

Government of Western Australia Department of Health Public and Aboriginal Health Division

Guidelines and enrolment form for the WA syphilis pointof-care testing program

Use of syphilis point-of-care tests provided as part of the WA syphilis point-of-care testing program

Revision History					
Version	Date	Changes			
1.0	June 2020	Original			
1.1	November 2020	Introduction Additional information, metropolitan and Southwest region inclusion. Attachment C			
2.0	May 2024	New information regarding the changes to the program, considerations for embedding syphilis point-of-care testing within service delivery			

health.wa.gov.au

1. WA syphilis outbreak and syphilis PoC testing in WA

1.1 Introduction

Syphilis is a highly contagious and serious infection caused by the bacterium *Treponema pallidum*. It has a complex disease progression and early symptoms are often unnoticed. Left untreated it can have significant health effects in several organ systems. In pregnant people it can lead to miscarriages, stillbirth and birth complications. It is treated with long-acting penicillin injections.

An outbreak of infectious syphilis began in northern Queensland in January 2011, extending to the Northern Territory in July 2013 and the Kimberley region in Western Australia (WA) in June 2014. Since reaching WA in 2014, syphilis has spread across the state, resulting in the Chief Health Officer authorising a state-wide public health response to infectious syphilis in 2020.

1.2 Syphilis PoC test

The *Determine Syphilis* TP^{TM} immuno-chromatographic test manufactured by Abbott and is currently the only syphilis PoC test registered by the Therapeutic Goods Administration in Australia. The *Determine Syphilis* TP^{TM} is a treponemal antibody lateral flow immunoassay test and provides a reactive or non-reactive result to syphilis antibodies within 15 minutes. A reactive syphilis PoC test in a client with no history of syphilis allows treatment and contact tracing on the day of presentation, compared to waiting for the results of syphilis serology and follow-up.

The use of PoC tests needs to be carefully considered and, if utilised, integrated within the broader outbreak response as an **additional tool and not a substitute for best-practice serology-based testing**.

It is preferable not to use syphilis PoC tests as stand-alone tests because of:

- their inability to detect new infections in people who have previously been fully treated for syphilis;
- marginally inferior sensitivity and specificity compared with serology;
- no recognition of PoC test in infectious syphilis national case definition; or
- lack of a centralised mechanism to record PoC tests results; these are only recorded in individual patient records.

A reactive PoC test should always be confirmed by syphilis serology.

2. WA syphilis PoC testing program

The WA Department of Health (DoH) syphilis PoC testing program has been active since mid-2020. In mid-2024 the model changed to allow for more flexibility and reduce the burden on services.

2.1 Eligible services

Health services that meet the following requirements are eligible to enrol the PoC test program:

- The health service employs at least two health professionals (Registered Nurse, Aboriginal Health Worker/Practitioner, or Medical Practitioner) who are competent in performing a syphilis PoC test.
- 2. The health service agrees to adhere to the responsibilities outlined in section 2.3.

2.2 Model of service governance

Health services enrolled in this program are responsible for the clinical governance of their program. Health services operating in more than one clinic or geographic location should list all locations where syphilis PoC tests are being administered in their enrolment form. The form should be amended and resubmitted when additional clinics/locations are added.

2.3 Responsibilities of enrolled health services

2.3.1 Nominated Syphilis PoC Testing Champion/s

To monitor and coordinate syphilis PoC programs internally, enrolled health services should nominate a position, which includes the functions of a Syphilis PoC Testing Champion in the job description.

Syphilis PoC Testing Champions are responsible for:

- stock management and ordering supplies
- updating and monitoring adherence to health services' policies and procedures regarding syphilis PoC testing
- liaising with WA DoH
- reporting of testing data to the WA DoH.

2.3.2 Embedding syphilis PoC testing into service delivery

Health service management and Syphilis PoC Testing Champions are responsible for considering how PoC testing will be implemented and embedded into clinical processes. Aboriginal health workers/practitioners and locally based clinicians are central to planning and negotiating with local communities on use of syphilis PoC testing.

For more information on how to embed syphilis PoC testing into service delivery, see section 3.0

2.3.3 Ensuring staff competency to conduct syphilis PoC testing

Enrolled services need to ensure all staff performing syphilis PoC testing are competent to do so. If services require resources to upskill staff, there are number of resources available through Abbotts and WA DoH.

Training resources:

- <u>Abbotts website</u> demonstration video and resources on how to complete a syphilis PoC test
- Abbotts endorsed training and assessment PowerPoint emailed via WA DoH upon request
- Abbotts virtual real-time training (approx. time 30 minutes) available via WA DoH upon request.

Employees who are not medically trained can perform syphilis PoC testing on clients provided the health service can ensure adherence with occupational safety and health standards and best practice patient care.

