Public Health England

Protecting and improving the nation's health

National HIV self-sampling service
November 2018 to October 2019

Contents

Executive summary

In 2015, following the success of 2 national pilots, Public Health England led a procurement process to appoint a provider to a new framework for HIV self-sampling. The national HIV Self-Sampling Service (branded as www.test.hiv) until October 2020 was launched in November 2015.

Local authorities can sign up to the Framework to allow their residents to access the service. The service can be made available to all residents of a participating area or can be a targeted offer for residents from communities most at-risk of HIV. PHE has funded the service during designated periods of national promotion including National HIV Testing Week for all residents of England.

PHE is owner of the HIV Self-Sampling Framework and involves stakeholders in the strategic development and oversight of the service via the National HIV Self-Sampling Steering Group.

Report objectives

The self-sampling service is part of a combination prevention programme for the elimination of HIV in England with the following objectives:

- to share data and learning from the national HIV self-sampling service with national, regional and local stakeholders
- to enhance understanding of who is accessing the service and whether it is reaching key groups (including gay and bisexual men and black African communities) and first-time testers

Methods

Disaggregated anonymised data from service users ordering and returning kits from 1 November 2018 to 31 October 2019 were analysed. Data analysis included: ethnicity, gender, sexual orientation, self-reported risk factors, local authority residency, and HIV testing information. Reactive results have been split into low and high reactive based on their Predictive Cut-Off Index (PCOI)1.

1 High reactive result: Specimens with reactivity above the Predictive Cut-Off Index (PCOI) of 50 (4th gen assay) or 10 (5th gen assay). Low reactive result: Specimens with reactivity between 1 and the Predictive Cut Off Index (PCOI) for high reactive.

Main findings

Between November 2018 and October 2019, 43,016 kits were ordered of which 23,966 (55.7%) were returned.

A total of 1,833 kits were tested from black African service users, which represented 7.5% of all kits tested.

The proportion of high reactives was significantly higher in kits from users who identified themselves as Latin American (1.9% overall reactivity, 0.8% high reactivity), black African (1.4% overall reactivity, 0.7% high reactivity) and other black ethnic background (1.8% overall reactivity, 0.9% high reactivity), than kits from white service users.

Of those tested (24,342), 0.8% (194) of specimens were reactive overall and 0.3% (78) were high reactives – this translates to a cost per overall reactive specimen of £1,185 and a cost per high reactive specimen of £2,947.

The service has been successful at engaging first time testers and those who have not tested for more than a year:

- a quarter of the kits tested (6,107; 25.1%) were from users who had never had an HIV test before
- nearly three-quarters of the high reactive services users (58/78; 74.4%) reported never testing or testing over a year ago

Demand for the HIV self-sampling service is highest among gay and bisexual men who made up 67.2% (16,353/24,342) of kits tested, of these 0.4% (58/16,353) were high reactive.

Conclusions

The national self-sampling service continues to be successful at engaging most at-risk populations for HIV acquisition across the nation and those who have not tested for HIV as frequently as recommended in national guidelines, including many who have never tested before.

The national HIV self-sampling service offers a low-cost HIV testing service that can complement current service provision to key populations and will continue as part of a combination prevention programme implemented for the elimination of HIV in England.

1. Background

The aim of the national HIV self-sampling service is to provide a cost efficient and clinically robust remote HIV self-sampling service for sexually active individuals aged 16 years and over. Emphasis is placed on increasing HIV testing amongst key populations including gay and bisexual men, black African populations, as well as other individuals at increased risk of HIV.

Preventx Limited was the provider of the National HIV Self-Sampling Service (branded as www.test.hiv) between November 2015 and October 2019. The service was free to residents of participating local authorities and to all eligible residents of England during the PHE-funded periods of national promotion.

Following the expiration of the first framework and a procurement process to appoint to a new framework, SH:24 has been the provider of the service (now branded as www.freetesting.hiv) since October 2019.

The data presented in this report is for the final 12 months of the first framework.

ESPO (Eastern Shires Purchasing Organisation) manages the HIV Self-Sampling Framework on behalf of PHE (see Appendix 1 for further details on the process for signing up to the framework).

1.1 Service scope

Preventx Limited was the operator of the National HIV Self-Sampling service (then branded as www.test.hiv) between November 2015 and October 2019. Preventx Limited was responsible for maintaining the website, kit fulfilment and testing returned samples from their Sheffield based laboratory. Communication of reactive results has been subcontracted to Yorkshire MESMAC who was responsible for contacting the service user to signpost and facilitate their transition to a specialist sexual health service local to them and of their choice for confirmatory testing and support.
For further information on service provision, see Appendix 2 for the HIV self-sampling service user pathway.

1.2 Service promotion

Local authorities procuring the service are responsible for local promotion. National promotion of the service is conducted during pre-approved periods of time supported by the national HIV prevention programme (www.hivpreventionengland.org.uk) including National HIV Testing Week.

1.3 Governance

PHE is the owner of the HIV Self-Sampling Framework and is responsible for performance management and contract compliance. A steering group conformed by stakeholders has the role of providing strategic oversight and to advise PHE on the management of the Framework. The group includes public health expertise, local authority commissioners, specialist virological expertise and procurement expertise. The group meets on a quarterly basis to review activity, manage performance and guide developments.

1.4 Cost benefits

The HIV self-sampling service complements current local HIV test provision by offering an online alternative to those who either have never tested for HIV or wish to test more regularly. Procurement of the national HIV self-sampling service currently offers cost benefits to both local and national government bodies. This large-scale procurement process offers low cost HIV testing; increased capacity and the potential to increase earlier diagnosis.

2. Service overview

Between November 2015 and October 2019 there was a total of 1,397,230 visits to the service website and with new visitors accounting for 74% of all traffic. A total of 165,455 kits was requested of which 93,884 (56.7%) were returned and 93,726 tested (see Table 1).

