The Monthly Summary

- Maintaining a monthly summary of testing outcomes at your site is a key responsibly of the Quality Assurance Lead.
- This report is also a good opportunity to review kit usage at your site – information you need before you can order more kits through the Inventory Management Portal (www.hivpoct.ca)
- An Excel template is available for your monthly summary report at: http://hivtestingontario.ca/point-of-care-testing/managing-a-site/quality-assurance-templates/
- The Monthly Summary records must be securely stored at your site as part of your quality assurance commitments.

The Purpose of the Monthly Summary

- Help you identify discrepancies that should be reported to the HIV and Hepatitis C Program
- Monitor trends in outcomes and kit usage at your site that may require action on your part
- As a resource for you when investigating an incident at your site

  For example: If two invalid tests occurred during client testing and you were try to determine why, the monthly summary would allow you to easily see whether other invalid tests had occurred recently.
- As a record of practices at your site in the event of an audit of your program by the HIV and Hepatitis C Program

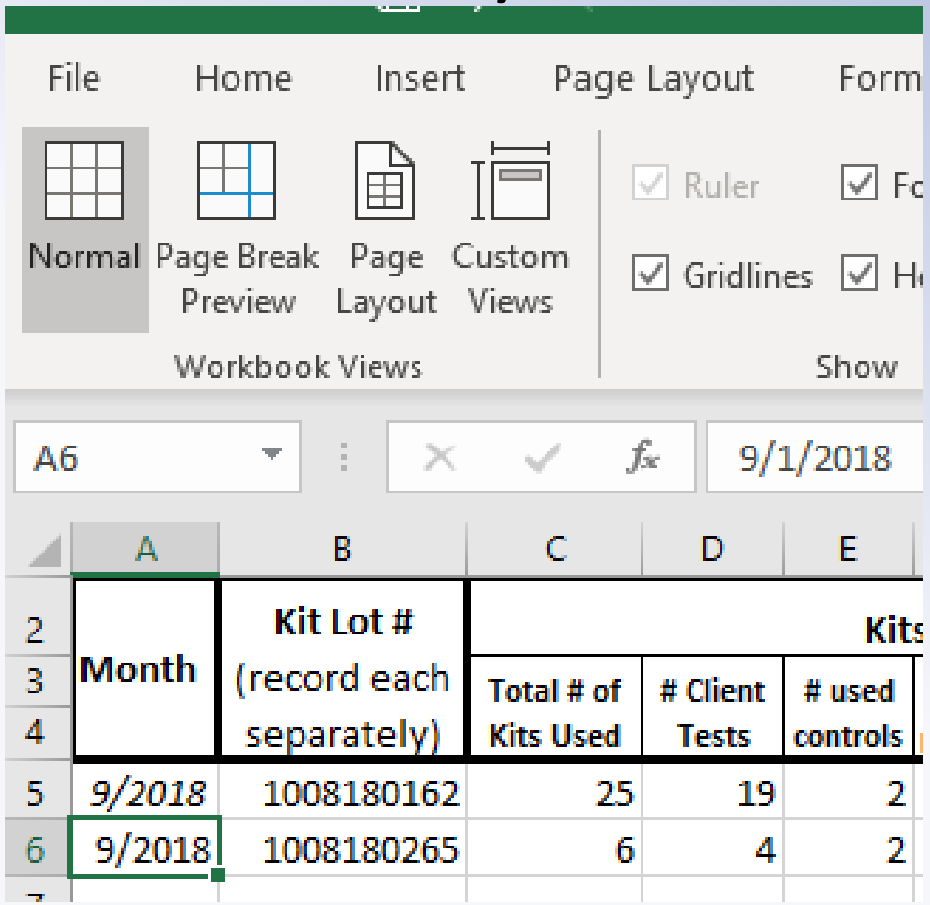
Completing the Monthly Summary

Each row of the summary report describes the use of one kit lot over one month of testing. For smaller sites, only one kit lot is likely to be used, however if you begin using a second lot of kits, you need to enter records separately for each lot.

For example:

In this record, the site was using lot 1008180162 for most of September, a total of 25 kits.

Late in September, they began using lot 1008180265, using a total of 6 kits including the necessary initial quality control testing and 4 client tests.

