

A PROCESS REVIEW OF THE USE OF RAPID HIV POINT OF CARE (POC)TESTING IN SASKATCHEWAN:

Recommendations for Future Expansion

June 2013

ACKNOWLEDGEMENTS

This report, the "A Process Review of the Use of Rapid HIV Point of Care (POC) Testing in Saskatchewan: Recommendations for Future Expansion", was prepared by the Saskatchewan HIV Provincial Leadership Team (PLT) with the collaboration of the regional HIV Strategy Coordinators, and the HIV POC testing sites that participated in the survey. This report would not have been possible without the participation and support of the testing sites licensed to conduct HIV Point of Care Testing in the province of Saskatchewan.

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LETTER FROM THE MEDICAL HEALTH OFFICER

One key objective of the Saskatchewan HIV Strategy 2010 -2014 is to increase the number of individuals that are aware that they are infected with HIV in the early stages of their infection. Early identification of HIV infection offers a significant opportunity to address the chronic inflammatory effects of long-term HIV infection and reduce, and perhaps altogether avoid, the most serious complications associated with uncontrolled HIV infection.

The overall purpose of the provincial HIV Point of Care (POC) testing program is to increase uptake of HIV testing in the province by providing an acceptable and accessible alternative to standard HIV testing. This program provides HIV POC tests and consumable materials free-of-charge to health care settings that meet the program standards, upon receipt of an approved medical laboratory licence for HIV POC testing. The use of rapid HIV POC testing will increase the number of people in Saskatchewan that have access to HIV testing overall. For those who opt for this form of testing this will increase those that know their HIV status, especially amongst communities and populations where HIV testing has not been readily available thus far.

This is the first time that this type of evaluation had been conducted in Saskatchewan, and anecdotally some testing sites reported that they found the external evaluation useful as it was a good reminder of the performance expectations from the provincial perspective.

Dr. Johnmark OpondoMedical Health Officer
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EXECUTIVE SUMMARY

The standard method of testing for HIV diagnosis can take several days for the results to be available. HIV Point of Care (POC) Testing attempts to address this delay by providing preliminary antibody results and is beneficial in situations where immediate knowledge of a client's HIV status is considered important.

In 2010, the Saskatchewan Disease Control Laboratory (SDCL) introduced HIV POC testing technology to the province of Saskatchewan. At the time of introduction it was anticipated that the HIV POC testing technology would enhance access to and the quality of the HIV testing in the province, particularly among difficult to engage clients that were at the time most impacted by the HIV Saskatchewan HIV epidemic.

In 2011, the Saskatchewan HIV Provincial Leadership Team (PLT) developed the Saskatchewan HIV Point of Care (POC) Test Evaluation (Evaluation) survey to evaluate the effectiveness of the introduction of HIV POC testing technology to the province as well as to help plan for future expansion. The purpose of this report is to communicate the results from the process review of the HIV POC test sites that participated in the survey.

As of December 2011, when the *Evaluation* commenced, 16 sites were licensed to administer HIV POC testing in Saskatchewan. Although all sites were eligible for review, 13 testing sites chose to participate in the *Evaluation*. This represents a response rate of 81.2 percent.

All the testing sites that completed the *Evaluation* were classified into facility types, of which there were three categories: Community Clinics, Hospital Laboratories, and Public Health Clinics. *Community Clinics* were defined as primary care facilities that provided out-patient care only. *Hospital Laboratories* were defined as lab facilities that were located within health institutions that provided both in-patient and out-patient care and were generally found to also operate as a diagnostic lab. *Public Health Clinics* were defined as facilities that offered some of the specialized diagnosis and treatment of Sexually Transmitted Infections (STIs) and in addition had the legislative mandate to gather and report communicable diseases to the Ministry of Health on a routine schedule. Of the thirteen testing sites that participated, one was classified as a Community Clinic, nine were classified as Hospital Laboratories, and three were classified as Public Health Clinics.

By asking each interview respondent to estimate the population covered by their facility, it was estimated that approximately half the population of Saskatchewan - or 587,500 people - had access to a facility that was licensed to conduct HIV POC testing.

Site supervisors indicated that the following health care professionals currently perform HIV POC tests; medical technologists (69%) and registered nurses (31%). In total, across the thirteen facilities in Saskatchewan that participated in the *Evaluation*, there were 120 personnel trained to administer HIV POC tests. The personnel engaged at the facilities perform a range of duties in addition to HIV POC testing. On average, there were 9.2 personnel trained in HIV POC test administration per facility. Note: at certain levels of care (e.g., Hospital Laboratories) this type of service is required to be available 24 hours a day every day of the year which requires the cross training of large numbers of health care professionals and providers.

All facilities use the INSTI™ test kits for HIV POC testing. Currently, all facilities use whole blood samples for the initial HIV POC test. Most of the facilities, 84.6% (11/13), then use serum specimens to confirm reactive HIV POC test results¹.

All facilities maintain the *Ministry of Health Guidelines for the use of HIV POC Test Kits in Saskatchewan* except one which has developed Regional Health Authority (RHA) guidelines.

All facilities have incorporated practice tests and Standard Operating Procedures (SOPs) in the HIV POC testing training. The majority, 84.6% (11/13), require that personnel performing HIV POC testing undergo an initial observation (or evaluation) by other person(s) to demonstrate competency. All sites are enrolled in an external proficiency program arranged by the College of Physicians and Surgeons of Saskatchewan. However, only 61.5% (8/13) of facilities require that that all personnel performing HIV POC testing participate in proficiency testing.

Most facilities, 66.6% (8/12), reported that there had <u>not</u> been public education (or promotion) of the HIV POC testing in the local communities.

Hospital Laboratories primarily indicated that HIV POC testing was being used for:

- aiding decision making in needle stick post-exposure treatment; and
- the expedited testing of pregnant women who come in to labour and delivery with no HIV test on file.

Other facilities (i.e., Community Clinics and Public Health Clinics) primarily indicated that HIV POC testing was used for:

- voluntary HIV counselling and testing;
- the routine testing of all clients/patients seen in the facility; and,
- initial screening for diagnosis of symptoms compatible with HIV infection.

Approximately 85% (11/13) of the facilities stated that all HIV POC testing is performed on-site. All of the facilities designated as Hospital Laboratories only performed HIV POC testing on-site. Approximately 15% (2/13) of facilities stated that HIV POC testing is performed on-site <u>as well as</u> at off-site locations in the community (e.g., non-health region community based facilities and correctional facilities). These facilities were the public health clinics in Saskatoon and Regina².

The majority of the facilities, 90.9% (10/11), indicated that for confirmed HIV test results there are either formal or informal protocols in place to refer the client for follow-up care³.

In 2012, the highest volume testing sites were Public Health Clinics that performed 78.7% (440/559) of the province's annual HIV POC tests conducted in 2012 (Refer to Table 1.) The mean and standard deviation for the number of HIV POC tests performed per facility type is 7.7 and 8.7 for Hospital Laboratories and 147.7 and 101.3 for Public Health Clinics.