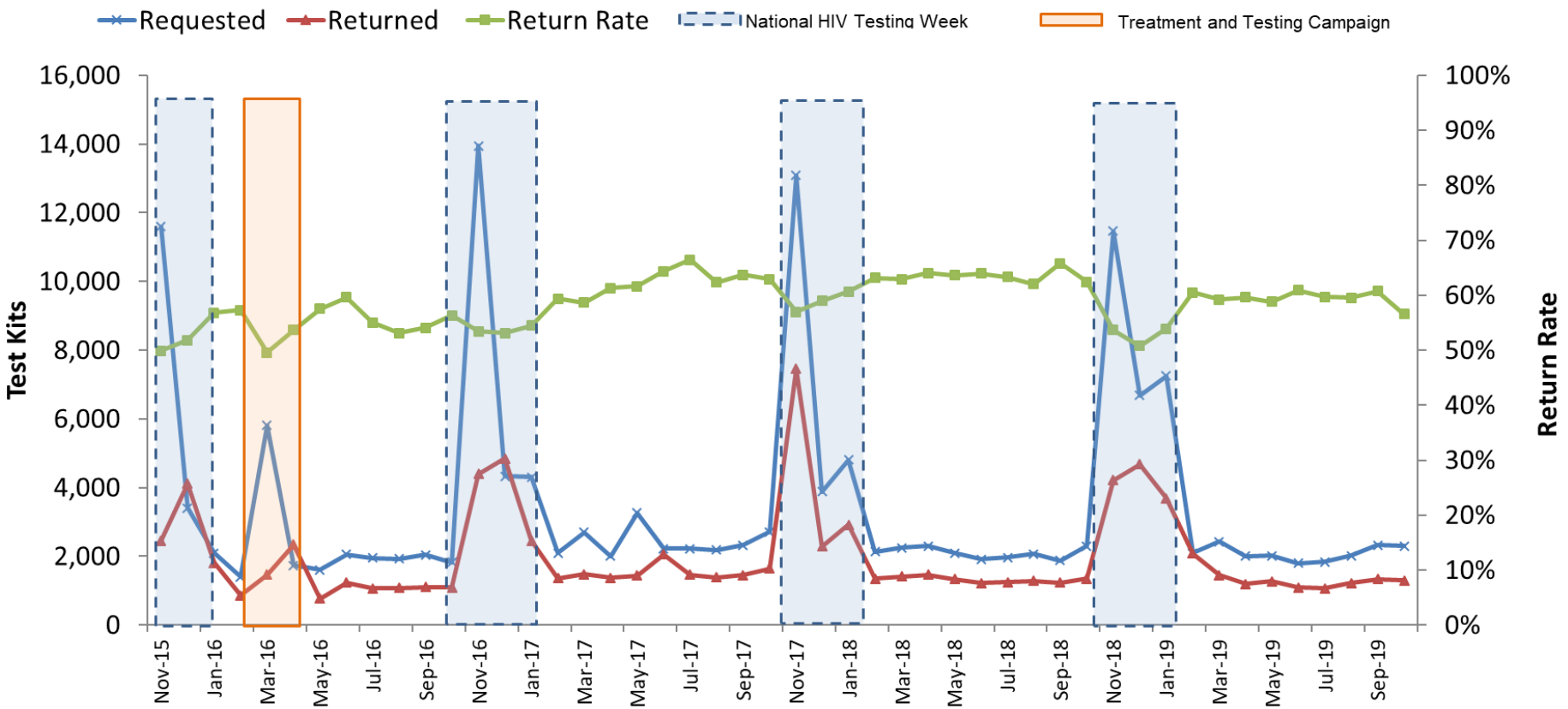
Demand for the HIV self-sampling service peaks during the National HIV Testing Week (NHTW) (see Figure 1). The number of kits requested during the NHTW campaigns increased from 11,596 in November 2015 to 13,869 in November 2018. The rate of returned kits varied from 49.6% to 66.5% between November 2015 and October 2019 (see Figure 1).

Table 1: Comparison by year and total (November 2015 to October 2019) demand for the national HIV self-sampling service.

Service Users	Y1 (November 2015 - October 2016)	Y2 (November 2016 - October 2017)	Y3 (November 2017-October 2018)	Y4 (November 2018 -October 2019)	Total (November 2015 - October 2019)
Visitor sessions	255,797	318,905	326,531	495,997	1,397,230
New visitors	187,550	239,683	241,252	365,966	688,485
Service lookups	129,262	145,046	143,672	159,314	577,294
Kits requested	37,449	44,309	40,681	43,016	165,455
Kits returned	19,727	25,633	24,558	23,966	93,884
Kits tested	19,421	25,372	24,591	24,342	93,726
Return rate	52.70%	57.90%	60.40%	55.70%	56.70%
Reactive results (rate)	237 (1.2%)	310 (1.2%)	246 (1.0%)	194 (0.8)	987 (1.1%)
High reactive (rate)	145 (0.7%)	143 (0.6%)	156 (0.6%)	78 (0.3%)	522 (0.6%)
Low reactive (rate)	92 (0.5%)	167 (0.7%)	90 (0.4%)	116 (0.5%)	465 (0.5%)

Term	Definition
Visitor sessions	Visitors to the service website
Service lookups	Visitors entering age and postcode to check eligibility
Kits requested	Number of kits orders during the time period
Kits returned	Total number of kits returned to laboratory. This number has been adjusted to match the time period when they were requested

Figure 1: National HIV self-sampling service demand: numbers of kits requested and returned for November 2018 to October 2019.



2.1 Reactive results

The HIV self-sampling service provided by Preventx used a fourth generation assay between November 2015 and October 2017 after which a fifth generation assay was implemented. Specimens identified as reactive were categorised as either high or low reactive. This is not equivalent to a confirmed HIV diagnosis but empirical evidence from an internal quality assurance process (see 2.2 below) indicate that high reactivity is predictive of probably HIV infection whereas low reactive results are rarely associated with likely HIV infection. All individuals with a reactive result are referred to clinical services for full confirmation of HIV infection. See Appendix 2 for details of the referral pathway.

The national service test algorithm includes a dual reactive result using the same testing platform performed by the contracted laboratory (Preventx). Currently reactive results are re-tested by an external laboratory as part of the internal quality assurance process.

2.2 Low vs high reactive results

To better understand how many positive diagnoses are being made through the service, we divide reactive results into 2 categories based on their Predictive Cut Off Index (PCOI). The PCOI for the 4th generation assay is 50 and for the 5th generation is 10. The definition for low and high reactives is as follows:

- low reactive result: specimens with reactivity between 1 and the PCOI of 50 or 10
- high reactive result: specimens with reactivity above the PCOI of 50 or 10

The internal quality assurance process of reactive results demonstrated that most high reactives were likely to have an HIV infection confirmed by the alternative testing platform. Specimens with a low reactive result were less likely to have an HIV infection confirmed by the alternative platform. Nonetheless all reactive results are immediately referred to appropriate services for further testing and clinical confirmation.

Results are delivered by telephone through a dual-script approach, 1 for low reactives and 1 for high reactives. This approach helps manage users' expectations while providing further information on the clinical pathway and offering other needed support.

The HIV self-sampling service has an overall combined reactivity rate of 1.1%, with a total of 987 reactive results from November 2015 to October 2019. Of these, 522 were categorised as highly reactive and 465 as low reactive, rates of 0.6% and 0.5% respectively. A lower reactivity rate was observed in year 4 (0.8%), compared to the 3 previous years of the service (see Table 1).

2.3 Laboratory results

Equivocal samples are those that are initially identified as reactive results but could not be repeated (for example, due to insufficient volumes of blood) or, less frequently, gave a non-reactive result on the repeat test. There were 11 (0.1%) equivocal samples between November 2018 and October 2019. These results are included as reactive in the subsequent tables and analysis. This is because service users with equivocal results are mostly likely to be reactive and as such are referred for follow-up in the usual way (see Table 2 and Appendix 2).

Haemolysed samples are those where the membrane of the red blood cells has broken down, causing the release of haemoglobin and other internal components into the surrounding fluid. Haemolysis is a common occurrence seen in serum samples and can compromise the laboratory's test parameters. Some known causes are: delays in postal services, not allowing alcohol from the swab to fully dry before sample collection and extreme weather. During Year 1 of the service, the proportion of haemolysed samples was 7.0% (n=1,362). Improvements implemented to mitigate the causes of haemolysis have helped to keep a low proportion of haemolysed samples (4.1% in year 4; n=991).

