health services as well as other options for free self-sampling
- Providing information in a format designed to inform and support decision making by Service Users.

- The platform should be accessible 24 hours a day, 7 days a week with the exception of planned downtime for maintenance. Any periods of downtime should be kept to a reasonable minimum, and a suitable message should be displayed to Service Users visiting the site during this period.
- To encourage uptake of the self-sampling offer, the Service Provider should undertake focused marketing activities (for example, social marketing and search engine optimisation). All activities will complement nationally, regionally and locally commissioned campaigns promoting testing for HIV.
- Online information and guidance for using the self-sampling kits including an instructional video.
- The option for Customers to add syphilis testing into the Service.

⁵ For the purposes of this contract "accessible to all Service Users" including those with limited literacy, visual impairments, learning difficulties and those with a preference for information in other languages other than English. This may include but will not be limited to the following for Service Providers considering digital platforms: The ability to change text size; Instructions in video form; Use standard UK Government Access Keys Systems; Is compatible with any browser; Web Accessibility Initiative's (WAI) conformance to level 'A' standard; Embed a multilingual translator into the website with English as the default language. Where communication with Service Users is via a telephone, services for the purpose of language translation would be acceptable.

Kit Order Fulfilment

i) Online Ordering of Self-Sampling Kits

- Supply of self-sampling kits containing: in-date consumables for capillary or finger- tip blood sampling; easy-to-read and comprehend sampling instructions; sexual health promotion messaging and Service information leaflets; branded microbiology form; prepaid postage return envelope suitable for Category B UN 3373, diagnostic and clinical specimens containing biological and infectious substances.
- Facility for local Customers to add in local information leaflets (provided by Customer) on request.
- Delivery of a sampling kit to the Service Users' preferred address which may, given the option, differ from their place of residence, in discrete and unbranded packaging. Fulfilment of HIV self-sampling kit orders free of charge to the Service User.
- Collation of adequate Service User information to facilitate remote HIV-sampling, pathology, reactive and negative results notification, recall and repeat testing.
- Facility to provide syphilis screening on the same specimen and reactive and negative result management.

ii) Supply of Kits for Offline Distribution

Supply of kits for offline distribution where requested by Customers. These kits will be identical to the online kits but will contain a paper questionnaire to allow for the collection of all relevant personal and epidemiological information. The Service Provider will enter this information onto their laboratory information management system on receipt of the returned kit

Pathology

- CE marked 4th generation assay testing for HIV antibody and p24 antigens simultaneously as a minimum
- The Service Provider must provide details of the testing algorithm for HIV screening that will be employed and provide evidence of how the algorithm maximises both its Positive Predictive Value & Sensitivity and minimizes the frequency of ambiguous/ equivocal results. Tenderers should refer to the national HIV testing algorithm when preparing responses.
- CE marked total antibody testing for syphilis to report reactive results requiring further tests, or non-reactive results.
- 24 hour capacity to perform pathology on a high volume of specimens (around 40 000 tests per year)

Results Management

Following a result that has been confirmed reactive as per section 4.4 of this requirement the Service Provider must provide the following:

- Secure return of Service User results to the part of the service that delivers the results to the Service User and to the Service User themselves, through agreed methods of communication, in an appropriate manner.
- Provision of reactive results (with health promotion advice and referral pathways) by trained and clinically competent advisory services.
- Pro-active referral (with the Service User's consent which the Service Provider must obtain) for confirmatory testing to the HIV and/or sexual health service chosen by the patient, with service user confirmation of attendance
- Standard operating procedures for issues that may arise when informing Service Users of their results including (but not limited to) child protection and safeguarding, human trafficking, A&E and sexual assault services.

Following a result that has returned as non-reactive as per section 4.4 the Service Provider must provide the following:

- Provision of negative results via text message with signposting to appropriate local sexual health services local to the address the kit was ordered to and further sexual health and HIV information sources.

Management Information

- Provision of information and data in accordance with the specification for contract monitoring, invoicing and evaluation of the Service.
- Provision of real-time management information at upper tier local authority/Customer level, to include:
 - Number of Service Users ordering a HIV sampling kit and how they ordered.
 - Service User demography, sexual orientation, ethnicity and sexual behaviour.
 - Number of specimens not viable for processing.
 - Number of HIV samples returned and processed.
 - Number of reactive samples including syphilis reactive samples if relevant.
 - Number of individuals contacted with reactive results and referred to specialist services.
 - Percentage of referred Service Users that self-report attendance at specialist services.

The Service will be delivered in accordance with the quality outcomes indicators stipulated in section 8 of this specification.