Broader sexual health training and upskilling

Staff conducting syphilis PoC testing should feel competent and confident discussing syphilis and sexual health with clients.

Syphilis and sexual health training opportunities include:

- <u>ASHM Syphilis Outbreak Training</u> an online module regarding the outbreak, staging and other useful information (approx. time 30 minutes)
- <u>AHCWA's Birds and the BBVs training</u> aims to increases knowledge, skills and confidence to yarn with clients and communities about sexual health
- <u>WA Syphilis Outbreak Response website</u> a range of resources, event and training calendar.
- Contact your local Public Health Unit, Aboriginal Community Controlled Health Service or local sexual health team or clinical service they may be able to deliver training and information sessions relevant for your region.

2.3.4 Managing and ordering stock

Services are to monitor their stock levels and place orders with WA DoH as required.

Ordering

PoC testing stock can be ordered from WA DoH by emailing syphilispoct@health.wa.gov.au. Details of the different items are listed below

- 1. 7D2443 Determine Syphilis Tests (100 pack)
- 2. 7D2442- Determine Syphilis Tests (30 pack)
- 7D2243- Determine Chase Buffer (100/30 tests/bottle) (for use with Determine Syphilis TP Rapid for WB)
- 4. 1050-100 Microsafe tubes 50µL tubes (100/30 tests) (this is used to measure and transfer the blood from the patient's finger onto the test strip).

Stock normally arrives less than a week after placing the order.

Note: Abbotts cannot deliver to a PO Box

Storage

The health service must store the syphilis PoC testing kits in a cool, dry area between 2 and 30 degrees Celsius, such as a service's medicines storage room (in accordance with the specifications of the <u>supplier</u>).

2.3.5 Recording and reporting of syphilis PoC testing results

Services are required to record data related to syphilis PoC testing. DoH requires quarterly reports with de-identified quantitative data on client PoC testing and serology testing numbers. Reports are due within four weeks at the end of each quarter.

Syphilis PoC test results should always be recorded in the patient's medical record. Data required for reports to DoH may be stored:

- In the patient's medical record and extracted for reporting . The WA DoH may be able to support some patient management systems to add a syphilis PoC testing clinical item for ease of extracting data. This is the preferred option as it avoids duplicate data entry.
- In a separate system that records the required data elements (see Attachment C).

Data provided by services will be de-identified and aggregated so whole of program aggregated data reports can be analysed as part of the WA Syphilis Outbreak Response Group and evaluation of the program. Health services will retain full ownership of their data.

For further information on recording and reporting of patient PoC test results, please contact the WA DoH at syphilispoct@health.wa.gov.au.

2.3.6 Quality and assurance measures

All enrolled health services (hubs and spokes) must ensure:

- competency of staff performing syphilis PoC tests
- pre-screening of all clients to check for a previous syphilis infection
- local public health units are contacted for reactive PoC tests to check the client's syphilis infection history
- syphilis serology is completed for non-reactive results (unless the patient refuses) and for all reactive results.

For further information please contact WA DoH syphilispoct@health.wa.gov.au

Refer to <u>Attachment B PoC testing Activation and Maintenance Chart</u> for further information regarding the maintenance of syphilis PoC testing.

2.4 Flexibility of responsibilities

WA DoH understands that there may be times when services are unable to meet all the responsibilities outlined in Section 2.3. These services are encouraged to discuss individual requirements with the WA DoH Syphilis PoC Testing Coordinator to assess and adapt requirements on a case-by-case scenario.

If you wish to discuss any of the responsibilities outlined, please contact the WA DoH at <u>syphilispoct@health.wa.gov.au</u>.

2.5 Non-adherence with the WA syphilis PoC testing program

Services who are not meeting the WA syphilis PoC testing requirements will be contacted by WA DoH. WA DoH will provide support where possible to enable services to remain in the program. Long periods of non-adherence and poor communication with the WA DoH may result in removal of the program. Services that are continually unable to meet the requirements of the program will be sent a letter of non-adherence and may be removed from the program.

2.6 Application process

Health services which meet the criteria outlined in 2.1 and can adhere to the responsibilities outlined in 2.3 or to alternative mutually agreed responsibilities with the WA Department of Health Syphilis PoC Testing team, are highly encouraged to complete the Enrolment Form in this document (<u>Attachment A</u>)

2.7 Activating and embedding syphilis PoC testing within your health service

Planning

Consistent monitoring and maintenance of syphilis PoC testing is essential to ensure it is working effectively in the health service. It is recommended that management and Syphilis PoC Testing Champions consider how PoC testing will be used and embedded into their processes. Aboriginal health workers/practitioners and locally based clinicians are central to planning and negotiating with local communities on use of syphilis PoC testing.