Insufficient samples are those that are received with too little blood to conduct the required testing. In Year 1, the proportion of insufficient samples was 2.3% (n=448). A higher proportion of insufficient samples was observed in year 4 (n=871; 3.6%). In cases where the specimen received is not eligible for testing due to lack of volume or haemolysis, users are prompted to request a new kit to collect a new specimen.

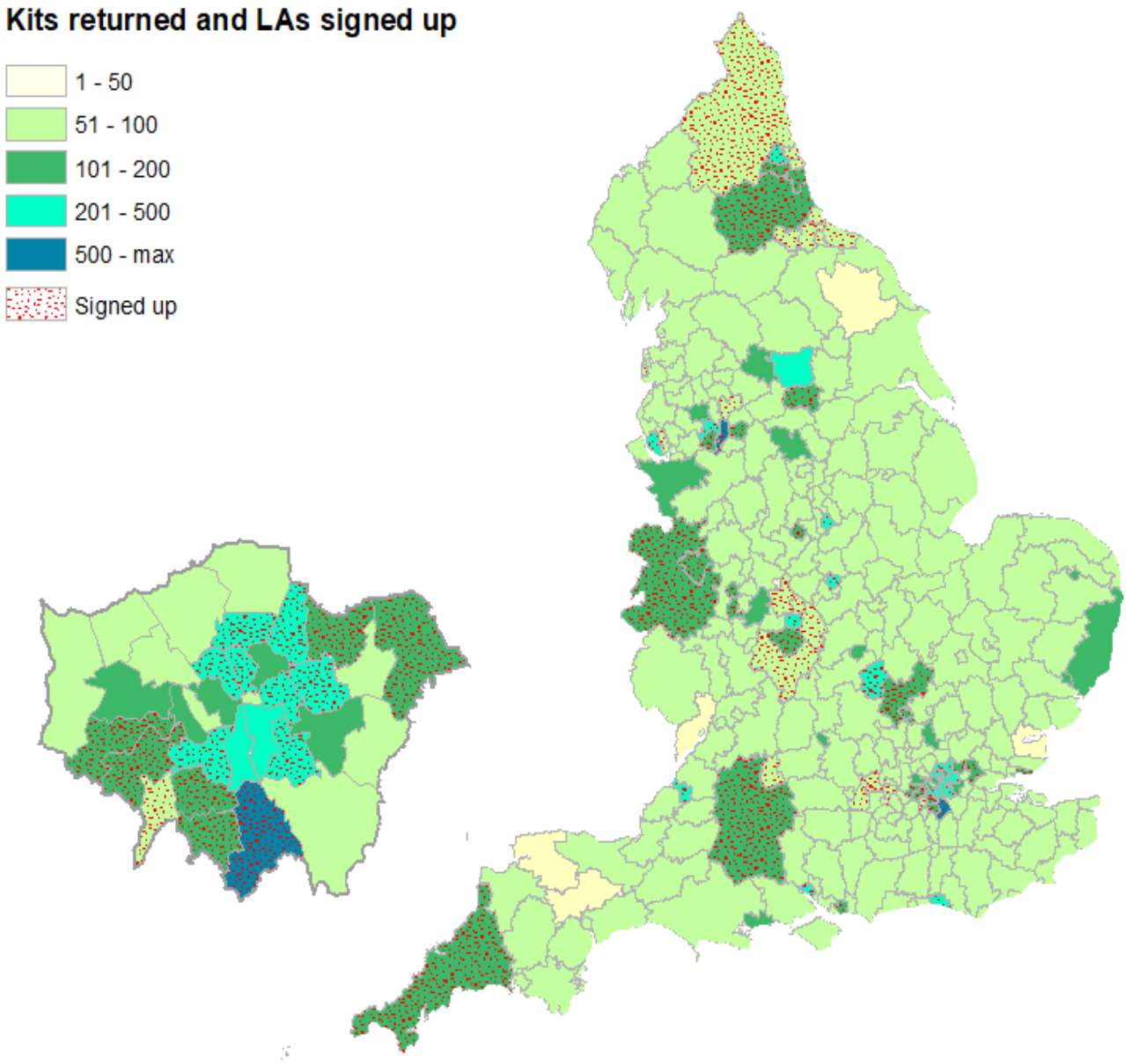
Table 2: National HIV self-sampling service laboratory records for specimens received between November 2018 to October 2019.

	Samples	Proportion of total kits returned
Equivocal	11	0.1%
Haemolysed	992	4.1%
Insufficient	871	3.6%

2.4 Geography

The service provided by Preventx was available to residents of all Local Authorities (LAs) during periods of national campaigns and to residents of LAs that commission the service outside of these time periods. Between November 2018 and October 2019, 71 local areas commissioned the service with 2 LAs ending the service in January 2019, and 26 ending the service in March 2019. The most kits returned per LA was 1,002, the lowest number was 1 (see Figure 2).

Figure 2: Number of kits returned and local authorities that signed up to the HIV self-sampling service. November 2018 to October 2019.



Of all the kits tested during this year period nearly over a quarter (n=6,480) came from London residents. After London, the regions of the North West (n=3,856) and the South East (n=3,373) had the highest total number of kits tested. Testing reflects the size of the population in each region, the size of the populations most at risk in each region and the number of LAs signed up to the service (Table 3 below).

Table 3: Number of kits tested, proportion of total kits tested, number of reactives and reactive rates by PHE region. November 2018 to October 2019.

PHE centre	Number of Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	ONS population estimates[1]
East Midlands	2,121	8.7%	18	8	0.8% (0.4%)	3,910,325
East of England	2,599	10.7%	19	10	0.7% (0.4%)	5,000,231
London	6,480	26.6%	60	26	0.9% (0.4%)	7,073,286
North East	1,188	4.9%	11	4	0.9% (0.3%)	2,182,911
North West	3,856	15.8%	29	14	0.8% (0.4%)	5,897,142
South East	3,373	13.9%	19	9	0.6% (0.3%)	7,378,358
South West	1,468	6.0%	17	3	1.2% (0.2%)	4,612,827
West Midlands	1,877	7.7%	16	3	0.9% (0.2%)	4,740,406
Yorkshire and The Humber	1,380	5.7%	5	1	0.4% (0.1%)	4,433,234
Total	24,342	100.0%	194	78	0.8% (0.3%)	45,228,720

1. ONS 2018 population estimates for residents aged 16 and over.

2.5 Cost per reactive

Between November 2018 and October 2019, 194 specimens were reactive translating to an overall cost per reactive of £1,185 and a cost per high reactive of £2,947. These costs have increased compared to the previous year as few tested reactive (see Table 4 below).

Table 4: Cost[1] of self-sampling service by kits reactive by year, November 2017 to October 2019.

	Numbers and costs	
Number of kits	**November 2017-October 2018**	**November 2018-October 2019**
Kits requested	40,686	43,016
Kits returned	24,508	23,966
Reactive results		
Reactive results (rate)	241 (0.98%)	194 (0.80%)
High reactive (rate)	152 (0.34%)	78 (0.32%)
Cost per reactive result		
All reactive results	£948.80	£1,185
High reactive	£1,502.76	£2,947

1. Costs include online platform, testing kits, laboratory processing, results management and provision of data. Costs do not include the national campaign or costs associated with management and oversight of the service.

