

SOP47 Provision of an STI and HIV Screening Service (Formerly: Providing an STI Screening Service)

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1 Introduction

1.1 Context

The HSE Sexual Health Strategy 2015 promotes the provision of improved access to crisis pregnancy supports, STI/HIV testing and other supports and counselling for all sexually active adults. This includes guidance on home based STI testing and the use of point of care HIV testing.

Supporting this strategy, Allcare Pharmacies provide sexual transmitted infection (STI) testing kits to promote sexual health screening and improve ease of access to screening where appropriate.

1.2 Purpose

- Adherence to this SOP ensures that in Allcare pharmacies, STI Self Tests will be supplied safely and appropriately to all patients who request them while adhering to the legislation and guidelines that govern this supply.
- **This SOP covers:**
 - LetsGetChecked.ie® STI Screening Kits
 - HIV Self Testing Kits
 - Patient consultation and counselling
 - Documentation and record keeping
- **This SOP must be used in conjunction with all relevant SOPs and guidance including:**
 - SOP 13 Managing Pharmacy Errors and Near Misses
 - SOP22 Use of Patient Consultation Areas
 - SOP 38 Management of disposal of sharps clinical waste needle stick injury and body fluid spillage
 - HPRA Point of Care Testing in Primary and Community Care
 - PSI Pharmacy Practice Guidance (Current version)
 - PSI Guidance on the provision of testing services in pharmacies (Version 1 February 2014)

1.3 Scope

- This SOP covers every aspect of the provision of an STI and HIV screening service in an Allcare pharmacy.
- This SOP applies to all staff in the pharmacy.
 - It is the ultimate responsibility of the supervising pharmacist to ensure that all staff are appropriately trained, and the SOP is implemented.
 - It is also the responsibility of the supervising pharmacist to ensure this SOP reflects the day-to-day practice in their pharmacy.
 - All pharmacists are expected to exercise their professional judgement when needed.

1.4 Staff training

- All staff in the pharmacy who may be involved in the provision of an STI and HIV screening (including pharmacists, pharmaceutical assistants, technicians, trainee technicians, interns, APPEL students and front of shop staff) should be trained on this SOP.
- All staff working in pharmacies providing a STI screening service must complete LetsGetChecked® online training. Contact the Allcare Pharmacy Trainer for further information.
- The supervising pharmacist must ensure appropriate staff can provide members of the public with information on the service, in an open and informative manner.

2 Procedure

2.1 LetsGetChecked® STI Screening Kits

- LetsGetChecked® supplies an accurate laboratory testing service that can be provided through community pharmacy.
- Tests kits are manufactured and despatched from an ISO 13485 accredited LetsGetChecked® facility. This is the highest level of accreditation for medical devices.
- Customers can purchase CE marked test kits and the pharmacist will help them to register the kits and collect required blood sample (urine sample must be collected by the individual).
- Alternatively, patient can self-collect samples at home.
- Samples are sent to a Clinical Pathology Accreditation (CPA) approved laboratory using the pre-paid shipping label to get the sample back into the laboratory for processing within 24 hours.
- Results are then provided within 48 hours, and all those with a positive result are contacted by a nursing support team who will give advice on treatment and guidance.

2.1.1 Types of tests available in Allcare Pharmacies

Simple 2	Standard 6	Complete 12
<ul style="list-style-type: none"> •Chlamydia •Gonorrhoea 	<ul style="list-style-type: none"> •Chlamydia •Gonorrhoea •HIV •Syphilis •Hepatitis B •Hepatitis C 	<ul style="list-style-type: none"> •Chlamydia •Gonorrhoea •Trichomoniasis •Gardnerella •Mycoplasma •Ureaplasma •Herpes Simplex 1 •Herpes Simplex 2 •HIV •Syphilis •Hepatitis B •Hepatitis C

2.1.2 Identifying suitable patients

- An STI screening service is suitable for;
 - Any member of the public concerned about their sexual health.
 - Any person who has unprotected sexual intercourse.
 - Any female planning or trying to conceive (as some STIs can cause infertility).
 - Pharmacists should be mindful of any specific welfare, social protection or public health considerations, in respect of which relevant guidance and protocols such as the 2011 Children First: National Guidelines for the Protection and Welfare of Children (or any equivalent replacement document) must be applied.
 - The pharmacist should refer the patient to their GP, if the patient raises any concerns that the pharmacist, in their professional judgement, deems that such a referral is warranted.