Policy and procedure

It is recommended that a comprehensive programmatic approach is considered when planning and using syphilis PoC testing. Health services should review their current policies and processes to determine how they will implement syphilis PoC testing within their existing clinical governance and service delivery structures.

Health services should consider:

- 1. Which clients will be offered a syphilis PoC test? (e.g. will tests be offered to every client, those in certain populations, those who access certain services, in an outreach model?)
- 2. Do staff have efficient time and opportunity to complete a syphilis PoC test and other necessary tasks with a client?
- 3. How will staff be encouraged to use syphilis PoC test for relevant clients? (e.g. easy access to tests, changes to policy and procedure, visual reminders, data presented at team meetings)
- 4. How will the skills of staff be assessed and upskilling be offered?
- 5. Are staff confident and skilled to talk about sexual health and syphilis? If not, how will this be addressed?
- 6. Do staff have access to provide treatment to reactive results? Are they skilled to do contact tracing?
- 7. How will staff record the necessary PoC testing data?
- 8. What is the staff turnover rate? If it is high, how will the service ensure enough staff are trained to consistently offer PoC testing?

List of key documents and resources to consider when considering syphilis PoC testing

<u>Abbotts Determine [™] Syphilis TP test</u> – contains information, resources and instructional video on how to perform a syphilis PoC test.

<u>Structured Administration and Supply Arrangements</u> – enables Registered Nurses, Midwives and Aboriginal Health Practitioners to administer treatment for syphilis infections in confirmed and/or symptomatic cases and sexual contacts of confirmed cases.

<u>'Talk Test Treat and Trace Manual'</u> - to assist in planning, implementing and monitoring a comprehensive approach to the syphilis outbreak.

6

<u>'Silver book'</u> for clinical management of syphilis and other sexually transmitted infections.

South Australian Health and Medical Research Institute (SAHMRI) <u>Clinical Practice and Resource</u> <u>Manual.</u>- includes clinical guidelines and updates

3. References

- i. National strategic approach for an enhanced response to the disproportionately high rates of STI and BBV in Aboriginal and Torres Strait Islander people.
- ii. Action Plan: Enhanced response to addressing STI (and BBV) in Indigenous populations.
- iii. Syphilis Series of National Guidelines for Public Health Units (SoNG).
- iv. Abbotts Determine Syphilis PoC testing webpage

Attachments

- Attachment A: Health service syphilis PoC testing Enrolment Form
- Attachment B: PoC testing Enrolment Flow Chart
- Attachment C: Template for reporting of syphilis PoC testing data



Attachment A

Enrolment Form for Western Australian Health Services to conduct client Syphilis Point-of-Care Testing.

Provided by the WA Department of Health

Health service name:

I agree that my service will meet the criteria to access the PoC testing provided by the WA Department of Health. The criteria are outlined in *Guidelines for Health Services: Use of Syphilis Point of Care Tests provided by the WA Department of Health (2024).* This includes:

- 1. The health service employs at least two health professionals (Registered Nurse, Aboriginal Health Worker/Practitioner, or Medical Practitioner)
- 2. The health service agrees to adhere to the responsibilities outlined in 2.3, unless an alternative agreement is reached with the WA Department of Health Syphilis PoC Testing team, listed on page 12.
- 3. The health service understands not fulfilling the responsibilities may result in removal from the program.

Primary Syphilis PoC Testing Champion Position*:	
Name of Primary Syphilis PoC Testing Champion:	
Contact number:	
Email:	
Secondary Syphilis PoC Champion Position *:	
Name of Syphilis PoC Testing Champion :	
Contact number:	
Email:	

*Person responsible for PoC test stock management and program implementation in all sites

Sites where syphilis PoCT will be administered*:

1. Clinic name:	
2. Clinic name:	
Street address for delivery:	
3. Clinic name:	
Street address for delivery:	

*Print additional copies of this page if more sites are required

Planning for syphilis PoC testing

- How will PoC test be used in your service? (e.g., every client, clients in certain populations, clients who access certain services, in an outreach model)
- 2. How will staff be encouraged to use syphilis PoC testing for relevant clients? (e.g., easy access to tests, changes to policy and procedure, visual reminders, staff meetings)

3. How will your service record syphilis PoC testing data?

Patient Management System: (e.g., Communicare/MMEX/):