2.6 User satisfaction

All service users were asked by the service provider (Preventx) to rate their experience online. Between November 2018 and October 2019, the service received feedback from 514 patients which showed that 96% (497/513) rated their satisfaction as good or excellent. Most of the concerns of those not satisfied with the service (16/513) were about having difficulties taking their blood sample (that is, large amount of sample required, not reading the instructions before taking the sample).

3. Service users

3.1 Overall

Upon accessing the self-sampling website, users are asked their age, gender, the gender of their sexual partners, their ethnicity and HIV testing history. Data from kits returned and tested show that the service is most frequently used by gay and bisexual men. Overall, 14,050 kits (57.7%) were received from men having sex with men only and 2,303 from men having sex with men and women. Individuals reporting only heterosexual sex were the second largest group to use the HIV self-sampling service from whom a total of 6,306 kits (25.9%) were tested. Compared to the previous year of the programme the number of heterosexual men tested increased from 2,986 to 3,300. Between November 2018 and October 2019, the demand for the service among those reporting only heterosexual sex was 21% higher among women (4,003) compared to men (3,300) (see Table 5).

The median age of users for whom kits were tested was 28 but ranged from 16 to 97 years of age. High reactivity was higher in older age groups and users between 46 and 65 had significantly higher rates of reactivity (0.8%) compared to those aged between 16 and 25 (0.2%) (see Table 5).

Almost 4 in 5 (18,558; 76.2%) of the kits were from service users who identified themselves as being of white ethnicity of whom 0.3% were high reactive. High reactivity was significantly higher in kits from users who identified themselves as other black ethnic background (0.9%), Latin American (0.8%) and black African (0.7%) than kits from white service users (0.3%) (see Table 5).

A quarter of kits tested (6,107; 25.1%) were from service users that reported never having had an HIV test before and of those 0.3% were high reactive. A further 33.2% (8,082) came from users that reported testing more than 12 months prior to this test and of those 0.5% were high reactive. A small number of tests were from users with unknown testing history (141; 0,6%) of whom 0.7% were high reactive.

Table 5: All service users. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and rates by gender, sexual behaviour, age group, ethnicity and testing history. November 2018 to October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value*[2]
Gender and sexual behaviour[1]						
Men						
Men reporting sex only with men	14,050	57.7%	120	52	0.9% (0.4%)	-
Men reporting sex with men and women	2,303	9.5%	15	6	0.7% (0.3%)	0.32
Men reporting sex only with women	3,300	13.6%	28	8	0.8% (0.2%)	0.975
Women						
Women reporting sex only with men	4,003	16.4%	28	11	0.7% (0.3%)	0.339
Women reporting sex with men and women	561	2.3%	2	0	0.4% (0%)	0.219
Women reporting sex only with women (WSW)	125	0.5%	1	1	0.8% (0.8%)	0.948
Age group						
16-25	9,511	39.1%	71	19	0.7% (0.2%)	-
26-35	8,344	34.3%	56	27	0.7% (0.3%)	0.550
36-45	3,659	15.0%	34	14	0.9% (0.4%)	0.292
46-55	1,991	8.2%	24	16	1.2% (0.8%)	**0.042**
56-65	650	2.7%	7	2	1.1% (0.3%)	0.353
>65	187	0.8%	2	0	1.1% (0%)	0.615
Ethnicity						
White	18,558	76.2%	129	47	0.7% (0.3%)	-
Black African	1,833	7.5%	26	13	1.4% (0.7%)	**0.001**
Other Black	548	2.3%	10	5	1.8% (0.9%)	**0.003**
Asian	767	3.2%	3	1	0.4% (0.1%)	0.323
Other Asian Background	576	2.4%	4	2	0.7% (0.3%)	0.999
Latin American	265	1.1%	5	2	1.9% (0.8%)	**0.028**
Other[3]	1,795	7.4%	17	8	0.9% (0.4%)	0.229
Testing history						
Within the last year	10,012	41.1%	58	19	0.6% (0.2%)	-
Over 1 year ago	8,082	33.2%	79	37	1% (0.5%)	**0.002**
Never tested	6,107	25.1%	55	21	0.9% (0.3%)	**0.019**
Unknown	141	0.6%	2	1	1.4% (0.7%)	0.526
Total	24,342	100.0%	194	78	0.8% (0.3%)	

1. Trans individuals are included in this table according to the sex of their reported partners.
2. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression.
3. Category 'Other' includes service users who self-describe as: other ethnic group and other mixed background.

3.2 Gay and bisexual men

Despite recent declines in numbers of new HIV diagnoses among gay and bisexual men they remain the group most at risk of HIV infection in the UK(1). In this analysis men reporting sex with men only (n=14,050), both men and women (n=2,258) and trans men reporting sex with men (n=36) and both men and women (n=45) are included. The median age for kits tested from gay and bisexual men service users was 28 years with the youngest service user aged 16 years and the oldest 97 years (see Table 6).

The highest proportion of high reactives (0.8%) was observed in specimens from the 46 to 55 age group. However, this was not significantly higher than in the youngest age group (p=0.153) (see Table 6).

Of the kits tested from gay and bisexual men the majority (85.3%) were from service users who reported their ethnicity as white. The proportion of high reactives in this group was 0.3%. The ethnic groups with the highest proportion of high reactives were black Africans (1.1%) and Latin Americans (1.0%). However, these were not statistically significant when compared with users of white ethnicity (see Table 6).

National guidelines advise that gay and bisexual men should test for HIV at least once a year and up to once every 3 months if they are having condomless sex with new partners (2, 3). In the National HIV Self-Sampling Service nearly 1 in 5 (n=2,926) of gay and bisexual men tested came from individuals who reported this as their first ever HIV test and of those 0.4% were high reactive (p=0.007). A further 5,382 (32.9%) had tested over a year ago and of these 0.5% were high reactive (p=0.001) (see Table 6). In the last 3 years of the HIV self-sampling programme, there has been a similar proportion of gay and bisexual men service users testing for HIV within 12 months (47.2% in year 2, 49.4% in year 3 and 48.7% in year 4).

Those who reported having condomless sex with more than 12 partners had the highest promotion of high reactives (1.2%) followed by those who reported between 6 and 12 condomless partners in the previous 12 months (0.7%). The proportion of gay and bisexual men service users who report more than 1 condomless partner in the last 12 months has increased from 43.6% (n=7,270) to 45.8% (n=7,490) between year 3 and year 4.

Over half (54.2%) of the gay and bisexual men tested reported usually or always having sex under the influence of alcohol or drugs and 0.9% and 0.4% respectively were high reactive. Nearly 1 in 5 (17.9%) gay and bisexual men tested (n=7,098) reported never having sex under the influence of alcohol or recreational drugs and 0.5% of them had a high reactive result (see Table 6).