¹SouthEast Integrated Care Centre (Moosomin) reported that they send whole blood

West Side Community Clinic at the time of the survey reported that they "Have not had any finger sticks that were indeterminate but have had several venous samples that were. For these, they were sent a sample to prov lab for traditional (standard) HIV test."

² Saskatoon Public Health (Sexual Health Clinic) on site, off site (community outreach), off-site (other collecting facility). Communicable Disease & Sexual Health

^{- (}Regina) on site, off site (community outreach), off-site (other collecting facility: Carmicheal Outreach), client's homes

³lt is recommended that Saskatchewan develop a work standard around follow-up and linkage to care for reactive POC tests

TABLE 1: NUMBER OF HIV POC TESTS PERFORMED PER FACILITY TYPE IN 2012 (N =13)

	Community Clinics	Hospital Laboratories	Public Health Clinics	Total	Percent (%)
Reactive Tests	3	4	19	26	4.6
Non-Reactive Tests	46	64	419	530	94.9
Indeterminate Tests	1	1	1	3	0.5
Total No. of Tests	50	69	439	558	100.0
Percent of all tests (%)	8.9	12.3	78.8	100.0	

Site supervisors at each of the facilities identified the advantages and disadvantages of HIV POC testing for clients in comparison to standard testing. The responses fell under the following themes.

Advantages of HIV POC testing for clients compared to the standard testing indicated by testing sites include:

- clients are more likely to get test results and be linked to treatment;
- decreased anxiety for clients due to reduced wait times;
- increased test availability in non-clinical, non-institutional settings;
- ease of test administration; and,
- allows more people, especially high risk people, to know their HIV status and reduce at risk behaviours.

Disadvantages to HIV POC testing for clients compared to standard testing indicated by testing sites include:

- extra costs in terms of staff and time, especially in areas with low volume number tests;
- issue of false-positive results that requires a confirmation test;
- clients may not be prepared for the results of the test and non-optimal conditions for giving clients results;
- training of personnel and quality; and,
- on-going requirement to participate in quality assurance programs and the need for documentation of problems encountered.

Overall, the four main issues identified by the facilities conducting HIV POC Testing included:

- training needs and ongoing proficiency for personnel that administer HIV POC testing;
- time commitment needed for pre- and post-counselling;
- education and increasing awareness of both health care professionals and the public; and,
- administration of the service and data collection tasks.

The recommendations of this report are:

- 1. Strengthen testing site oversight to maintain licensing and quality assurance and quality control requirements.
 - a. All testing sites need to designate an onsite "HIV POC Coordinator⁴." The guideline section on designating a coordinator should be enhanced to remove any further confusion on the importance and role of this position to the delivery of the HIV POC program in the province.
 - b. All testing sites need to ensure that there are policies and procedures in place to maintain client confidentiality and privacy.
- 2. All sites should follow personnel training requirements as per the "Guidelines for the Use of HIV Point of Care (POC) Test Kits in Saskatchewan" document.
- 3. The requirement for formal referral to and linkage to care for all newly diagnosed cases as stated in the provincial HIV Testing Policy (21 December, 2012) should be included in all testing sites Standard Operation Procedures and trainings.
- 4. Develop a work standard around follow-up care for reactive POC tests.
- 5. This is the first evaluation of the Saskatchewan HIV POC testing program. Program supervisors and evaluators both felt that this was a useful process and the on-site visits revealed some opportunities for quality improvement. Discussions on the frequency and process for conducting future evaluations will need to be held.
 - a. It is recommended that all licenced HIV POC test sites participate in all future program evaluation efforts as a condition to maintain a valid lab licence.
- 6. Improve reporting processes
 - a. The legislative requirement to formally report all confirmed and suspect HIV cases to local public health authorities should be re-emphasized to all HIV POC testing sites. Reporting of HIV/AIDS cases is a provider's legal obligation under provincial public health law.
 - b. The requirement for the reporting of the outcomes of all HIV POC tests performed through the regional HIV Strategy Coordinators should be included in the site Standard Operating Procedures and trainings.
 - c. It is recommended that a method or process to document (electronically) the non-reactive tests be put in place in Saskatchewan e.g. via LIMS
- 7. It has been advocated that provincial legislation be changed to allow non-lab personnel, non-Registered Nurses be permitted to perform HIV POC in select sites, with specific, specialized training. This may be a great opportunity to address some issues, which sometimes create barriers to testing and accessing results in a timely manner.

⁴Designating a Coordinator

Each site will designate a coordinator - a health care professional with the ultimate responsibility for the quality assurance and quality control (QA/QC) and technical aspects of each site's HIV POC testing. Each site will designate a coordinator. For Health Regions this is a single person. This person is responsible for:

Training

II. Ensuring external quality assurance results are sent to the College of Physicians and Surgeons of Saskatchewan Quality Assurance in a timely manner.III.

Notifying Saskatchewan Disease Control Laboratory (SDCL) of invalid kit results

SECTION 1.0 – INTRODUCTION

Health Canada, in 2005, approved the use of the INSTI™ HIV-1/HIV-2 Rapid Antibody Test kits produced by BioLytical Laboratories. In 2006, the rapid HIV testing technology became commercially available. Since then, this rapid HIV testing technology has been extensively field-tested in Canada and other places throughout the world. At the time of this report, the INSTI™ was the only rapid HIV testing technology approved by Health Canada and can provide test results in as little as 60 seconds (BioLytical, 2014).

In 2010, the Saskatchewan Disease Control Laboratory (SDCL) introduced a rapid HIV testing technology pilot to the province of Saskatchewan following provincial reports of expanding clusters of HIV and Hepatitis C (HCV) infected individuals being identified in the Prince Albert Seroprevalence Survey (CFEP, 2006) and in a HIV outbreak investigation report from the Saskatoon Health Region (Opondo, 2006). At the time of introduction of the pilot it was hoped that the rapid HIV testing technology would enhance access to and the quality of the HIV testing program in the province, particularly among difficult to engage clients that were impacted by the HIV outbreak.

During the pilot phase of the HIV POC testing initiative specimens were submitted to the SDCL for parallel testing, regardless of the test result (i.e., reactive, non-reactive, or indeterminate) so that the performance of the assay and user ability and compliance with the training could be assessed. Of the specimens received during the pilot phase (n=67), 100% of the HIV POC test results correlated with inhouse screening and confirmatory testing.

After a year of implementation of the new HIV testing technology, testing sites were advised that they were no longer required to submit parallel specimens for non-reactive HIV POC tests. Note: testing sites are still required to submit a confirmatory venous sample for a reactive or an indeterminate test result. Furthermore, the INSTI™ tests could now be performed on a fingerpick whole blood sample. The decision to use a fingerpick whole blood sample instead of using only plasma was adopted because using only plasma required that facilities have access to a micro-centrifuge, which for some of the early adopters of this technology was a burden.