3.3 Population Covered

The Service Provider must lead on the co-ordination, development and operation of HIV Self- Sampling Service for sexually active individuals aged 16 years and over. The Service will target mainly two key populations: MSM and black African populations (and other black communities at increased risk of HIV) however this may be varied based upon local need identified by a commissioning Customer. This will operate at no expense to the Service User and will run independently from all other online STI remote sampling services. All Service Users must reside within the geographical locality stipulated by the relevant Customer (i.e. the body with whom the Service Provider has entered a Call-Off agreement under the Framework Agreement or Public Health England during times of national campaign such as National HIV Testing Week, during which times Service Users can reside anywhere in England).

3.4 Dependencies and Interdependencies

The Service Provider shall ensure that Service Users receive consistent and continuous care through the establishment of data and care pathways. Data and information needs to flow rapidly and seamlessly between the user interface, order fulfilment, pathology services and the results advisory function.

The Service will need to interface with local specialised HIV services, local sexual health services as well as locally driven campaigns and activities. To achieve this, the Service is dependent upon up to date lists of local sexual health services and specialised HIV services within and beyond commissioned localities. The Service Provider will source these lists from approved sources e.g. NHS choices and supplemented by the Steering Group and Customers. The Service Provider is expected to actively participate in regional and national networks, relevant trials, training, as well as research and audit programmes where applicable.

3.5 Relevant Organisations and Anticipated Usage

The Framework is primarily intended for use by Public Health England and local authorities in England; however it will be open for use by the following:

- Public Health England;
- any local authority in England; or
- the NHS Commissioning Board;
- any clinical commissioning group, NHS Trust or NHS Foundation Trust in England

Between November 2015 and April 2019 more than 150,000 kits were ordered of which just under 86,000 (56%) kits were returned through the current National HIV Self-Sampling Service. The Service Provider must have the flexibility to adapt to surges in demand. During periods of normal activity the estimated number of kits requested will be approximately 2,000 per month. This compares to periods of peak demand between October and December when the number of kits requested peaks at around 12,000 in November. The Service Provider will be expected to maintain the quarterly return rate at at least 60% and work towards improving on this. Over the lifetime of the current framework a total of 87 Local Authorities have entered into a Call-Off agreements under the Framework. Findings from a survey of Customers demonstrated that most intended to continue to sign-up to the Framework. Tenderers should however note that this information is provided for guidance and does not constitute a binding commitment at this stage. Such binding agreements will be created by each Customer at the point at which it enters into a Call-Off agreement under the Framework.

3.6 Acceptance and Exclusion Criteria and Thresholds

Service User exclusion criteria include:

- Those under the age of 16 years.
- Those without a valid postcode of residence within the relevant Customer area.
- Those unwilling to provide at least one means of contact for their results.
- Optional if applicable: Those who are not identified as either MSM or black African (or others identified as being at increased risk of HIV). (It is recognised that the Service Provider can only take reasonable steps to apply this exclusion criterion, and is expected to work cooperatively with the relevant Customers to agree such steps).

3.7 Activity Planning Assumptions

Service planning and improvement should always include Service Users and public engagement.

3.8 Sampling Methodologies

The Framework will include from the outset one type of blood sample collection methodology. Alternative testing and sampling collection methodologies may be considered and permitted by the Steering Group and Customers at a later stage in the Framework term depending on the merits of doing so.

4. Applicable Service Standards

4.1 The Service is to be underpinned by the following national standards and guidelines:

- HIV testing: increasing uptake among people who may have undiagnosed HIV (NICE 2016)
- Service Standards for Sexual and Reproductive Healthcare (FSRH 2013)
- British HIV Association Standards of Care for People Living with HIV (BHIVA 2013)
- UK National Guideline on Safer Sex Advice (BASHH & BHIVA 2012)
- Standards for psychological support for adults living with HIV (British Psychological Society, BHIVA & MEDFASH 2011)
- PH34 Increasing the uptake of HIV testing among men who have sex with men (NICE 2011)
- PH33 Increasing the uptake of HIV testing among black Africans in England (NICE 2011)
- Standards for the Management of Sexually Transmitted Infections (BASHH & MEDFASH 2010)
- UK National Guidelines for HIV Testing (BHIVA 2008)
- Progress and Priorities - Working Together for High Quality Sexual Health (MEDFASH 2008)
- Recommended Standards for Sexual Health Services (MEDFASH 2005)
- Research Governance Framework for Health and Social Care (Department of Health 2005)
- Government Service Design Manual: Digital By Default Service Standard
- UK national guidelines on the management of syphilis (BASHH 2015)
- Standards for Online and Remote Providers of Sexual and Reproductive Health Services (FSRH/BASHH 2019)

Relevant UK clinical guidance covering the specialities of Sexual & Reproductive Healthcare and Genitourinary Medicine can be found at www.fsrh.org and www.bashh.org. The Service Provider must ensure Services reflect updates in guidance and recommendations as and when produced.