2.1.3 Patient Consultation

- Staff members must explain:
 - The three types of kit available and key differences.
 - The kit must be registered online, sample taken and sent to a laboratory.
 - Patient will receive results within 48 hours.

- If they test positive for any STI, a member of the LetsGetChecked® nursing team will contact them directly with advice on how to proceed.
- A blood and urine sample is required.
- The pharmacist can assist with registration of the kit and collection of blood sample.
- That each STI has a different incubation period (see below) therefore an STI test immediately after unprotected sex may give a false negative.
- Members of the public should be encouraged to register the kit and prepare blood sample in the pharmacy consultation room.
- If the kit is purchased on a Friday or at the weekend, they should be advised to wait until the following working day to post the sample.
- If a member of the public is unsure if they require a test, they should be invited to complete the sexual health questionnaire (Appendix 3) with the pharmacist in the consultation room.

Incubation periods of common STI's: source (NHS/CDC February 2019)

Sexually Transmitted Disease	Typical Incubation Period
Chlamydia	7 – 14 days or longer (Majority are asymptomatic)
Genital Herpes	3 – 7 days
Genital Warts	2 weeks to 8 months
Gonorrhoea	14 days, or longer: Most men becoming symptomatic within 2-5 days after exposure.
Syphilis	From 10 to 90 days. Syphilis blood test results will be negative during this time.
Trichomoniasis	Unknown: Thought to be 5 to 28 days
General Bacterial Infections	10 – 21 days
Hepatitis B	1.5 to 6 months (average 4 months)
Hepatitis C	14 to 180 days
HIV	Window for antigen/antibody test is 28 days

2.1.4 Documentation and Recordkeeping

- Pharmacists must ensure that patients sign the consent form (Appendix 2) to confirm that they consent to the pharmacist taking a blood sample for the purpose of STI testing, and that they approve the confidential recording of their details.
- All documentation should be retained in the pharmacy health services folder for two years. Alternatively results can be scanned to the patient's file using the MPS scanner.
- Following a consultation, the pharmacist should complete Appendix 4: LetsGetChecked® Consultation Checklist.

2.1.5 Kit Registration

- Each Kit listed as a product on MARS, and must be sold through the till prior to supply to customer.
- The kit registration should be completed prior to sample collection.
- In the consultation room, the pharmacist can assist the customer with the online test registration on Letsgetchecked®.com
 - Log onto LetsGetChecked®.com and follow instructions for online registration to create a patient's personal "LetsGetChecked® Dashboard."
 - Choose the "Activate Your Test" option and input the Order ID and UNID from the kit box.
 - The patient must supply a personal email address and phone number as these are required to contact the customer with results.

- Note: there is an input field for a delivery address - this is not relevant to pharmacy sales, so the pharmacy name can be entered.

2.1.6 Blood Sample Collection

- The pharmacist must assemble the necessary equipment prior to blood sampling (See Appendix 1)
- The finger is the preferred site for blood samples in an adult patient. A disposable lancet should always be used. The Accu-Chek Safe-T-Pro Plus lancet is a single -use lancing device available to order from Unipharm: code: 323713.
- **NOTE: A warm hand and good blood flow from the puncture site is essential to collect a good sample.**
- Ensure the patient is sitting comfortably before the procedure.
- **Perform hand hygiene.** If using soap and water, use disposable paper towels.
- Put on nitrile gloves.
- Swab the entry site with an alcohol swab and allow to air dry.
- Choose a spot to the side of one of the centre fingers. Firmly prick the skin with the lancet to achieve a good flow of blood and to prevent the need to repeat the puncture.
- Wipe away the first drop of blood with gauze (not cotton wool) because it may be contaminated with tissue fluid or debris (sloughing skin).
- Avoid squeezing or massaging the finger excessively because this dilutes the specimen with tissue fluid (plasma) and increases the probability of haemolysis (cell rupture).
- **Repeat until the blood collection tube is filled to the upper line on the side of the tube. Use another sample site if necessary to achieve the required level of blood.**
- When the sampling is complete, apply firm pressure to the site to stop the bleeding and cover with a small hypoallergenic plaster.
- Dispose of all sharps and other contaminated waste as per SOP 38 'Management of disposal of sharps clinical waste needle stick injury and body fluid spillage'
- **Repeat hand hygiene.**

2.1.7 Posting the Kit

- Every kit contains a pre-paid envelope label to return the test to LetsGetChecked®.
- The customer must take the kit home to take the urine sample, and it is their responsibility to post the samples.
- If the kit is purchased on a Friday or at the weekend, they should be advised to wait until the following working day to post the sample.