The Saskatchewan HIV Strategy 2010-2014 called for a reduction in the rate of new HIV infections by 50 percent over a period of five years. Widespread HIV testing and early diagnosis with linkage and referral to care were stated as critical strategies to reducing the rate of new HIV infections. It is in this context that the Saskatchewan HIV Provincial Leadership Team (PLT) developed the Saskatchewan HIV Point of Care (POC) Test Evaluation in 2012 to evaluate the effectiveness of introducing HIV POC Testing technology to the province. The completion of the Evaluation would also help plan for future expansion based on lessons learned during the process.

The purpose of this report is to communicate the results from the *Evaluation* completed in 2012.

SECTION 2.0 - METHODOLOGY

At the time of the *Evaluation* (December 2011) there were 16 testing sites licensed to conduct HIV POC testing in the province of Saskatchewan. Refer to Appendix A for information regarding the requirements for licensed HIV POC testing sites.

The intent of the evaluation exercise was to administer the survey instrument at all of the testing sites that were licensed to conduct HIV POC testing at the time of the survey. Two sites at that time had not yet begun to offer POC testing, one site declined to participate in the evaluation process so 13 sites were finally evaluated⁵:

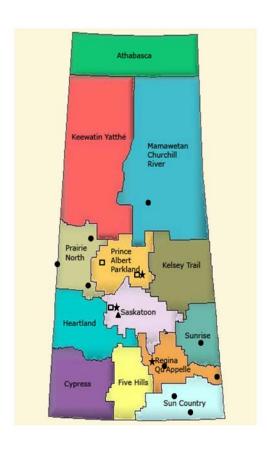
- 1. South East Integrated Care Centre (Moosomin, SK)
- 2. La Ronge Health Center (La Ronge, SK)
- 3. Meadow Lake Hospital (Meadow Lake, SK)
- 4. Prince Albert Sexual Health Clinic (Prince Albert, SK)
- 5. Communicable Disease & Sexual Health Programs (Regina, SK)
- 6. Saskatoon Public Health (Sexual Health Clinic) (Saskatoon, SK)
- 7. Yorkton Regional Hospital (Yorkton, SK)
- 8. Weyburn General Hospital (Weyburn, SK)
- 9. St. Joseph's Hospital (Estevan, SK)
- 10. Westside Community Clinic (Saskatoon, SK)
- 11. Battlefords Union Hospital (Battleford and North Battleford, SK)
- 12. Lloydminster Hospital (Lloydminster, SK)
- 13. All Nations Healing Hospital (Fort Qu'Appelle, SK)
- 14. Saskatoon Tribal Council Health Center (Saskatoon, SK)
- 15. Spiritwood Health Center (Spiritwood, SK)
- 16. Victoria Hospital (Prince Albert, SK)

Thirteen of the sixteen testing sites completed the survey. This represents a response rate of over 80 percent of the eligible sites.

Response Rate: 81.2%

st is recommended that all licenced HIV POC test sites participate in all future program evaluation efforts as a condition to maintain a valid lab licence.

FIGURE 1:LOCATION OF TESTING SITES (PER FACILITY TYPE) LICENSED TO OFFER HIV POC TESTING IN THE PROVINCE OF SASKATCHEWAN (DECEMBER 2011)



Legend:

- ▲ Primary Care Clinics
- Hospital Laboratories
- ★ Public Health Clinics
- ☐Site not evaluated

Note: Each symbol represents a single testing site licensed to offer HIV POC testing.

The survey used to collect data was composed of three separate sections containing both closed and open ended questions. The Site Supervisor at each testing site was asked to complete Section 1 of the survey in advance to the site visit and Sections 2 and 3 were completed by the survey team at the time of site visit with the Site Supervisor. The survey collected data regarding the testing sites, including: type of facility, areas of geographic coverage, specimen collection and testing practices, as well as personnel experience and training, quality assurance practices, and patient related information. Finally a visual inspection of the testing sites was completed and confirmed the absence or presence of critical HIV POC testing related equipment.

There are limitations of the *Evaluation*. Upon data analysis it became apparent that for certain questions not all testing sites interpreted the questions in the same way: wherever possible testing sites were followed-up for clarification and validation. While the overall response rate of the survey was acceptable -81.2% (13/16), the response rate for each question differs: this has been taken into account throughout the report, which explains the different denominators in some specific questions.

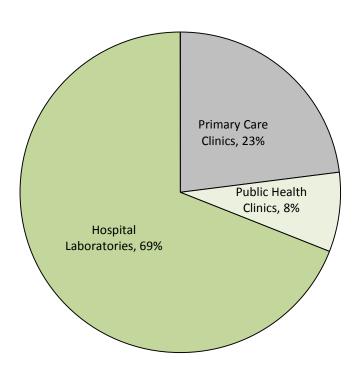
other two were classified as hospital laboratories.

FACILITY TYPE

All testing sites that participated in the *Evaluation* were classified into facility types, of which there were three categories: Primary Care Clinics, Hospital Laboratories, and Public Health Clinics. *Primary Care Clinics* were defined as primary care facilities that provided out-patient care only. *Hospital Laboratories* were defined as lab facilities that were located within health institutions that provided both in-patient and out-patient care and were generally found to also operate as a diagnostic lab. *Public Health Clinics* were defined as facilities that offered some of the specialized diagnosis and treatment of Sexually Transmitted Infections (STIs) and in addition had the legislative mandate to gather and report communicable disease to the Saskatchewan Ministry of Health on a routine schedule.

Of the thirteen testing sites included one was classified as a Primary Care Clinic, nine were classified as Hospital Laboratories, and three were classified as Public Health Clinics. Refer to Figure 2. Of the facilities that did not participate in the survey, one was classified as a primary care facility and the

FIGURE 2: TYPE OF FACILITIES LICENSED TO CONDUCT HIV POC TESTING IN SASKATCHEWAN (2012)



CATCHMENT POPULATION

On the day of the site visit the annual number of visits by clients was estimated as reported by the Site Supervisor. Across all testing sites surveyed, the estimated catchment-population per facility ranged from 10,000 to 300,000; although, this is likely an overestimate as a result of multiple testing sites existing within one area. Of the facilities that identified the number of discrete clients attended per year, across all programs on-site and off-site, the number of clients ranged from 3,420 clients to 100,000 clients. Several sites were not certain of the estimated catchment population or geographic coverage as the sites reported seeing many out of region clients.

By asking each interview respondent to estimate the population covered by their facility, it was estimated that approximately half the population of Saskatchewan - or 587,500 people - had access to a facility that was licensed to conduct HIV POC testing.