The Service Provider will be required to demonstrate that they have a named lead, together with systems, processes and plans to ensure sound clinical governance. These systems, processes and plans should be in line with and adhere to NHS Clinical Governance Frameworks.

4.2 User Interface of the Service

The Service User interface must be fit for purpose on the day it is launched (1 October 2019) and will include, but not be limited to the following requirements:

- Be able to process high volumes of kit requests simultaneously and be able to accept orders from Service Users 24 hours a day, 360 days a year.
- Comply with security standards at all times and should be registered with the Information Customers' Office (ICO).
- Comply with the General Data Protection Regulation 2018.
- Be accessible to all Service Users including those with visual impairments, learning difficulties and those with a preference for information in other languages other than English
- Must assure and inform Service Users of their privacy and confidentiality
- For the Service Provider and/or relevant parties under this contract to be certified members of The Information Standard, NHS England

4.3 Link into Clinical Services

The Service Provider must provide an efficient and effective method for the follow-up of Service Users with reactive results. Those with reactive specimens should be contacted by telephone at the earliest opportunity followed by multiple attempts should the Service User not answer the call. The Service Provider may use discreet text messaging and letters to contact Service Users if telephone contact proves difficult. The Service Provider must facilitate the transfer of Service User into a clinical service most convenient for the Service User, liaising with the Service User to remove or reduce barriers to this transfer. The Service Provider will provide general support throughout this process as required. The Service Provider will request confirmation from the Service User of their attendance at clinical services.

4.4 Remote Self-Sampling Consumables and Pathology

The pathology services must be fit for purpose on the day the Service is launched and will include, but not be limited to the following requirements:

- The pathology provider must have capacity to perform high volume pathology on specimens with capability to cope with surges in demand during peak times such as National HIV Testing Week. The Service delivers around 2,000 kits per month during normal service, which increases between October and December, peaking to around 12,000 in the month of November.
- CE marked 4th generation assay testing for HIV antibody and p24 antigens simultaneously as a minimum.
- A testing algorithm that maximises both its Positive Predictive Value & Sensitivity and minimizes the frequency of ambiguous/ equivocal results.
- The pathology provider must have capacity to include serology tests for Syphilis at the request of the National HIV Self-Sampling Steering Group.
- Full participation in the UK NEQAS for HIV serology.
- Full participation in the UK NEQAS for syphilis microbiology
- The pathology provider must be accredited with either ISO 15189 or ISO 17025 under the United Kingdom Accreditation Service (UKAS) and shall comply with all requirements for the handling, processing and storage of samples.
- The provider must quality assure and evidence pre and post analytical elements of the service.
- In line with The Service Provider should seek registration with the Care Quality Commission (CQC) for provision of the entire Service and adhere to its incidence reporting policy.
- Compliant with UK Standards for Microbiology Investigations – Anti-HIV Screening⁶.

4.5 Results Management Including Clinical Advice

The results management services must be fit for purpose on the day the Service is launched and will include, but not be limited to the following requirement:

- Where the Service Provider is responsible for transport services, triage and medical advice provided remotely, they will also need to seek registration under the Health and Social Care Act (HSCA) with the Care Quality Commission (CQC) and adhere to its incidence reporting policy.
- Where the Service Provider is an NHS body they should participate in NHS system reporting.

4.6 Service Availability

The Service Provider is required to accept inbound calls from Service Users (e.g. to answer questions about the ordering process or for advice about how to collect and return samples) during normal working hours Monday to Friday 9am – 5pm), at least one evening a week until 9pm, and 9am – 12noon on Saturdays.

The Service Provider is required to operate the results management function during the same operating hours as above.

Service Users who contact the Service out of hours should be sign posted to an appropriate 24 hour service such as NHS 111 or equivalent, and in case of emergency, sign posted to where Post-exposure Prophylaxis (PEP) is available for free on the NHS.

Coordination and management functions of the Service (including dispatch of kits) should be delivered, as a minimum, during business operating hours 9am-5pm (GMT) Monday to Friday.

4.7 Applicable Local Standards

Individual Customers may require the Service Provider to operate in accordance with their own (i.e. the Customer's) local standards. Unless such standards are demonstrably outside whatever would reasonably have been taken into account by the Service Provider in Tendering, then the Service Provider must comply with such standards.

4.8 Data Requirements

Provision of data within the Service should flow securely. Service Users must be advised of appropriate care as swiftly as possible.