2.1.8 Patient Counselling

- The individual should be provided with written and oral information about the test that they are about to take part in, and the procedure explained.
- The patient should be encouraged to ask any questions, and the pharmacy phone number supplied.
- The patient should be counselled about how they will receive their results, and suitable resources they might find useful if any further action advised.

2.2 HIV Self Tests

- HIV self-tests are classified as in-vitro diagnostic medical devices and there are several of them on the market which may be supplied by Allcare Pharmacies. E.g. autotest VIH® Mylan.
- The HPRC have issued guidelines around these self-tests. Pharmacists should be aware of the following:
 - The most accurate test available for HIV is a laboratory based confirmatory test. Laboratory based HIV testing is available in STI clinics, genito-urinary medicine (GUM) clinics, GPs, some Non-Governmental Organisations (NGOs) and student health clinics.
 - Ensure the test is CE marked - A valid HIV self-test bears a CE mark and a four-digit number to confirm it meets important safety and design standards.
 - Check there is a European address on the packaging - Medical devices that are CE marked and sold on the European market must have a registered business premises in Europe.

- Always source the test from a licenced wholesaler: check the packaging is intact and product expiry date prior to supply.
- Ensure you have read the instructions and can counsel the patient on the correct use, determinants that might affect results, and limitations of the product.
- When using a HIV self-test, it is important to know the window period for the test. The time between when a person may have been exposed to HIV and when a test can detect if they have acquired HIV is called the window period. The window period varies from person to person and depends on the test used.
- Most HIV self-tests (antibody tests) have a window period of 3 months following exposure to HIV. The use of HIV self-tests is normally only reliable 3 months after the potential exposure to HIV. Use of these tests before the manufacturer's recommended time after exposure to HIV could result in false negative results or failure to detect HIV.
- If patient is being treated for HIV with antiretroviral therapy (ART) or they are taking preexposure prophylaxis (PrEP), it is important that patient is being monitored by their doctor for HIV. HIV Self Tests are not a reliable way to monitor these clinical scenarios.
- If patient thinks they may have been exposed to HIV in the previous 72 hours, direct them to your nearest STI/GUM (genitourinary medicine) clinic or hospital emergency department as soon as possible as they may be a candidate to go on HIV post-exposure prophylaxis (PEP).

2.3 Pharmacovigilance

- Any quality issues that arise from the use of these devices must be reported to the manufacturer of the device. Incidents that may affect an individual's health or cause or contribute to an injury can also be reported directly to the HPRC via their online user report form or email: devices@hpra.ie.

3 Further Information for patients

- All patient's seeking information on STIs and STI screening services should be referred to HSE information points such as:
 - <http://www.thinkcontraception.ie/>
 - <https://www.sexualwellbeing.ie>

4 References

- Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases (STD)'s https://www.cdc.gov/std/healthcomm/fact_sheets.htm (accessed 25/2/19)
- HPRC Information Notice HIV Self Tests: https://www.hpra.ie/docs/default-source/default-document-library/in201803_msp32593_hivselftest_020818_final.pdf (accessed 25/2/19)
- HPRC Medical Device Safety: <https://www.hpra.ie/homepage/medical-devices/safety-information> (accessed 25/2/19)
- HPRC: Point of Care Testing in Primary and Community Care: <http://www.hpra.ie/docs/default-source/default-document-library/guidelines-for-point-of-care-testing-02.pdf> (accessed 25/2/19)
- LetsGetChecked® Website: <https://www.letsgetchecked.com/ie> (accessed 27/2/19)
- PSI Guidance of the Provision of Services in Pharmacies Version 1 February 14 https://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/PPGF_02_3_Provision_of_Testing_Services_in_Pharmacies.sflb.ashx (accessed 27/2/19)

5 SOP Revision History

March 2019 Version 2. Updated to include:

- Section 1.4: New "Contact the Allcare Pharmacy Trainer for further information"
- Section 2.1: Enhanced ISO information
 - Replaced envelope with prepaid shipping label as per their website
- Section 2.1.2: Deleted "in last month"
 - New information around Child First 2011 and focus on welfare

- Section 2.1.13: Revised in line with **(NHS/CDC February 2019)**
- Section 2.1.4: New: “results can be scanned to the patient’s file using the MPS scanner”.
- Section 2.1.5: Registering the kit section reduced.
- Section 2.1.6: revised to reflect WHO guideline
- Section 2.2 New Section
- Section 2.3: New Section
- Appendix 2: Revision and reformat of Pharmacy consent form