SECTION 4.0 – RESULTS – HIV POC TESTING PERSONNEL & HIV POC TESTING TRAINING

SITE SUPERVISORS

Of the Site Supervisors that completed the *Evaluation*: two defined their position as a Facility Director (or Manager); three defined their position as a Nurse Supervisor; three defined their position as a Nurse; and, five defined their position as a lab personnel.

POC1A: What is your position?

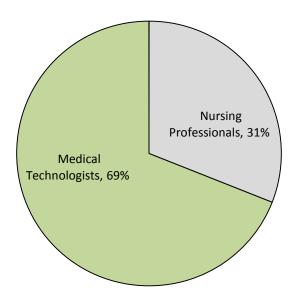
Licensed Facility Name	Facility Type	Position
All Nations Healing Hospital	Hospital/Community Clinic	Nursing supervisor/woman's
(Regina)		helper/WHC NP/Lab
Communicable Disease & Sexual	Public Health	Registered Nurse
Health – (Regina)		
SouthEast Integrated Care Centre	Hospital/ Regional	Lab manager
(Moosomin)	Diagnostic Lab	
Saskatoon Public Health (Sexual	Public Health	Nursing officer in charge
Health Clinic)		
West Side Community Clinic	Community Clinic	Facility Manager
(Saskatoon)		
Meadow Lake Hospital Laboratory	Hospital Laboratory	Lab Supervisor
PA Sexual Health Clinic	Community Clinic. Health	HIV Nurse
	centre	
La Ronge Health Center	Regional Diagnostic Lab	nursing supervisor (lab)
Lloydminster Hospital	Hospital	Lab supervisor
Battlefords Union Hospital	Hospital	Lab Supervisor
St Joseph's Hospital (Estevan)	Hospital	Nursing supervisor
Weyburn General Hospital	Hospital	Facility manager
Yorkton regional hospital	Hospital	MLT Section Head in Chemistry

HIV POC TESTING PERSONNEL

In Saskatchewan, only health care professionals can administer HIV POC Tests. All of the facilities classified as Hospitals Laboratories (i.e., nine) reported that laboratory staff performs HIV POC testing on a regular basis. All of the facilities classified as Primary Care Clinics or Public Health Clinics reported that a nursing officer in-charge, nurse practitioner, or nurse performs HIV POC testing on a regular basis.

Persons performing HIV POC tests were primarily medical technologists and Registered Nurses/RN(NP)s. Refer to Figure 3.

FIGURE 3: PERSONS PERFORMING HIV POC TESTING



In total, across all thirteen testing sites that participated in the *Evaluation*, it was reported that there were 120 staff trained to administer HIV POC tests. On average, there was 9.2 staff per testing site with a range of 3 to 18. Although the human resources initially appear adequate, at certain levels of care (e.g., Hospital Laboratories) this type of service is required to be available 24 hours every day of the year which requires the cross training of large numbers of health care professionals and providers.

TABLE 2: AVERAGE NUMBER OF HIV POC TEST HEALTH CARE PROFESSIONALS PER FACILITY TYPE (N = 13)

Facility Type	Average Number of HIV POC Test Personnel per Facility	Range
Primary Care Clinics	3.0	-
Hospital Laboratories	10.3	6 - 18
Public Health Clinics	8.0	5 - 12

HIV POC TESTING TRAINING

Across all facilities, the majority of staff was reported to have attended one or more of the HIV POC testing training sessions.

The top three responses regarding type of training available were:

- training offered by the kit manufacturer;
- review of provincial guidelines on HIV POC testing; and,
- training organized by the Regional Health Authority (RHA).

Furthermore, all surveyed facilities also conduct "in-house" training or training within the RHA for HIV POC testing. Seven of the facilities require that trainees read through the provincial guidelines on HIV

POC testing. Six of the facilities offered training by the "kit" manufacturer in the past. Two facilities, one Hospital Laboratory and one Public Health Clinic, offered training in counselling specific to HIV POC testing.

Most facilities, 84.6% (11/13), require that personnel performing HIV POC testing undergo an initial observation (or evaluation) by other persons (e.g., Site Supervisor) to demonstrate competency, and pass a Quality Control and Proficiency sample panel. However, only 61.5% (8/13) of facilities require that that all personnel performing HIV POC testing participate in proficiency testing.

All facilities incorporate a practice test and Standard Operating Procedures (SOPs) in their HIV POC testing training. Most facilities include reading the package insert in the HIV POC testing training as well as an external quality assurance, and quality control. Only two of the facilities include counselling in the HIV POC testing training.

SECTION 5.0 - RESULTS – CURRENT HIV POC TESTING SERVICE PROVISION

INTEGRATION OF SERVICES

The majority of facilities (in 2013), 92% (12/13), reported that the facility had begun performing HIV POC testing more than one year ago but less than two years ago. All of the licensed facilities surveyed offer HIV POC testing alongside other health services. Most care facilities that offered HIV POC testing had already integrated HIV POC testing with other clinical care services such as the testing and treatment of Sexually Transmitted Infections (STIs), including HIV, and the treatment of addictions.

Other Integrated services offered at testing sites by facility type included:

- Primary Care Clinics
 - STI Treatment & Prevention
 - HIV/AIDS Prevention & Treatment
 - Addiction Services
 - General Health Care
 - Maternal & Child Health Services
- Hospital Laboratories
 - HIV/AIDS Treatment
 - General Health Care
 - Maternal & Child Health Services
 - Blood Banking and Transfusion Services
- Public Health Clinics
 - STI Treatment & Prevention
 - HIV/AIDS Prevention
 - Harm Reduction Services
 - Maternal & Child Health Services

Although no licensed testing sites at the time of *Evaluation* reported to offer correctional services, Saskatchewan Provincial Correction Services had expressed an interest in being able to offer this type of service as a part of the intake medical. In the interim some regional outreach testing teams do visit some provincial correctional facilities.

HIV POC TESTING

All surveyed facilities indicated that their facility currently performs HIV POC testing. The average, the number of HIV POC tests offered by all facilities increased from 2010 to 2012. Refer to Table 3.

On average, Public Health Clinics conduct more HIV POC tests compared to Community Clinics or Hospital Laboratories.

In 2012, the highest volume testing sites are Public Health Clinics that performed 78.8% (439/558) of the province's annual HIV POC tests conducted in 2012. Refer to Table 1. The mean and standard deviation for the number of HIV POC tests performed per facility type is 7.7 and 8.7 for Hospital Laboratories and 146.3 and 100.7 for Public Health Clinics.