The appointed Service Provider will also ensure data (including aggregate Service User demography and diagnoses, including confirmed diagnoses) is provided to the relevant Customer via an online portal or platform controlled by usernames and passwords. These data should be for contract monitoring and evaluative purposes and will include, but is not limited to, the number of website visits, number of kit requests, number of kits returned and the number of reactive results and the demographic details of the services users (see section 9.4).

4.9 Multiple Orders from the Same Service User

The Service Provider must contact an individual that has accessed the Service more than four times in a six month period. Where this is the case, the Service Provider is required to intervene not in order to prevent them using the Service, but to facilitate a one-to-one consultation for an individual who appears to be at a very high risk of infection.

4.10 Multiple Orders from the Same Address

The Service Provider must alert the Customer concerned in the event that a non-residential address is used multiple times to place a kit order. Where a Customer has set their testing threshold at less than 500 per annum, no more than 10% of the kit orders should have the same commercial address recorded as a residential address. Should a testing threshold exceed 500 per annum no more than 5% of the kit orders should have the same commercial address recorded as a residential

address. The purpose is not to prevent the Service being used by residents, but to encourage local conversations between Customers and the Service User about self-sampling provisions.

5. Location of Service Provider Premises and Liability for Sub-contractors

The location of the Service Provider's premises (including the location of premises at which any subcontracted components of the Service are provided) is not critical to this contract. It is however essential that regardless of such locations, the Service is delivered entirely in accordance with this specification. This includes an obligation on the Service Provider to ensure that any sub-contractors comply fully with the requirements of the specification and the contract (the Service Provider will be held liable for the failure to comply by any sub- contractor). The Service Provider will be required to attend quarterly Framework management meetings with the National HIV Self-Sampling Service Steering Group. The Steering Group will also pay a visit to the Service Provider site at least once during the period of the Framework.

6. Safeguarding Policies

- 6.1.** The service must have a safeguarding policy. This policy must include clear protocols to deal with dangerous, exploitative or unsafe behaviour and practice and provide training to all of the Provider's Staff to develop appropriate skills and knowledge. The Service Provider shall have in place and implement robust up-to-date procedures, (including, disciplinary procedures, whistle-blowing policy and recruitment checks), for avoiding and responding to actual or suspected physical, sexual, psychological, financial or material and discriminatory abuse and acts of neglect or omission. Such procedures shall be reviewed at least once every year.
- 6.2.** The Service Provider will be required to ensure that all individuals engaged in the provision of the Services are subject to a valid enhanced disclosure check undertaken through the DBS including a check against the barred lists. The provider will be responsible for ensuring that it has no reason to believe that any person who is or will be employed or engaged by the Provider in the provision of the Services is barred from the regulated activity as defined by the Safeguarding Vulnerable Groups Act 2006.
- 6.3.** In dealing with Service Users under the age of 16, the provider must ensure that they adhere to the Department of Health's guidance document "Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health" . The Service Provider should put in place reasonable steps agreed with the service steering group to facilitate the identification of under-age service users. In the event it is discovered a Service User is under the age of 16, practitioners also need to be aware of the specific responsibilities that they have for young people aged 13-15 and for those under the age of 13.
- 6.4.** The provider must ensure that they adhere to Department of Health's guidance document Safeguarding adults: The role of Health Service Practitioners . The provider should put in place reasonable steps agreed with the service steering group to facilitate the identification of vulnerable service users over the age of 16.
- 6.5.** The Provider shall have in place a robust safeguarding training programme for all Staff (including volunteers) appropriate to their level of responsibility. Further the Provider shall maintain appropriate records of training for audit purposes.

7. Incidents Requiring Reporting Procedure

All safeguarding incidents should be reported immediately to PHE and the authority under which the care was provided i.e. the Local Authority from which the kit was ordered. In participating in the framework, Customers may acquaint the Provider with their own safeguarding protocols and requirements, with which the Provider must act in accordance.

The Service Provider will produce a quarterly summary report providing full details of all complaints and how they were resolved. The Service Provider will have awareness of, and will respond to, infectious diseases outbreaks and other threats to health. A clinical governance report will be submitted to Public Health England on an annual basis and full details of any Serious Incidents (SIs) will be communicated to the relevant Local Authority and Public Health England without delay.

8. Quality Outcomes Indicators

In order to secure maximum effectiveness from the Framework in terms of delivering against its overarching objectives, the Service Provider's performance will be monitored against relevant quality outcomes indicators. The following table sets out various such indicators, based on national standards and experience from the current Framework. Reporting against these indicators will be as per the requirements of paragraph 8 of this specification.