SOP 47 Appendix 1: Equipment

All pharmacies providing the STI testing must have the following equipment;

- ✓ Clinical waste bin
- ✓ Disposable gloves
- ✓ Disposable tissues/swabs
- ✓ STI information leaflets
- ✓ LetsGetChecked® testing kits containing:
 - 1 x name label
 - 2 x moist wipes
 - 1 x Alcotip swab
 - 1 x plaster
 - 1 x blood collection tube
 - 1 x protective packing wallet
 - 3 x lancets

SOP 47 Appendix 2: Pharmacy Consent form for LetsGetChecked® Sexual Health Screening

LetsGetChecked® Sexual Health Screening Consultation Record Form		
Patient Name		
Order ID:		
UNID:		
Date of Birth:		
Date of Blood Collection:		
I have spoken to the pharmacist and and hereby consent to the drawing of a blood sample for the purpose of sexual health screening.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I hereby release LetsGetChecked®, this pharmacy and any other organisation(s) associated with this screening, their affiliates, directors, officers, employees, successors and assign from any and all liability arising from or in any way connected with this blood drawing or from data derived thereof.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I agree that the details I have supplied have been recorded and those records will be kept in the pharmacy.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I allow Allcare Pharmacy to contact me in relation to health services and other promotions in pharmacy.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Advice given regarding LetsGetChecked® STI Screening I understand that: <ul style="list-style-type: none"> • The results derived from the test are to be considered preliminary and do not represent a definitive diagnosis. • I understand that while LetsGetChecked® will assist with a referral, the responsibility for initiating a follow-up examination to confirm a positive result and obtain professional medical assistance is mine alone, and not that of any organisation(s) associated with the screening. 		
Patient Signature and date _____		
Pharmacist Signature: _____ PSI Registration Number: _____		
<input type="checkbox"/> Entry made on PMR under OTC scheme		

SOP 47 Appendix 3 Sexual Health Questionnaire

Patient Details:

Date			
Name		D.O. B	
Address			
Email			
Telephone			
Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender	Sexual Orientation:	<input type="checkbox"/> Heterosexual <input type="checkbox"/> MSM (Men who have sex with men) <input type="checkbox"/> Lesbian <input type="checkbox"/> Bisexual <input type="checkbox"/> Other <input type="checkbox"/> Rather not say
Has the customer ever been tested for sexually transmitted infections before? <input type="checkbox"/> Yes <input type="checkbox"/> No*			
Has the customer had unprotected sex in the last year/since last test? <input type="checkbox"/> Yes* <input type="checkbox"/> No			
Has the customer had unprotected sex with more than 1 partner? <input type="checkbox"/> Yes* <input type="checkbox"/> No			
Has the customer ever experienced any of the following symptoms? * <input type="checkbox"/> Penal/Vaginal discharge <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Pain/bleeding during sex <input type="checkbox"/> Discomfort during urination <input type="checkbox"/> Irritation of genital area <input type="checkbox"/> Blisters or sores in genitalia <input type="checkbox"/> Bleeding between periods			
Have you informed the customer of the symptomless nature of the following STIs? <input type="checkbox"/> Chlamydia - asymptomatic in women (70%) and men (50%) <input type="checkbox"/> Gonorrhoea – asymptomatic in women (86%) and men (55%) <input type="checkbox"/> Trichomoniasis – asymptomatic in women and men (50%)			

*If the customer has answered with this then they are at risk for Sexually Transmitted Infections and should be tested accordingly

SOP 47 Appendix 4 LetsGetChecked Consultation Checklist

Sales Channel: Emergency Contraception Walk in Other

1. Incubation Periods

I have informed the customer of the time it takes for the following infections to become detectable for testing

- Bacterial Infections (from 10-21 days)
- HIV (from 28 days)
- Syphilis (from 10-90 days)
- Hepatitis B (from 30-180 days)
- Hepatitis C (from 2 weeks to 6 months)
- Herpes (3-7 days)

2. Kit Registration

I have registered the kit in store

Please provide a reason if you have not registered the kit in store:

3. Sample Collection – When the sample is not taken in pharmacy

- I have informed the customer that the stabilizing fluid in the urine tube should not be removed.
- I have told the customer that the blood must be filled to the upper line
- I have informed the customer that the kit must be registered before the sample is taken
- I have explained that the customer must provide a correct phone number and email address
- I have demonstrated the contents of the kit to the customer
- I have demonstrated the best method to conduct the finger prick blood test

Pharmacist Signature and PSI number: _____

Date: _____