TABLE 3:SUMMARY OF HIV POC TESTING DATA FOR TESTING SITES LICENCED TO CONDUCT HIV POC TESTING IN SASKATCHEWAN 2010, 2011, AND 2012

	2010 (12 Testing Sites) N=11*	2011 (13 Testing Sites) N=12*	2012 (13 Testing Sites) N=13
No. of POC HIV tests	99 Mean (x) = 9.9 StdDev (s) = 20.4	449 Mean (x) =40.8 StdDev (s) = 79.7	558 Mean (x) = 42.9 StdDev (s) = 73.2
No. of HIV POC tests Reactive	3	16	24
No. of HIV POC Tests Non-reactive	90	427	507
No. of HIV POC Tests Indeterminate	1	0	3
Positivity Rate HIV POC Tests Reactive	3%	3%	4%

^{*} One testing site responded unknown to each question

Note: Number of HIV POC Tests that are reactive, non-reactive, and indeterminate may not add up to the total number of HIV POC Tests because one or more testing sites responded unknown responded unknown to one or more of the questions.

Eight of the facilities responded to the question, "How many requests for HIV POC tests were declined based on the fact that the individual did not meet the criteria for HIV POC testing?" Of those that responded the number of requests declined ranged from zero to three, with a median of zero. The one facility that reported declining testing was a Public Health Clinic who indicated that they have refused to test clients who were intoxicated.

HIV POC TESTING LOCATIONS

Approximately 85% of facilities stated that all HIV POC testing is performed on-site, while approximately 15% of facilities (Public Health Clinics) stated that HIV POC testing is performed on-site as well as off-site. Of those facilities that perform HIV POC testing off-site the testing occurs in a multitude of settings.

TABLE 4: FACILITY TYPES THAT CONDUCT ON-SITE AND OFF-SITE HIV POC TESTING (N = 13)

Facility Type	On-site	Percent (%)	Off-site	Percent (%)
Primary Care Clinic (1)	1/1	100.0	0/1	0.0
Hospital Laboratories (9)	9/9	100.0	0/9	0.0
Public Health (3)	3/3	100.0	2 ⁶ /3	66.6
Total	13/13	100.0	2/13	15.4

In Hospital Laboratories, while specimens are collected in a number of different settings (i.e., Admission, Emergency Room, Employee Health (or Infection Control), Labour and Delivery, Central Lab, Unit

^{*}Saskatoon Public Health (Sexual Health Clinic) on site, off site (community outreach), off-site (other collecting facility). Communicable Disease & Sexual Health – (Regina) on site, off site (community outreach), off-site (other collecting facility: Carmicheal Outreach), client's homes

(Ward), Long-term Care), all specimens are tested in the lab itself. Only two of the three Public Health Clinics at the time of *Evaluation* reported that they conduct HIV POC testing in outreach community settings.

About half, 54% (7/13), of the facilities offered HIV POC testing at least once within the past month. Nine of the thirteen facilities, 69% (9/13), offer HIV POC testing on-site, 24 hours per day, 7 days per week. Three of the nine facilities that offer HIV POC testing on-site, 24 hours per day, 7 days per week do so by having trained personnel on-call. For those testing sites that do not offer HIV POC testing on-site 24 hours per day, 7 days per week most offer testing Monday to Friday during daytime hours (e.g., 8:00am – 4:30am).

PURPOSE(S) FOR OFFERING HIV POC TESTING

The survey collected information regarding the purpose(s) of testing sites for offering HIV POC testing.

Hospital Laboratories primarily indicated that HIV POC testing was being used for:

- post-exposure prophylaxis treatment; and
- testing of pregnant women.

Other facilities (i.e., Primary Care Clinics and Public Health Clinics) primarily indicated that HIV POC testing was used for:

- voluntary HIV testing and counselling;
- testing all clients/patients seen in the facility; and
- initial screening for diagnosis.

TARGET POPULATIONS

Participants were asked to note if any particular group was targeted for HIV POC testing. All facilities selected "any at risk client/patient;" of these, 92.3% (12/13) further identified one or more "high risk" categories. The top "high risk" target populations identified were:

- high-risk women (e.g., sex workers) 66.6% (8/12);
- injection drug users 50.0% (6/12);
- men who have sex with men (MSM) 25.0% (3/12); and
- homeless 25.0% (3/12).

HEALTH EDUCATION & PROMOTION

Most facilities, 66.6% (8/12), reported that there <u>had not</u> been public education (or promotion) of HIV POC testing in the local communities. Of the facilities that engaged in public education (or promotion) 75% (3/4) were Hospital Laboratories and 25% (1/4) were Public Health Clinics.

Approximately 60% (7/11) of the facilities reported that they offered educational material and other information that encouraged HIV testing. Of the facilities that offered educational material, 86% (6/7) offered take-home leaflets, 57% (4/7) displayed posters and one 14% (1/7) offered counselling cards as well as a phone line for patient's to call for more information. Refer to Table 6.

TABLE 6: EDUCATIONAL MATERIAL AND OTHER INFORMATION TO ENCOURAGE HIV TESTING (N=11).

Facility Type	Counselling Cards	Leaflets	Posters	Other
Primary Care Clinic (0)	-	-		-
Hospital (9)	-	44% (4/9)	22% (2/9)	-
Public Health (2)	50% (1/2)	100% (2/2)	100% (2/2)	50% (1/2)

IDENTIFIED ISSUES

Ten of the thirteen facilities (76.9%) identified at least one problem in terms of "rolling out" the HIV POC testing.

- 1. Training: Five of the facilities identified training as an important issue. Site Supervisors indicated that "ensur[ing] that new staff are adequately trained" and that old staff "remain competent" in the collection of samples to ensure consistency as well as being capable of dealing with difficult situations that might occur during HIV POC Testing encounter could be an issue.
- 2. Adequate time to provide pre- and post-counselling: Four of the facilities identified the time commitment needed for pre- and post-counselling as an important issue. Site Supervisors expressed this issue through statements such as, "When you get a [reactive test] result having enough time to spend with clients" or "client calls the next day after receiving a reactive [test] result and still needs more support."
- 3. Awareness of HIV: Two of the facilities identified education and increasing HIV awareness as an important issue. For example, one Site Supervisor stated that there those that "[don't] feel [the] population... is at risk" and that "few routine HIV tests [are conducted] other than pre-natals." This idea is further captured in the statement that there is a need to "reach out to [populations that need] testing." Furthermore, one facility indicated that there is a need to communicate that professionals need to determine whether or not a client meets the criteria for HIV POC Testing.
- **4. Inadequate Infrastructure and Resources:** One of the facilities indicated a need for additional resources (i.e., space and personnel) to administer and manage the HIV POC testing along with the other programs being administered.
- **5. Data Collection:** One of the facilities indicated issues in data collection and proposed an electronic database to keep track of HIV POC Testing.

Overall, the three main issues identified by the facilities conducting HIV POC testing include:

- training:
- time commitment needed for pre- and post-counselling; and,
- education and increasing awareness.