Table 6: Gay and bisexual men[1]. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and rates by age group, ethnicity, testing history, condomless sex and sex under the influence of alcohol and recreational drugs. November 2018 and October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value*[2]
Age group						
16-25	5,931	36.3%	51	18	0.9% (0.3%)	-
26-35	5,774	35.3%	38	20	0.7% (0.3%)	0.210
36-45	2,462	15.1%	20	8	0.8% (0.3%)	0.829
46-55	1,508	9.2%	19	12	1.3% (0.8%)	0.153
56-65	521	3.2%	5	0	1% (0%)	0.814
>65	157	1.0%	2	0	1.3% (0%)	0.584
Ethnicity						
White	13,943	85.3%	113	44	0.8% (0.3%)	-
Black African	178	1.1%	2	2	1.1% (1.1%)	0.646
Other Black	182	1.1%	1	1	0.5% (0.5%)	0.698
Asian	415	2.5%	2	1	0.5% (0.2%)	0.464
Other Asian Background	409	2.5%	2	2	0.5% (0.5%)	0.477
Latin American	202	1.2%	3	2	1.5% (1%)	0.299
Other[3]	1,024	6.3%	12	6	1.2% (0.6%)	0.223
Testing history						
Within the last year	7,971	48.7%	45	18	0.6% (0.2%)	-
Over 1 year ago	5,382	32.9%	58	27	1.1% (0.5%)	**0.001**
Never tested	2,926	17.9%	31	13	1.1% (0.4%)	**0.007**
Unknown	74	0.5%	1	0	1.4% (0%)	0.387
Condomless sex						
No	2,484	15.2%	24	9	1% (0.4%)	-
Yes, with 1 partner	6,379	39.0%	53	21	0.8% (0.3%)	0.538
Yes, with 2-5 partners	6,259	38.3%	44	18	0.7% (0.3%)	0.208
Yes, with 6-12 partners	763	4.7%	6	5	0.8% (0.7%)	0.650
Yes, with more than 12 partners	434	2.7%	8	5	1.8% (1.2%)	0.112
Unknown	34	0.2%	0	0	0% (0%)	-
Sex under the influence of alcohol or recreational drugs						
Never	7,098	17.9%	60	33	0.8% (0.5%)	-
Sometimes	7,586	46.4%	53	31	0.7% (0.4%)	0.310
Usually	1,284	7.9%	18	12	1.4% (0.9%)	0.059
Always	271	1.7%	4	1	1.5% (0.4%)	0.278
Unknown	114	0.7%	0	0	0.0% (0%)	n/a
Total	16,353	100.0%	135	58	0.8% (0.4%)	

1. 81 trans men who reported sex only with men or with men and women are included in this table.
2. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression.
3. Category 'Other' includes service users who self-describe as: other ethnic group and other mixed background.

3.3 Black African service users

In 2007, black African men and women comprised 68% of heterosexual adults newly diagnosed with HIV(4, 5). Whilst this proportion has decreased to 44% in 2018, they remain a population at increased risk of HIV infection and a key group towards which the HIV self-sampling service is targeted.

A total of 1,833 kits were tested from service users reporting their ethnicity as black African and of those 13 (0.7%) were high reactive. Most kits tested from black African service users reported heterosexual sex (1,583; 86.4%) with a high reactivity of 0.6% (6 high reactive tests in heterosexual women and 4 in heterosexual men).

The median age of black African service users was 29 years and ranged from 16 to 72 years of age. Service users with ages between 26 and 45 had the highest proportion of high reactivity (1.1%) (see Table 7).

One in 5 (20.9%) of kits tested from black African service users came from first time testers who had the highest proportion of high reactives (2.1%). The second highest proportion of high reactivity rate was observed in those who tested over a year ago (0.7%) (see Table 7).

Two in 5 (40.9%) of kits tested from this population were from service users that reported condomless sex with more than 1 partners in the last year but there was no significant difference in reactivity according to the number of partners reported. The highest proportion of high reactivity was observed in those who reported not having condomless partners in the last year (2.0%).

Over half of black African service users (57.1%) reported never having sex under the influence of alcohol or recreational drugs. Of these 0.8% were high reactive. Service users who reporting sometimes having sex under the influence of alcohol or drugs had the same proportion of high reactivity (0.8%).

Table 7: Black African service users. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and rates by gender, sexual behaviour, age group, ethnicity and testing history. November 2018 to October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value*[1]
Sexual orientation						
MSM	178	9.7%	2	2	1.1% (1.1%)	-
Heterosexual	1,583	86.4%	23	10	1.5% (0.6%)	0.350
Women reporting sex with both men and women	45	2.5%	0	0	0.0% (0%)	n/a
Women reporting sex only with women (WSW)	27	1.5%	1	1	3.7% (3.7%)	0.980
Age group						
16-25	720	39.3%	8	2	1.1% (0.3%)	-
26-35	569	31.0%	9	6	1.6% (1.1%)	0.464
36-45	373	20.3%	7	4	1.9% (1.1%)	0.308
46-55	139	7.6%	1	0	0.7% (0%)	0.680
56-65	29	1.6%	1	1	3.4% (3.4%)	0.283
>65	3	0.2%	0	0	0.0% (0%)	n/a
Testing history						
Within the last year	712	38.8%	5	0	0.7% (0%)	-
Over 1 year ago	701	38.2%	9	5	1.3% (0.7%)	0.277
Never tested	384	20.9%	12	8	3.1% (2.1%)	**0.005**
Unknown	36	2.0%	0	0	0.0% (0%)	n/a
Condomless sex						
No	205	11.2%	5	4	2.4% (2%)	-
Yes, with 1 partner	871	47.5%	12	4	1.4% (0.5%)	0.279
Yes, with 2-5 partners	694	37.9%	9	5	1.3% (0.7%)	0.254
Yes, with 6-12 partners	38	2.1%	0	0	0.0% (0%)	n/a
Yes, with more than 12 partners	16	0.9%	0	0	0.0% (0%)	n/a
Unknown	9	0.5%	0	0	0.0% (0%)	n/a
Sex under the influence of alcohol or recreational drugs						
Never	1,046	57.1%	17	8	1.6% (0.8%)	-
Sometimes	655	35.7%	8	5	1.2% (0.8%)	0.502
Usually	88	4.8%	0	0	0.0% (0.0%)	n/a
Always	20	1.1%	1	0	5.0% (0.0%)	0.272
Unknown	24	1.3%	0	0	0.0% (0.0%)	n/a
Total	1,833	100.0%	26	13	1.4% (0.7%)	

1. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression

3.4 Women

All those identifying as women (including 84 trans women) are included in this analysis including: women reporting sex with men only (n=4,003), women reporting sex with both men and women (n=561) and women reporting sex with only women (n=125). A total of 12 high reactive specimens (0.3%) were identified from 4,689 kits tested. The median age of women was slightly younger than overall at 25 years and ranged from 16 to 77 years of age. The highest proportion of high reactivity in women (0.7%) was in kits from users aged 36 to 45 years (see Table 8).

The majority of kits tested from women (59.1%) came from those reporting their ethnicity as white (n=2,857) with 0.67% of them with high reactive results. One in 5 (21.5%) kits were from women who reported their ethnicity as black African (n=1,007) and other black ethnic background (268), had statistically significant high reactivity rates (0.7%; p=0.001 and 0.4%; p=0.011 respectively) compared to those with white ethnic group (see Table 8).