Quality outcomes indicator	Threshold	Technical guidance reference	Method of measurement	Consequence of breach
Clinical Management				
Percentage of individuals accessing the Service who have sexual history and STI/HIV risk assessment ⁴ undertaken	>85%	BASHH Standard 1 ⁵	Contract monitoring	Remedial Action Plan
Percentage of kits packaged and posted to Service User within 2 working days of request.	>95%	N/A	Contract monitoring	Remedial Action Plan
Percentage of specimens to be returned to the laboratory by Service User for processing within 30 days of receipt	>60%	N/A	Contract monitoring	Remedial action plan
Percentage of specimens that could not be processed by the laboratory due to sampling error	<5%	N/A	Contract monitoring	Remedial action plan
Percentage of HIV-negative Service Users receiving sexual health promotion messaging and signposting where to access information for other sexual health services	100%	N/A	Clinical Audit	Remedial action plan
Percentage of Service Users with negative results that received their results through their preferred method of contact within 5 working days of receiving sample	100%		Audit and feedback from Service User	Remedial Action Plan
Percentage of reactive results attempted to be communicated to Service Users within 5 working days of receiving the sample	100%	N/A	Contract monitoring	Remedial Action Plan
Percentage of reactive results actually communicated to Service Users within 5 working days of receiving sample.	75%	N/A	Contract monitoring	Remedial Action Plan
Percentage of reactive Service Users self-reporting attendance at chosen sexual health service in less than 10 working days from being informed	>80% patient confirmed	N/A	Audit	Remedial action plan
Percentage of HIV-negative Service Users invited to retest annually	100%	N/A	Contract monitoring Audit	Remedial action plan
Improving Productivity				
Percentage of staff delivering Services who have successfully completed nationally accredited training, according to their scope of practice, and fulfilled relevant update requirements	100%	BASHH Standard 2	Audit	Remedial action plan
Service User Experience				
Evidence of at least one Service User experience survey annually	100%	N/A	Annual Report	Remedial action plan
Percentage of Service User feedback on surveys that rates satisfaction as good or excellent (see paragraph 10 of this specification)	>70%	N/A	Ongoing Annual report	Remedial action plan

⁴ STI/HIV risk assessment as requested under Section 9: Sexual History and Risk Assessment Questions in this service agreement
<http://www.medfash.org.uk/publications>.

⁵ BASHH (British Association Sexual Health & HIV) and MEDFASH (2010). *Standards for the Management of Sexually Transmitted Infections*

Quality outcomes indicator	Threshold	Technical guidance reference	Method of measurement	Consequence of breach
Evidence of improvements made to Service as a result of Service User feedback	Demonstrable evidence of improvements and changes made to Service delivery in response to feedback	BASHH Standard 9	Ongoing	Remedial action plan
Number of Service Users making formal complaints about the Service (verbal or written)	Service Provider to notify the Customer	BASHH Standard 9	Ongoing	Remedial action plan
Access				
Accessibility of kit ordering services 24 hours a day 7 days a week	100% outside of planned downtime for maintenance	N/A	Ongoing	Remedial Action Plan
Reducing Inequalities				
An Equality Impact Assessment (EIA) is undertaken and outcomes utilised to inform forward year planning	Completion of EIA annually	N/A	Audit and Service User feedback	Remedial action plan
Contactors to demonstrate that all functions and policies are equality impact assessed	Agreed programme to achieve compliance	Locally determined	For local determination	Remedial action plan

9. Information Provision and Contract Monitoring

9.1 On a quarterly basis, the Service Provider will be required to report progress against all the Quality Outcome Indicators detailed under clause 8 above (or as otherwise agreed within the Framework Agreement) to ESPO (the Framework manager) who will gather such information on behalf of Public Health England.

The information will also be available to the Customers who participate in the Framework.

9.2 Separately, reports may be required by individual Customers detailing activity within the areas for which they are each responsible.

9.3 Where any Customer (including Public Health England) has stipulated a maximum level of expenditure or maximum number of test kits to be returned, the Service Provider shall provide a monthly report to that Customer detailing recent and cumulative activity under the Framework payment for which that Customer is responsible. Additionally, an alert shall be sent to the Customer when such activity reached 95% of the specified maximum.

9.4 Customers and ESPO shall have secure access (controlled by logins and passwords) to an online database so that they may monitor Framework usage. Levels of access shall be controlled to limit the data visible (in particular such access shall automatically manage controls required under relevant legislation e.g. as applies to data protection and patient confidentiality).