CLINICAL MANAGEMENT & GUIDELINE PROTOCOLS

All facilities have Standard Operating Procedure (SOP) guidelines or clinical management protocols. Three of the facilities have the *Public Health Agency of Canada Point of Care HIV Test Kits: Guidance for Health-Care Professionals.* All facilities have the *Ministry of Health Guidelines for the use of HIV POC Test Kits in Saskatchewan* except one which only offers RHA guidelines instead. Eight of the facilities that offer the *Ministry of Health Guidelines* also offer RHA guidelines. Twelve of the thirteen facilities indicated that they used the guidelines to design steps for managing the administration of HIV POC tests.

More than half, 55% (6/11), of the facilities indicated that personnel refer to the guidelines on a weekly or monthly basis, while the others indicated that personnel rarely refer to the guidelines. The Site Supervisors responding to the survey were asked to list in their opinion the advantages and disadvantages of HIV POC testing compared to standard HIV testing approach.

Advantages of HIV POC testing for clients compared to the traditional, non-POC testing:

- high risk clients are more likely to get results and access to treatment;
- decreased anxiety for clients due to reduced wait times;
- increased availability in non-clinical, non-institutional settings;
- ease of test; and,
- allows more people, especially high risk people, to know their HIV status and reduce at risk behaviours.

Disadvantages to HIV POC testing for clients compared to the traditional, non-POC testing:

- extra costs in terms of staff and time, especially in areas with low volumes number tests;
- issue of false-positive results that requires a confirmation test;
- clients may not be prepared for the results of the test and non-optimal conditions for giving clients results;
- training of personnel and quality; and,
- Quality Assurance needs or documentation problems.

HIV POC TESTING TURNAROUND TIME

In response to the question, "On average, how much time passes from collection of the specimen for HIV POC testing at your facility until preliminary test results are reported to the client?" Of the facilities that responded, 41.6% (5/12) stated less than 20 minutes, 25% (3/12) stated 20 minutes to 30 minutes and 33.3% (4/12) stated more than 30 minutes passes from collection of the specimen for HIV POC testing until preliminary test results are reported.

TABLE 7: TIME (IN MINUTES) TO OBTAIN A SAMPLE AND REPORT PRELIMINARY TEST RESULTS TO CLIENT PER FACILITY TYPE (N = 12)

Facility Type	Less than 20 min	20-30 min	More than 30 min
Primary Care Clinic (1)	1/1	-	-
Hospital (8)	1/8	3/8	4/8
Public Health (3)	3/3	-	-
Total	5/12 (42%)	3/12 (25%)	4/12(33%)

Three of the facilities stated that, on average, the total HIV POC testing process takes <u>less than 60</u> <u>minutes</u> including pre- and post-test counselling and delivery of the preliminary test results while the other three facilities that responded stated that, on average, the HIV POC testing process takes <u>60 to 120</u> minutes.

HIV POC REACTIVE & NON-REACTIVE TESTS

Nine of the thirteen (69%) facilities indicated that the results of HIV POC tests are provided to the client by the client's physician or other health care professional or a counsellor that did not perform the test. Four of the thirteen (31%) facilities indicated that the results of HIV POC tests are provided to the client by the person that performed the test.

Facilities designated as Hospital Laboratories indicated that either that the client's physician or other healthcare professional or a counsellor that did not perform the test informs the client of their results. Facilities designated as a Primary Care Clinic or a Public Health Clinic indicated that the person that performed the test informs of the client of their results.

HIV POC REACTIVE TEST RESULTS

Six of the facilities indicated that for initially reactive HIV POC tests the typical procedure [following the confirmatory test] for the client is to be directed to return to the individual that performed the initial HIV POC test to obtain confirmatory test results; three facilities indicated that clients are referred to another agency or service provider; and, four facilities indicated "other". Refer to Table 8.

TABLE 8: PERSON(S) THAT PROVIDES THE CONFIRMATORY TEST RESULT PER FACILITY TYPE (N = 13)

Facility Type	Client is directed to return to the individual that performed the initial HIV POC test	Clients are referred to another agency or service provider	Other
Primary Care Clinic (1)	-	-	1/1
Hospital (9)	3/9	3/9	3/9
Public Health (3)	3/3	-	-
Total	6/12	3/12	4/12
	(50%)	(25%)	(33%)

HIV POC NON-REACTIVE TEST RESULTS

All facilities that responded "Yes" to the question, "For non- reactive (Negative) HIV POC tests, is this test result given the same day to the client?" In these instances the person that performed the test or the client's physician or other health care professional gives the results of the HIV POC test to the client.

REFERRALS

Ten of the eleven (90.9%) facilities indicated that for a reactive HIV POC test result that is confirmed there is either a formal or informal protocol to refer the client for follow-up care; of those, seven indicated that there is a formal protocol, one indicated that there is an informal protocol, and two did not specify whether or not the protocol was formal or informal. Only one, of the eleven facilities (9%) indicated that that there is no protocol to refer the client for follow-up care. Note: all Primary Care Clinics and Public Health Clinics had formal protocols in place to refer the client for follow-up care.

For those facilities that have a protocol to refer a client for follow-up care after a reactive HIV POC test is confirmed the following options are included in the protocol:

- referral to a Heath care professional (approx. 90%)
- list of HIV resources (approx. 45%);
- Counselling options (approx. 70%);
- transportation (approx. 30%);
- public health department (approx. 30%);
- employee/occupational resources (approx. 20%);
- arranges own follow-up care (approx. 10%);
- follow-up (Referral) (approx. 90%); and
- other (approx. 10%).

Note: participants could select more than one response.

HIV POC INVALID OR INDETERMINATE TESTS & FOLLOW UP

In the instance that the initial HIV POC test result is indeterminate ⁷ or invalid ⁸ <u>all</u> thirteen of the facilities conduct further HIV testing for that client. The majority of facilities (10/13) then collect serum specimens for further standard HIV testing after an indeterminate or invalid HIV POC test.

HIV POC TESTING CONFIRMATORY PRACTICES

The majority of testing sites - 75% (9/12) - use a "prior blood draw, before HIV POC test," to obtain a specimen for a confirmatory test. One of the facilities uses a "new blood draw, after HIV POC test" and two facilitates uses both of these procedures to obtain a specimen for a confirmatory test. All facilities designated as Hospital Laboratories used a "prior blood draw, before HIV POC test" to obtain a specimen for a confirmatory test. Refer to Table 9.

In this scenario, a faint shadow in the form of a ring (when cellular components in the blood cause long flow times) may appear at the test spot location, but this should not be interpreted as a reactive result. This should be considered an indeterminate result. The test should be repeated with a new kit. If the result is still indeterminate, it should be explained to the patient that collection of a venous blood sample is necessary to send to the SDCL to be processed for confirmatory HIV testing

In this scenario no dot appears on the membrane or the test dot appears without the control dot. It is recommended that an invalid test be repeated with another kit. If the result is still invalid, it should be explained to the patient that collection of a venous blood sample is necessary to send to the SDCL for testing as there may be interfering substances which may invalidate the POC test. It is necessary to wait for the result from the SDCL for further counseling.