Over a third of women (37.6%) reported never having tested before (0.3% high reactives) and a further 35.6% had last tested over a year ago (0.4% high reactives) with no significant difference in reactivity according to testing history (see Table 8).

Just under half of the kits tested from women came from those who reported 2 or more condomless partners in the previous 12 months (49.3%; n=2,312). The highest proportion of high reactives was in (1.4%) was in female service users who reported not having condomless partners. Women who reported condomless sex with 2 to 5 partners had a statistically significant high reactive rate (0.1%; p=0.033) compared to those not having condomless sex (see Table 8).

Three in 5 women (62.6%) reported always, usually, or sometimes having sex under the influence of alcohol or recreational drugs. Although not significant, the highest proportion of high reactives (0.8%) was among women who reported always having sex under the influence of alcohol or recreational drugs compared to those who never did (see Table 8).

Table 8: Women[1]. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and rates by age group, ethnicity, testing history, condomless sex and sex under the influence of alcohol and recreational drugs. November 2018 to October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value*[2]
Age group						
16-25	2,414	51.5%	13	1	0.5% (0%)	-
26-35	1,389	29.6%	9	4	0.6% (0.3%)	0.669
36-45	612	13.1%	6	4	1% (0.7%)	0.223
46-55	223	4.8%	3	3	1.3% (1.3%)	0.152
56-65	43	0.9%	0	0	0% (0%)	-
>65	8	0.2%	0	0	0% (0%)	-
Ethnicity						
White	2,770	59.1%	9	3	0.3% (0.1%)	-
Black African	1,007	21.5%	14	7	1.4% (0.7%)	**0.001**
Other Black	268	5.7%	4	1	1.5% (0.4%)	**0.011**
Asian	81	1.7%	0	0	0% (0%)	-
Other Asian Background	79	1.7%	0	0	0% (0%)	-
Latin American	40	0.9%	1	0	2.5% (0%)	0.053
Other[3]	444	9.5%	3	1	0.7% (0.2%)	0.271
Testing history						
Within the last year	1,226	26.1%	10	1	0.8% (0.1%)	-
Over 1 year ago	1,668	35.6%	10	6	0.6% (0.4%)	0.490
Never tested	1,764	37.6%	11	5	0.6% (0.3%)	0.537
Unknown	31	0.7%	0	0	0% (0%)	-
Condomless sex						
No	351	7.5%	5	5	1.4% (1.4%)	-
Yes, with 1 partner	2,026	43.2%	17	6	0.8% (0.3%)	0.296
Yes, with 2-5 partners	2,061	44.0%	9	1	0.4% (0.1%)	**0.033**
Yes, with 6-12 partners	183	3.9%	0	0	0% (0%)	-
Yes, with more than 12 partners	62	1.3%	0	0	0% (0%)	-
Unknown	6	0.1%	0	0	0% (0%)	-
Sex under the influence of alcohol or recreational drugs						
Never	1,723	36.7%	16	8	0.9% (0.5%)	-
Sometimes	2,300	49.1%	11	3	0.5% (0.1%)	0.089
Usually	512	10.9%	1	0	0.2% (0%)	0.129
Always	123	2.6%	3	1	2.4% (0.8%)	0.123
Unknown	31	0.7%	0	0	0% (0%)	-
Total	4,689	100.0%	31	12	0.7% (0.3%)	

1. Women includes women reporting sex only with men (n=4,003), women who report sex with both men and women (n=561), women who report sex only with women (n=125) and trans women (n=84).
2. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression.
3. Category 'Other' includes service users who self-describe as: other ethnic group and other mixed background.

3.5 Heterosexual men

This analysis consists of people who identify as men (including 7 trans men) and reported only heterosexual sex. The median age of male service users engaging in heterosexual sex was 29 years and ranged from 16 to 75. Of the 3,300 kits tested 8 (0.2%) were high reactive and kits tested from men in the age groups between 56 and 65 had statistically significant higher proportion of high reactivity than those aged 16 to 25 (2.3%; p=0.009) (see Table 9).

Overall, 55.9% of kits tested from heterosexual men came from those that reported their ethnicity as white. None of these were high reactive. Of the kits returned by heterosexual men, those who identified as black African and other black ethic groups had significantly higher proportions of high reactivity (0.6%; p=0.004 and 3.1%; p<0.001, respectively) than other ethnic groups (1.74%; p=0.047) (see Table 9).

Kits from men reporting only heterosexual sex had lower proportion of high reactives (0.2%) than overall (0.3%). Two in 5 heterosexual men (42.9%) reported never having tested before. (see Table 9).

Excluding the 15 men for whom the number of condomless partners is unknown, kits from men who reported condomless sex with 6 to 12 partners in the previous 12 months had the highest proportion of high reactives (0.8%) (see Table 9).

Half of all kits tested from this group of men were from those who reported sometimes having sex under the influence of alcohol or recreational drugs (see Table 9).

Table 9: Men reporting heterosexual sex only[1]. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and rates by age group, ethnicity, testing history, condomless sex, sex under the influence of alcohol and recreational drugs. November 2018 to October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value*[2]
Age group						
16-25	1,166	35.3%	7	0	0.6% (0.0%)	-
26-35	1,181	35.8%	9	3	0.8% (0.3%)	0.635
36-45	585	17.7%	8	2	1.4% (0.3%)	0.110
46-55	260	7.9%	2	1	0.8% (0.4%)	0.756
56-65	86	2.6%	2	2	2.3% (2.3%)	0.09
>65	22	0.7%	0	0	0.0% (0.0%)	-
Ethnicity						
White	1,845	55.9%	7	0	0.4% (0.0%)	-
Black African	648	19.6%	10	4	1.5% (0.6%)	0.004
Other Black	98	3.0%	5	3	5.1% (3.1%)	<0.001
Asian	271	8.2%	1	0	0.4% (0.0%)	-
Other Asian Background	88	2.7%	2	0	2.3% (0.0%)	
Latin American	23	0.7%	1	0	4.3% (0.0%)	0.023
Other[3]	327	9.9%	2	1	0.6% (0.3%)	0.025
Testing history						
Within the last year	815	24.7%	3	0	0.4% (0.0%)	-
Over 1 year ago	1,032	31.3%	11	4	1.1% (0.4%)	0.101
Never tested	1,417	42.9%	13	3	0.9% (0.2%)	0.152
Unknown	36	1.1%	1	1	2.8% (2.8%)	0.08
Condomless sex						
No	448	13.6%	4	1	0.9% (0.2%)	-
Yes, with 1 partner	1,275	38.6%	9	2	0.7% (0.2%)	0.695
Yes, with 2-5 partners	1,376	41.7%	12	3	0.9% (0.2%)	0.967
Yes, with 6-12 partners	131	4.0%	2	1	1.5% (0.8%)	0.533
Yes, with more than 12 partners	55	1.7%	0	0	0.0% (0.0%)	-
Unknown	15	0.5%	1	1	6.7% (6.7%)	0.072
Sex under the influence of alcohol or recreational drugs						
Never	1,199	36.3%	15	5	1.3% (0.4%)	-
Sometimes	1,653	50.1%	11	2	0.7% (0.1%)	0.11
Usually	370	11.2%	1	0	0.3% (0.0%)	0.136
Always	47	1.4%	0	0	0.0% (0.0%)	-
Unknown	31	0.9%	1	1	3.2% (3.2%)	0.357
Total	3,300	100.0%	28	8	0.8% (0.2%)	

1. Heterosexual sex among men includes (n=7) trans men reporting sex with women.
2. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression.
3 Category 'Other' includes service users who self-describe as: other ethnic group and other mixed background.