The Service Provider will meet quarterly with ESPO and the National HIV Self-Sampling Service Steering Group to review performance, and at least ten working days ahead of such meetings provide or provide access to disaggregate data for all Service Users to the Public Health England service manager. Five working days ahead of each such meeting the Service Provider shall also send to ESPO a report which includes at least the following information:

- 1) How the Service User had found out about the Service
- 2) Where there is an online Service provision:
 - List of referrers and their volume of click-throughs to website
 - Total number of website visitors
 - Proportion of website visitors that result in a kit being requested
 - Aggregate summary of where ineligible Service Users reside by Lower-tier Local Authority of residence
- 3) Number of first and follow up Service Users ordering a HIV sampling kit and how they ordered
- 4) Number of Service Users ordering and returning HIV sampling kits by:
 - Kit ordering channel
 - Age (Bands)
 - Gender
 - Ethnicity

- Sexual orientation
 - Lower-tier Local Authority of residence
- 5) Sexual History and Risk Assessment Questions
 - Number and gender of recent sexual partners
 - Number of recent unprotected sexual partners
 - Last time of an HIV test
 - 6) Number of HIV samples processed by the Service
 - 7) Number of reactive samples
 - 8) Provision of data on discrepant HIV laboratory results
 - 9) Number of referrals of individuals with reactive results to sexual health services
 - 10) Total referrals by sexual health service
 - 11) Percentage of Service Users referred to chosen sexual health services as confirmed by the Service
 - 12) Quarterly NEQAS reports on laboratory performance
 - 13) Quarterly Laboratory summary report on the rate of initial 'Reactive' HIV test results and the rate of 'repeat reactives' found from among the initially 'reactives'
 - 14) Outcome of additional analysis on specimens undertaken in a recognised reference laboratory

10. Service User Survey

The Service Provider will conduct an annual anonymised survey with a sample of Service Users to assess both Service satisfaction and trends in relation to uptake of the Service. The survey will assess Service User satisfaction with the Service provided and the results are to be made available in a timely manner to ESPO for dissemination to the Customers as part of the process of evaluating the Service and to inform and reshape this specification and Service delivery.

Whilst the use of Patient Reported Experience Measures (PREMs) would be preferred, the appropriate methodology for the survey will be agreed via ESPO acting with and on behalf of Public Health England and the Customers. This will include setting adequate sample sizes to provide statistical confidence in the results.

11. Prices and Costs

Tenderers are advised that the ONLY costs which Customers will pay will be the costs per test kit issued (Note: Customers will consider a different cost for online and offline kits), and the costs per returned samples analysed and results-managed. No separate payment will be made for any other elements of the Service (for instance, setting up the necessary infrastructure, creating a website, promotional activity, etc). All costs associated with setting up and providing the entire Service, as described in this invitation to Tender, must be included within the unit costs Tendered.

12. Service Quality Performance Reports

ESPO, acting on behalf of Public Health England and the Customers, will require the Service Provider to produce and submit reports detailing their performance against the parameters shown below, at the frequency shown in each case. The right is reserved to amend the indicators from time to time to monitor different aspects of the Service and also to undertake verification audits if required.

Indicator		Method of measurement	Threshold	Frequency
Information Governance	Record keeping: Completion of the Care Quality Commission Essential standards of quality and safety 2010 Provider Compliance Assessment tool for Outcome 21 (Records)	Annual notes audit	Meets in full the CQC Provider Compliance Assessment tool for Outcome 21	Annually
	Information governance: Compliance with the requirements of the DH/HSCIC information governance assessment		Meets annually in full the DHSC information governance assessment tool	Annually

Indicator		Method of measurement	Threshold	Frequency
Clinical Governance	Completion of the Care Quality Commission Essential standards of quality and safety 2010 Provider Compliance Assessment tool for: <ul style="list-style-type: none"> Outcome 4 (Care and welfare of people who use services) Outcome 15 (Statement of purpose) Outcome 16 (Assessing and monitoring the quality of service provision) Outcome 17 (Complaints) Outcome 20 (Notification of other incidents) Outcome 21 (Records) 	Organisational compliance, Annual PPI plan and survey reports, quarterly complaints and incidents (and exception reporting), notes audit SCC quality reviews and visits	Meets in full the CQC Provider Compliance Assessment tool for Outcomes 4, 15, 16, 17, 20 and 21	Annually
	Number of Serious Incidents within Services Evidence of learning resulting from incident review	Service Provider to notify Customer in accordance with Incidents Requiring Reporting Procedure		Real time/ Monthly review Quarterly
	Incidences of implementing safeguarding children & vulnerable adults protocols – , plus update on training for staff	Protection incident reports		Monthly
	Clinical governance structure, updates on changes and improvements			6 Monthly
	Evidence of appropriate Insurance cover	Copies of insurance documentation		Annually
	Evidence of maintaining Service risk register	Service clinical risk register	High level risks and mitigation to be discussed Action plans and ongoing monitoring to be shared with Customers	Quarterly
Appropriately Trained Staff	Competence to deliver services: Completion of the Care Quality Commission Essential standards of quality and safety 2010 Provider Compliance Assessment tool for: <ul style="list-style-type: none"> Outcome 12 (Requirements relating to workers) Outcome 13 (Staffing) Outcome 14 (Supporting workers) 	Organisational compliance and self-assessments. Annual service staff survey. SCC quality reviews and visits	Meets in full the CQC Provider Compliance Assessment tool for Outcomes 12, 13, and 14	Annually
	Percentage of Service Provider staff delivering HIV & STI services who have successfully completed nationally accredited training, according to their scope of practice, and fulfilled relevant update requirements		Training Plan & thresholds to be agreed	Quarterly
	Percentage of staff undertaken safeguarding training		Trajectory from baseline to be agreed	Quarterly
Links to other Services	Care pathways/referral protocols linking all providers of sexual health provision across commissioning Local Authorities	Evidence of documented local care pathways or a sexual health network	Threshold to be agreed	Quarterly
	Completion of the Care Quality Commission Essential standards of quality and safety 2010 Provider Compliance Assessment tool for Outcome 6 (Co-operating with other providers)		Meets in full the CQC Provider Compliance Assessment tool for Outcome 6	Annually

CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX B

FRAMEWORK PRICES

Online kits

Description	Price	What is Included	Price Per Kit
Online kit issue	Price per kit issued	Inclusive price up to and including kit issue to Service User individual addresses	£2.72
Online kit clinical pathway	Price per kit returned	Add on price payable for returned kits which is inclusive of all remaining operational and clinical pathway elements	£9.64
			£12.36

Offline kits

Description	Price	What is Included	Price per Kit *
Offline kit issue	Price per kit issued	Inclusive price to cover bulk delivery in multiples of 50 kits to a single Customer location.	£3.42
	Inclusive price to cover bulk delivery in multiples of 50 kits to a single Customer location.	Inclusive price to cover bulk delivery in multiples of 100 kits, each to a single Customer location.	£2.72
		Inclusive price to cover bulk delivery in multiples of 500 kits, each to a single Customer location.	£2.72
Offline kit clinical pathway	Price per kit returned	Add on price payable for returned offline kits which is inclusive of all remaining elements of the clinical pathway. (NB carriage costs to include return from and results management for/communication with individual Service Users)	£9.64

Add on Syphilis testing

Description	Price	What is Include	Price
Syphilis Testing	Price per kit returned	Add on price applied where syphilis testing is specified and carried out– Price added to the offline or online HIV returned kit price as appropriate.	£8.54

CALL-OFF GENERAL TERMS AND CONDITIONS APPENDIX C-NA

SCHEDULE OF PROCESSING, PERSONAL DATA AND DATA SUBJECTS under the contract

1. The contact details of the Service Providers Data Protection Officer are: [Anna Joyce \(Anna@sh24.org.uk\)](mailto:Anna@sh24.org.uk)
2. The contact details of the Customer's Data Protection Officer are: Alex Sienkiewicz
Alex.Sienkiewicz@phe.gov.uk
3. The Processor shall comply with any further written instructions with respect to processing by the Controller.
4. Any such further instructions shall be incorporated into this Schedule.

Description	Details
Identity of the Controller and Processor	The Parties acknowledge that for the purposes of the Data Protection Legislation, the Customer is the Controller and the Service Provider is the Processor in accordance with clause B38.1.
Subject matter of the processing	The processing is needed in order to ensure that the Service Provider can effectively deliver the contract to provide the services to members of the public.
Duration of the processing	01 October 2019 – 31 March 2022
Nature and purposes of the processing	<p>To ensure a safe and seamless experience for users, SH:24 has developed its own clinical record system 'Admin' (Admin CRS). This web-based system provides a comprehensive clinical record of all orders, detailing:</p> <ul style="list-style-type: none"> - Users contact details - Testing history - Risk assessment data - Safeguarding flags - All communications/contacts with SH:24 clinicians - Reactive results, treatment and referral into clinic
Type of Personal Data being Processed	<p>Personal identifiable data (PID) and order information collected via SH:24 are stored separately within the HSCN Network within different tables (also encrypted), associated via a third "lookup" table which is itself encrypted. See below for a list of data fields captured (this may not include all data fields captured):</p> <ul style="list-style-type: none"> - ID, SH:24 UUID, Lab UID, Customer ID, Order Type, New/follow-up, Postcode, LSOA, Default LA, Date, Site, Test Date, Age, Gender, Sexual Preference, Sexually assaulted, Unprotected Sex, Pressured into sex, Paid for sex, Drink/drugs, Depression/low mood, Older or younger partner, Clinic visited, User asked question, HIV diagnosed, Did not return, Did not attend, Attended clinic, Ethnicity, Sexuality, Offline kit, Referred From, Referred to, Referred via, Processing error, Test regime, Status, Created at, Created at month/year, Dispatched at, Dispatched at month/year, Lab receipt, notified at, notified at month/year, TOT, Refused at, Request time, Inbound SMS, Syphilis, HIV, Test notes, Test for HIV, Test for syphilis
Categories of Data Subject	Personal identifiable data (PID) and order information
Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	<p>AWS:</p> <p>Decommissioned servers are wiped with Shred before being officially decommissioned by AWS, who are ISO 27001 certified and security destroy any hard disks at end of life.</p> <p>SH:24:</p>