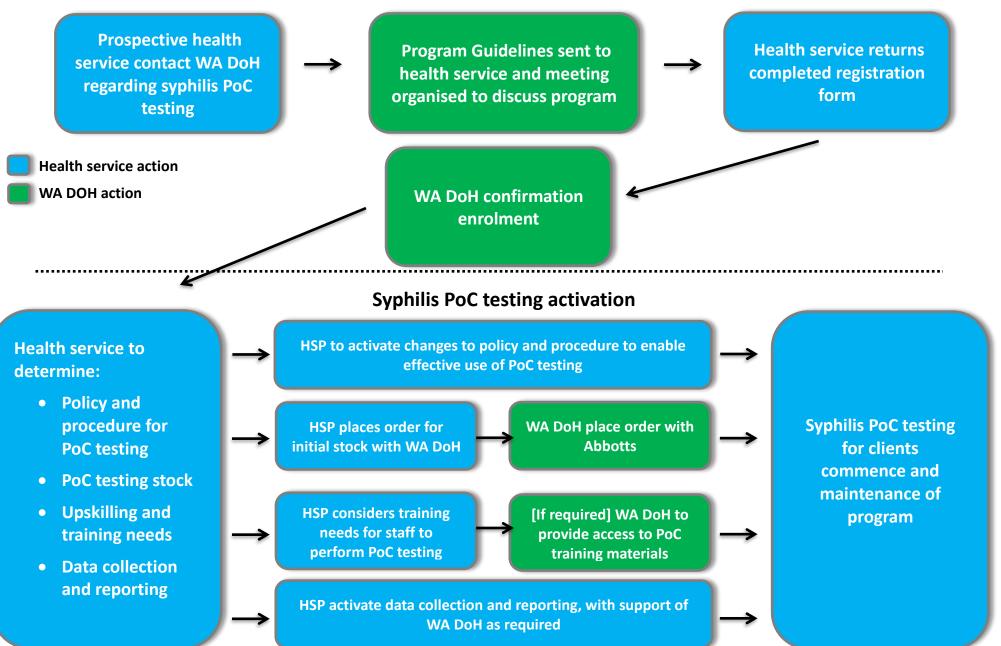
Authorised signatory for enrolment (E.g. Clinic Manager, Chief Executive).

Full name:		
Position:		
Email:		
Contact number:	_	_
Signature:		Date:

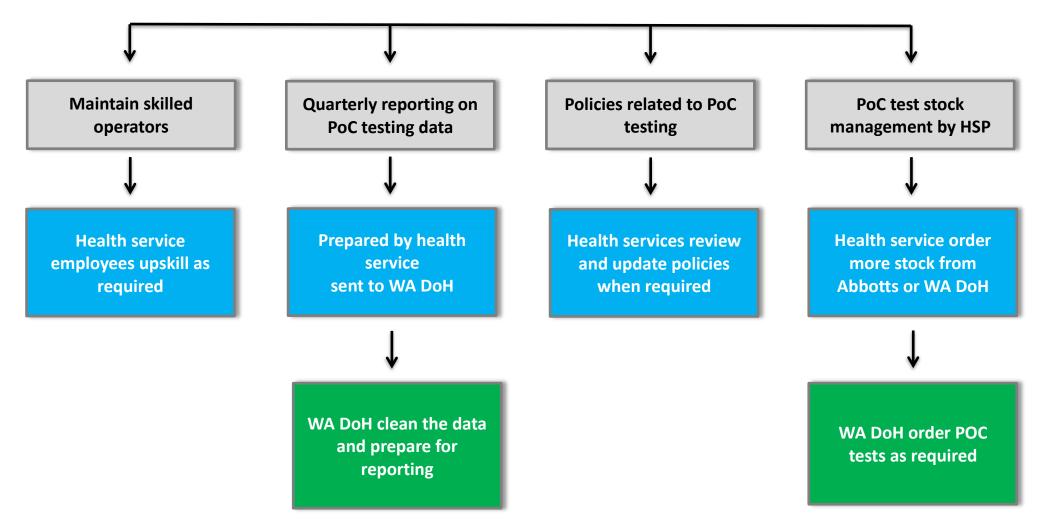
Please email completed form or forward any questions to WA DoH: syphilispoct@health.wa.gov.au

Syphilis PoC enrolment flowchart









Month an	nd year*	September 2024									
		Aboriginal				Non-Aboriginal					
	Number of	Clients attending	PoCT only	Serology only	Both serology + PoCT	Positive PoCT	Clients attending	PoCT only	Serology only	Both serology + PoCT	Positive PoCT
Male	15-19										
	20-24										
	25-29										
	30-34										
	35-39										
	40+										
	Total										
Female	15-19										
	20-24										
	25-29										
	30-34										
	35-39										
	40+										
	Total										
Non- binary And/or	15-19										
	20-24										
	25-29										
Gender	30-34										
Diverse	35-39										
	40+										
	Total				1						
Total											

* Reports are due within four weeks at the end of each quarter.

Attachment C

This document can be made available in alternative formats on request for a person with disability.

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