3.6 Trans people

Upon accessing the service individuals are given the option to report their gender identity as trans male or trans female. All those self-identifying as either trans female or trans male are included in this analysis. A total of 172 kits were tested from service users who identified as transgender and of these, none was reactive. A summary of their demographics and sexual behavioural data is included below and in Table 10.

The group of transgender service users was the youngest group overall with a median age of 23 and 63.4% of tests in this population being from the 16 to 26 age group (see Table 10).

Three-quarters (76.2%) of transgender service users reported their ethnicity as white (see Table 10).

Rates of previous HIV testing were low with 37.2% reporting this as their first HIV test and a further 33.1% reporting a test more than 12 months previously (see Table 10).

Nearly half of all kits tested (47.7%) were from transgender service users who reported more than 2 condomless partners. Three in 5 (64.0%) reported sometimes, usually or always having sex under the influence of alcohol or recreational drugs (see Table 10).

Table 10: Trans people. Number of kits tested, proportion of total kits tested, number of total reactive and high reactive and by age group, ethnicity, testing history, condomless sex, sex under the influence of alcohol and recreational drugs. November 2018 to October 2019.

	Kits tested	Proportion of total kits tested	Total reactive	High reactive	Reactive rate (high reactive rate)	*p-value1*
Age group						
16-25	109	63.4%	0	0	0% (0%)	-
26-35	32	18.6%	0	0	0% (0%)	n/a
36-45	17	9.9%	0	0	0% (0%)	n/a
46-55	12	7.0%	0	0	0% (0%)	n/a
56-65	1	0.6%	0	0	0% (0%)	n/a
>65	1	0.6%	0	0	0% (0%)	n/a
Ethnicity						
White	131	76.2%	0	0	0% (0%)	-
Black African	4	2.3%	0	0	0% (0%)	n/a
Other Black	3	1.7%	0	0	0% (0%)	n/a
Asian	7	4.1%	0	0	0% (0%)	n/a
Other Asian Background	3	1.7%	0	0	0% (0%)	n/a
Latin American	3	1.7%	0	0	0% (0%)	n/a
Other[2]	21	12.2%	0	0	0% (0%)	n/a
Testing history						
Within the last year	51	29.7%	0	0	0% (0%)	-
Over 1 year ago	57	33.1%	0	0	0% (0%)	n/a
Never tested	64	37.2%	0	0	0% (0%)	n/a
Unknown	0	0.0%	0	0	0% (0%)	n/a
Condomless sex						
No	29	16.9%	0	0	0% (0%)	-
Yes, with 1 partner	61	35.5%	0	0	0% (0%)	n/a
Yes, with 2-5 partners	64	37.2%	0	0	0% (0%)	n/a
Yes, with 6-12 partners	8	4.7%	0	0	0% (0%)	n/a
Yes, with more than 12 partners	10	5.8%	0	0	0% (0%)	n/a
Unknown	0	0.0%	0	0	0% (0%)	n/a
Sex under the influence of alcohol or recreational drugs						
Never	60	34.9%	0	0	0% (0%)	-
Sometimes	81	47.1%	0	0	0% (0%)	n/a
Usually	13	7.6%	0	0	0% (0%)	n/a
Always	16	9.3%	0	0	0% (0%)	n/a
Unknown	2	1.2%	0	0	0% (0%)	n/a
Total	172		0	0	0% (0%)	

1. Where the p value is reported as (–). This is the comparator group against which the other groups were tested using univariate logistic regression.
2. Category 'Other' includes service users who self-describe as: other ethnic group and other mixed background.

4. Discussion

A total of 24,342 tests were conducted through the national HIV self-sampling service between November 2018 and October 2019. In this period, with a higher overall reactivity (0.8% overall reactivity; 0.3% high reactivity) than in tests performed by the Public Health England Community HIV Testing Survey in 2018 (0.4% overall reactivity), reflecting the targeting of the service(1).

The service has been successful at engaging key populations most affected by HIV, particularly gay and bisexual men who make up three-quarters (16,353; 67.2%) of those having kits tested. The decrease in high reactives is a reflection of the decrease of HIV infections reported in England as a result of the combination prevention programme(1). Rates of high reactives between users of different sexual orientations are not significantly different indicating that the targeting of higher risk heterosexuals has been successful. The proportion of gay and bisexual men tested (67.2%) was higher than the proportion of tests carried out in gay bisexual men in community services (45.8%) or through eSexual Health Services (11.7%).

Challenges remain with engaging black, Latino Americans and other minority ethnic communities. Black African men and women 1 of the 2 second key populations towards whom the service is promoted but make up only 7.5% of overall service users. PHE continues to work with HPE and others to identify ways to make the service more attractive and accessible for black, Asian and other minority ethnic group service users.

The service was used by 172 people who identified as trans or non-binary, none of whom had a reactive result. This group of services was relatively young with 63% aged between 16b and 25 years old. Of all trans and non-binary service users 37% said that they had never had an HIV test before and the majority did report sex with 1 or more partners. It is therefore important that is service continues to be accessible to and monitor how the service is used by trans and non-binary people.

The service has been effective at engaging individuals who have never tested for HIV before. Overall, 1 in 4 (25.1%) kits tested were from users who reported never having tested before. Even in gay and bisexual men among whom testing rates are traditionally higher, half (50.8%) reported this as their first HIV test or had tested over a year ago. The highest rate of high reactivity was also seen among service users that reported never testing or testing more than a year ago. These findings confirm that online HIV testing services reach people at increased risk of HIV who are not accessing testing in other settings.

Trends in service activity correlate strongly with the linked HIV Prevention England campaigns, particularly National HIV Testing Week during which demand peaks and the service is open to all residents in England. The service is also promoted through local

and regional campaigns for example the London HIV Prevention Programme. This commissioning model has enabled LAs to provide access to an online HIV testing service to their residents whilst avoiding the cost of individual procurement processes. The National Framework was also able to benefit from economy of scale and this is demonstrated with a cost per reactive lower than published elsewhere and in other settings(2,6,7).

The multi-disciplinary steering group consisting of commissioners, public health and virology experts has provided a successful monitoring system that has produced service improvements for over 4 years. These have included using behavioural research to increase return rates(8), identifying, investigating and reducing specimen haemolysis rates and reducing testing kit dispatch times. The steering group is also responsible for overseeing the future development of the service.

Self-sampling and self-testing are part of a combination prevention programme(9) in a strategy to end the AIDS epidemic by 2030(10), and are likely to remain a feature of the HIV testing landscape for the foreseeable future. The demand for these options has increased over time and they succeed in widening access particularly for those less likely to engage with traditional sexual health services. With appropriate targeting and linkage to local and national campaigns delivery of HIV testing through online platforms will be integral in reducing undiagnosed infection and eliminating HIV.