TABLE 9: PROCEDURE USED TO OBTAIN A CONFIRMATORY BLOOD SAMPLE PER FACILITY TYPE (N=12)

Level of Facility	Prior Blood Draw	New Blood Draw	Both
Primary Care Clinic (1)	-	-	1/1
Hospital (8)	8/8	-	-
Public Health (3)	1/3	1/3	1/3
Total	9/12	1/12	2/12
	(75%)	(8%)	(17%)

HIV POC TEST PARTICULARS

The only HIV POC test kits reported to be used by facilities were the INSTI™ test kits.

All thirteen facilities responded to the question, "What sample type(s) do you use for HIV POC testing?" Six of the facilities use "serum"; two of the facilities use "whole blood, venous"; three of the facilities use "whole blood, finger stick"; one facility uses both "serum" and "plasma"; and, one facility uses "whole blood, venous" and "whole blood, finger stick." Refer to Table 10.

TABLE 10: TYPE BLOOD SAMPLE USED FOR HIV POC TEST PER FACILITY TYPE (N = 13)

Facility Type	Serum and/or Plasma	Whole Blood, Venous	Whole Blood, Finger Stick	Whole Blood, Venous & Finger Stick
Primary Care Clinic (1)	-	-	-	1/1
Hospital (9)	7/9	2/9	-	-
Public Health (3)	-	-	3/3	-
Total	7/13 (54%)	2/13 (15%)	3/13 (23%)	1/13 (8%)

Most of the facilities, 84.6% (11/13), use serum specimens to confirm initially reactive HIV POC test results while two 9 facilities (15.4%) use whole blood, venous specimens to confirm initially reactive HIV POC test results. Of the facilities that confirmed non-reactive HIV POC tests during the pilot phase, most of the facilities, 92% (11/12), use serum specimens.

SECTION 7.0 – RESULTS – QUALITY CONTROL

All facilities possess a valid lab license.

All facilities run quality control material received from SDCL separately when performing HIV POC testing. Eight of the thirteen facilities (62%) run quality control material received from SDCL separately when performing HIV POC testing approximately once per 24 specimens, but no less than once per week. Furthermore, six of the eight (75%) facilities also run quality control material received from SDCL when switching to a new lot number.

⁹SouthEast Integrated Care Centre (Moosomin) and Saskatoon Public Health (Sexual Health Clinic) uses both serum and whole blood at different times.

All of the facilities indicated that the external Proficiency Test (PT) is provided by Metrix Digital PT. In facilities designated as Hospital Laboratories, it is the lab personnel that performs PT or performance evaluation testing for HIV POC testing whereas in facilities designated as Primary Care clinics or Public Health Clinics it is either a site supervisor (or nursing officer in-charge), a nurse, or all personnel that perform PT or performance evaluation testing for HIV POC testing at the facility.

SECTION 8.0 – RESULTS – ADMINISTRATION AND MANAGEMENT

OVERSIGHT (SUPERVISION 10)

Seven of the thirteen facilities (54 %) reported that the facility had received a supervisory visit within the last six months with four facilities, approximately (60 %) reporting that the facility had a "supervisor on site." Fifty-six percent (5/9) of the Hospitals indicated that the facility had received a supervisory visit. Sixty-seven percent (2/3) of Public Health Clinics had received a supervisory visit.

The majority of facilities described the main purpose of the <u>last</u> supervisory visit as a way to: one, assess the availability of resources (e.g., personnel, supplies, etc.); two, review record keeping; three, collect data from records; four, assess the status of the facility (e.g., cleanliness); five, assist personnel in enhancing performance; six, identification of problems in management or delivery of services; seven, follow-up on problems identified in prior visits; and eight, provide feedback on performance.

Six of the thirteen facilities (46%) reported that the facility has "never" received a supervisory visit. Of those, four of the facilities stated that supervisory visits would be useful by assisting with tasks such as record-keeping and collection of data from records as well as with identification of and follow-up with problems and provision of feedback on performance.

EQUIPMENT AND CLINIC INFRASTRUCTURE

The majority of the thirteen facilities, 92% (12/13), had a storage area for HIV POC Test kits and other supplies that were satisfactory, while one of the facilities, a Hospital Laboratory, had a storage area that was not considered satisfactory. (On validation review this was reported as a coding error by the survey team).

Over the course of time that Saskatchewan has introduced HIV POC testing technology in the field, the equipment demands have changed; from a situation requiring a micro-centrifuge to spin down whole blood to obtain a serum sample for testing, to today where HIV POC testing can be done on a drop of blood from a finger stick. In 2012, the survey found that:

- All thirteen facilities (100%) had a centrifuge that was satisfactory (i.e., serviceable and in use).
- Of the twelve facilities observed, eleven (92%) had a refrigerator that was satisfactory and one, a Hospital Laboratory, had a refrigerator that was reported as unsatisfactory. On review this was reported as a coding error by the survey team. Note: one facility was not observed.
- Twelve of the thirteen (92%) facilities had a micropipette that was satisfactory, while one of the facilities, a Hospital, had a micropipette that was not satisfactory. (On validation review this was reported as a coding error by the survey team).

¹⁰Supervision in this context is trying to measure health system oversight by the health region i.e., a program management function

INFRASTRUCTURE

Majority of the facilities, 85% (11/13), had an examination area or room that provided client's privacy that was satisfactory, one facility had an examination area but was rated by the providers as not satisfactory, and one facility did not have an examination area or room. The two facilities that either did not have an examination area or room or one that was not satisfactory were within Hospitals Laboratories in Emergency Rooms. All of the facilities record at least in one place in the facility all client encounters and HIV POC tests conducted.

All thirteen of the facilities had water source with a running tap at/in the facility. Twelve of the thirteen (92%) facilities had a water supply that was satisfactory.

COMSUMABLE SUPPLIES

HIV POC TEST KITS

The majority of the thirteen facilities, 77% (10/13), had additional HIV POC test kits to meet increases in demand that were satisfactory, while 8% (1/13) of facilities had additional HIV POC test kits to meet increases in demand that were not considered satisfactory and 15% (2/13) did not have additional HIV POC test kits to meet increases in demand. These facilities maintained a "just in time" inventory system and stated that they could order additional HIV POC test kits as needed.

Eleven of the thirteen (85%) facilities keep a running tally of the number of all HIV POC test kits used in the facility. In the past 12 months, only two of the facilities, both Hospital Laboratories, ran out of HIV POC test kit with one facility uncertain whether or not this had occurred.

All facilities re-order supplies once stock levels reach a specified "re-order" level.

Only three of the facilities have had an issue with obtaining HIV POC testing supplies in a timely fashion. Of those facilities that encountered difficulties, difficulties arose from SDCL running out of supplies or SDCL not having new kits before old kits expired.