	<p>SH:24's Record Management and Retention Policy, sets out a framework within which the staff responsible for SH:24's records can manage and control records effectively commensurate with legal, operational and information needs.</p> <p>Retention and disposal schedules:</p> <p>It is a fundamental requirement that all of SH:24's records are retained for a minimum period of time for legal, operational, research and safety reasons. The length of time for retaining records will depend on the type of record and its importance to SH:24's business functions.</p> <p>Service user records</p> <p>SH:24 has adopted the retention periods set out in the Records Management: NHS Code of Practice and latest BASHH Guidance which states that the minimum retention period for health records is as follows</p> <p>Adults: 8 years after the last attendance</p> <p>Children: until the service user's 25th birthday or 26th if the young person was 17 at the conclusion of treatment, or 8 years after death</p> <p>Family planning: 10 years after the closure of the case</p> <p>Litigation dossiers (this strictly refers to complaints and legal claims, but could include patients presenting with a history of sexual assault): 10 years or as advised by legal representatives</p> <p>SH:24 will not adopt a shorter retention period to any user record than the minimum set out above. If the service ceases to trade arrangements will be put in place to provide access to the data for the organisations with a statutory duty to deliver services to those users. SH:24 has put in place funds to provision access for the periods set out above being its lifetime if it ceases to trade.</p> <p>The retention schedule will be reviewed annually. Retention periods are recorded in the asset inventory, which link directly to the articles of GDPR. SH:24 has hardwired the right to be forgotten (Article 17) into its website so that any data subject has the right to withdraw consent during the ordering process; SH:24 has processes in place to respond to the right to be forgotten.</p> <p>Disposal encompasses archiving or destruction of the records. SH:24 records that have reached their minimum retention period to decide whether or not a record is worthy of archival preservation, whether it needs to be retained for a longer period as it is still in use, or whether it should be destroyed.</p> <p>When SH:24 deems that a record should be destroyed it follows the steps below:</p> <p>SH:24 does not keep paper records of its users' data. If a packing label has been erroneously printed with their name and address on it should be shredded using the company shredder.</p> <p>For the destruction of electronically stored records, SH:24 will work with its hosting providers (AWS) to take the necessary measures.</p> <p>SH:24 maintains a log of the disposal decisions taken regarding user records, showing the unique identifier number and date of destruction so that it is aware of those records that have been archived or destroyed and are therefore no longer available in the organization.</p>
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INFORMATION REQUIRED BY SH:24 FROM CUSTOMERS

Please complete and return to SH:24, copying in care@espo.org together with your Call-Off contract (Form of Contract and Order Form)

For the purposes of the National HIV Self-Sampling Service, SH:24 will use the NHS website (<https://www.nhs.uk/Service-Search/Sexual%20health%20services/LocationSearch/1847>) for the clinic finder tool. All local authorities should review and update their locally commissioned sexual health services on the NHS website to ensure SH:24 signpost ineligible users to the correct local services. This is particularly important during periods of PHE funding when the service is opened up to all areas of England and may lead to signposting service users in areas that are not commissioning the Service themselves.

Organisation Name	Public Health England		
Address	Wellington House, 133-155 Waterloo Road, London SE1 8UG		
Customer Name Name Email Telephone			
Billing Address			
Reference or PO Number for Invoices			
Add on Syphilis Service option Required	Yes	Offline service required (SH:24 to clarify details of volumes, delivery address(es) and timings)	
Local Pathway information to be used in the case of reactive results			
Sexual Health Service Clinic Address	Not Applicable for the National Service		
Clinic Opening Times	N/A		
Appointment booking line phone number	N/A		
Health Advisor direct contact number for Syphilis/HIV reactives	N/A		
Sexual Health Service Website address	N/A		
Lead Clinician (name, contact number, email)	N/A		
Safeguarding Lead for Sexual Health service (name, contact number, email)	N/A		
Local Authority Safeguarding contact details	N/A		
SARC service contact details	N/A		
Details of local services checked / updated on NHS website (www.nhs.co.uk)	Date of last update/check: N/A		