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6. Appendices

Appendix 1

Who can sign up for the service?

The framework is specifically designed for use by PHE and English local authorities. However, it is available for use nationally by other public sector bodies, including, but not limited to:

- police and emergency services
- NHS and HSC Bodies
- central government departments and their agencies
- registered charities
- schools and academies

How to sign up for the service

Step 1

Complete the Customer Access Agreement and send it to ESPO at care@espo.org. The agreement will then be countersigned and returned. This does not commit the authority to anything, but it provides evidence of the transaction as part of an audit trail, helping to evidence the fact that you are procuring the framework. This ensures that the authority is exempt from undertaking EU-compliant advertising and supplier vetting.

Step 2

Complete the Master Contract Schedule order form and send it to care@espo.org. Please quote ESPO Framework 3173_15 on all correspondence.

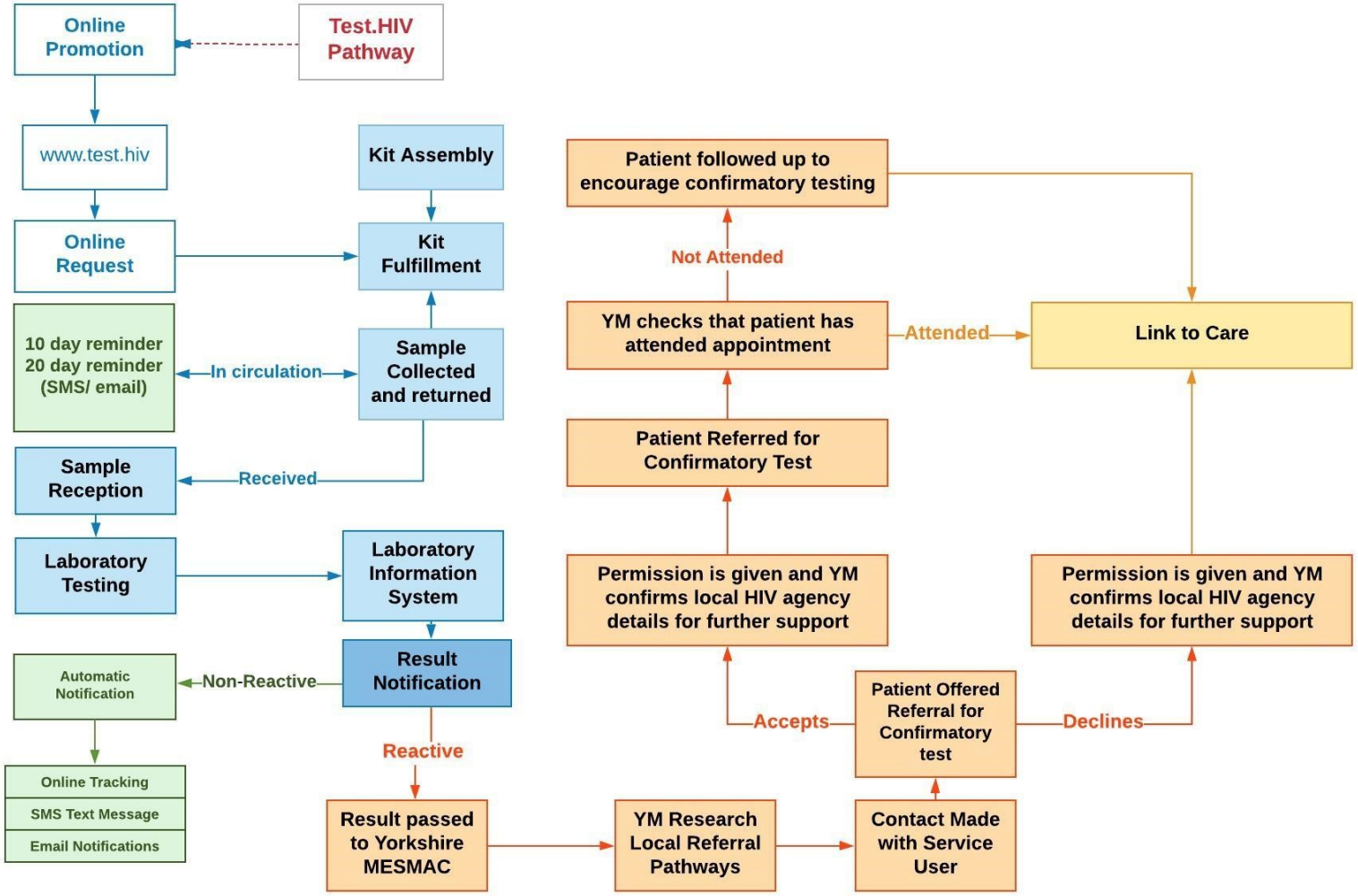
How to renew a current contract

To renew a contract, contact ESPO directly at care@espo.org quoting ESPO Framework 3173_15 on all correspondence.

Further information and all forms can be accessed through www.espo.org/Home or at the following direct link www.espo.org/Frameworks/Social-care/3173-HIV-Self-Sampling-Service. You can also contact Louise Logan at PHE at louise.logan@phe.gov.uk for further information on the service and how to sign up or renew a contract.

Appendix 2

The HIV self-sampling service user pathway on service provision
(The steps of this flow chart are explained in sections 1.1, 2.1 and 2.3, above.)



Appendix 3

Local areas that signed up to the HIV self-sampling service organised by Public Health England (PHE), by centre, November 2018 to October 2019.

East Midlands	East of England	London		North East	
Derby City C**	Bedfordshire Central C	Camden	Merton**	Darlington Borough C	North Tyneside C
Leicester City C	Hertfordshire CC	Croydon	Newham	Durham CC**	Northumberland C C**
Leicestershire CC	Luton Borough C**	Haringey C**	Redbridge	Gateshead C	Redcar & Cleveland Borough C
Northamptonshire CC	Norfolk CC	Havering	Richmond upon Thames	Hartlepool Borough C*	South Tyneside C
Nottingham City C**	Southend on Sea B C**	Hounslow	Sutton*	Middlesbrough C**	Stockton-On-Tees Borough C**
Nottinghamshire CC	Suffolk CC	Islington	Tower Hamlets**	Newcastle upon Tyne C**	Sunderland CC
		Kingston Upon Thames**	Waltham Forest**		
		Lewisham**	Wandsworth C		

North West		South East		South West	West Midlands	Yorkshire and Humbe
Blackpool C	Rochdale B C**	Brighton & Hove City C	Slough Borough C**	Bristol City Council	Coventry City C**	Wakefield**
Knowsley C**	Salford City C	Hampshire CC	Southampton City C	Cornwall Council	Dudley Met. Borough C	
Lancashire CC**	Tameside Met. BC	Kent CC	West Sussex	Swindon BC	Shropshire C**	
Liverpool**	Trafford Council	Milton Keynes C	Windsor & Maidenhead	Telford & Wrekin C	Warwickshire CC	
Manchester City C**		Oxfordshire CC	Wokingham	Wiltshire C**	Wolverhampton CC	
		Portsmouth City C				

*Service ended in January 2019, **Service ended in March 2019

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