All facilities have a process for disposing of expired HIV POC testing kits. Twelve of the thirteen facilities dispose expired HIV POC testing kits on site, with one facility returning expired HIV POC testing kits to SDCL. The most common method of disposal is the use of biohazard bags.

OTHER

Of the twelve facilities that responded to this question, eleven - 92% (11/12) - had enough disposable gloves and one facility, a Hospital Laboratory, reported an unsatisfactory situation with disposable gloves. (On validation review this was reported as a coding error by the survey team).

Of the twelve facilities observed, eleven - 92% (11/12) - had enough disposable needles and syringes that were satisfactory and one, a Hospital Laboratory, had disposable needles and syringes but reported that the situation was unsatisfactory. (On validation review this was reported as a coding error by the survey team).

SECTION 9.0 – CONFIDENTIALITY

Privacy issues were examined by asking sites if they provided anonymous HIV POC testing or had confidentiality procedures in place. Only one of the facilities (8%) offered anonymous HIV POC testing, while all facilities responded that they <u>do</u> protect the confidentiality of the client/patient being tested for HIV. All of the facilities protect the confidentiality of HIV results using a number of methods including but not limited to Oaths of Confidentiality of employees, results of test being offered only to the physician that ordered the test, and results kept in Medical Records stored in secured areas.

SECTION 10.0 - RECORDS & REPORTING

RECORDS

Five facilities indicated that the facility <u>did</u> record the number of false-positive tests, five facilities indicated that the facility <u>did not</u> record the number of false-positive tests, three facilities indicated that it is unknown whether or not the facility records the number of false-positive tests.

Twelve of the thirteen facilities indicated that personnel do not encounter difficulties in recording information on clients or client care.

With respect to documentation that is maintained at the HIV POC testing sites:

- sixty-two percent (8/13) of the facilities maintain records on personnel training;
- ninety-two percent (12/13) of the facilities maintain records on Proficiency Testing;
- all facilities maintain quality control logs;
- ninety-two percent (12/13) of the facilities maintain incidence logs to record invalid kit results;
- eight-five percent (11/13) of the facilities maintain incidence temperature logs; and
- fifty-four percent (7/13) of facilities maintain results logs that include the date the test is performed, lot number of the test kit used, expiration date of the test kit, client ID, tester ID, and results of the test.

REPORTING

Five of ten (50%) facilities indicated that reactive HIV POC test results are reported to an outside entity, while the other five facilities (50%) indicated that the reactive HIV POC test results are only reported after confirmation with a Western Blot test. Of those facilities that reported to an outside entity, all Hospitals, reported results to the client's physician or other health care professional.

Eight of the nine facilities designated as Hospital Laboratories - approximately 90% - indicated that the typical HIV POC testing results reporting procedure for the purposes of HIV surveillance is to report to the physician first and then the physician reports to the Health Department. Refer to Table 11.

TABLE 11: PROCEDURE USED TO REPORT RESULTS OF HIV POC TEST FOR SURVEILLANCE PURPOSES (N = 13)

Facility Type	Report to physician & physician reports to Health Dept.	Report to physician & Health Dept. simultaneously	Report to Health Dept.	Not Reported
Primary Care Clinic (1)	-	-	-	1/1
Hospital (9)	8/9	1/9	-	-
Public Health (3)	-	1/3	1/3	1/3
Total	8/13 (62%)	2/13 (15%)	1/13 (8%)	2/13 (15%)

For the one Primary Care Clinic it is unknown whether or not the facility reports confirmed HIV POC tests to health department(s). Eight of the nine Hospital Laboratories, approximately 90 percent, report confirmed HIV POC tests to the local Medical Health Officer (MHO), the Regional Health Authority, or both. One of the Public Health Clinics report confirmed HIV POC tests to the Ministry of Health while the other two report to both the local MHO and the Ministry of Health.

Suggestions for enhancing the record-keeping systems at the facilities include:

- record the results from HIV POC test in patients Electronic Medical Record;
- issues in consistency and information being updated in a timely manner in iPHIS and LIMS; and
- keeping HIV POC test results and confirmation test results together, feedback regarding confirmatory test results, information regarding the number of HIV POC tests completed and how many were reactive and how many were non-reactive.

APPENDIX A: SASKATCHEWAN REQUIREMENTS FOR HIV POC TEST SITES

Requirements for Licensed HIV Rapid Point of care POC Testing Sites

- A. Must maintain a valid laboratory licence from the Ministry of Health.
- B. Governing or oversight body must have policies that reflect the rapid testing site is aware of:
 - Legal implications and liabilities for conducting rapid POC test outside of laboratory conditions.
 - All sites must maintain standing delegation orders from their medical authority.
 - All sites must report the outcomes of rapid POC testing as requested by the Ministry of Health.
 - The correct method of reporting test results through local public health offices.
 - Procedure for dispensing of medical waste.
 - Procedures and guidelines to address an occupational exposure to blood and body fluids.
 - Designate a contact person in-charge of all enquires and management of rapid HIV point of care services at the designated facilities.
 - The importance of having an adequate number of HIV POC test kits available at all times and a system in place for re-ordering supplies.

C. Must receive all appropriate training for using the rapid testing, including (not all items will always apply):

- Training from the manufacturer of the rapid test.
- Site specific HIV testing and counselling educational programs e.g.,
- "HIV/STD Risk Reduction Groundwork".
- "Foundations of Counseling and Testing Pre-Course".
- "Foundations of Counseling and Testing" (includes post-counselling on positive HIV/HCV results).
- Basic training on HIV and HCV, such as the web based trainings: "Risk Reduction Groundwork" and "The Basics of Hepatitis."

D. Must following standard clinical procedures such as:

- Designate an initial point of contact within agency for clients seeking HIV testing.
- Develop a list of screening questions.
- Maintain a flexible appointment schedule process that can accommodate counsellors spending adequate time giving client's positive post-test counselling results.
- Designate when preliminary and confirmatory samples are to be collected; the best practice is to conduct a HIV confirmatory test using a blood specimen immediately following the preliminary reactive POC result
- Develop a process that accommodates appropriate space for clients waiting on test results (environment, confidential setting, time, etc.).
- Develop the type of documentation the client will receive, if any, of their test result.
- Develop a procedure to follow up with clients who leave prior to receiving test result.

E. Must demonstrate that they can refer clients to appropriate medical and social services, including:

- HIV treatment and care.
- HCV confirmatory testing resources and appropriate medical follow up.
- STI testing and treatment, as medically indicated.

- Immunization services for hepatitis A and B.
- Substance abuse treatment and mental health services.
- Any other appropriate program as indicated through post-test counselling.
- F. Must have policies and procedures in place to secure client information and maintain client confidentiality.
- G. Clinic sites must follow the most recent "Guidelines for the use of HIV Point of Care Test Kits in Saskatchewan" which are published on the ministry of health website. These guidelines clearly specify the Saskatchewan guidelines for maintaining competency and ensuring adequate record keeping.

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