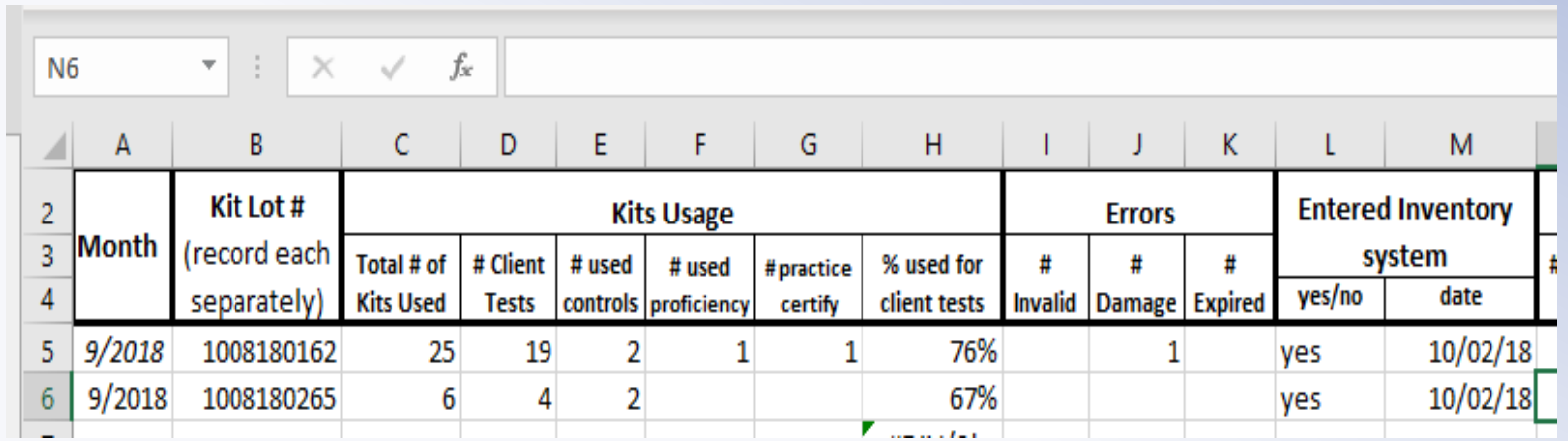


	A	B	C	D	E
2	Month	Kit Lot # (record each separately)	Kits		
3			Total # of Kits Used	# Client Tests	# used controls
4					
5	9/2018	1008180162	25	19	2
6	9/2018	1008180265	6	4	2

Kit Usage and the Monthly Summary

The Rapid Kit Usage Log at hivpoct.ca requires you to report:

- # of client tests
- # of quality control tests
- # of proficiency tests
- # of tests for staff use (training)
- # of usage errors



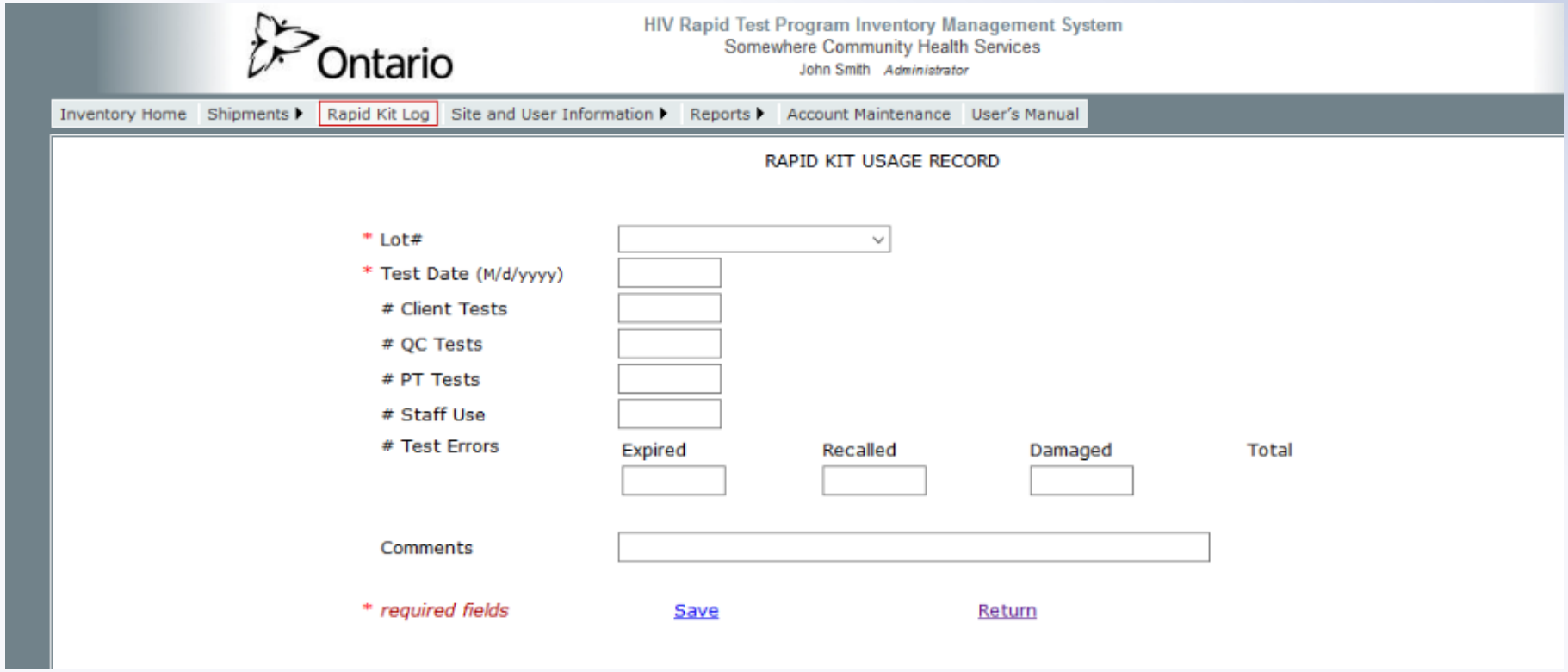
Month	Kit Lot # (record each separately)	Kits Usage						Errors			Entered Inventory system	
		Total # of Kits Used	# Client Tests	# used controls	# used proficiency	# practice certify	% used for client tests	# Invalid	# Damage	# Expired	yes/no	date
9/2018	1008180162	25	19	2	1	1	76%		1		yes	10/02/18
9/2018	1008180265	6	4	2			67%				yes	10/02/18

This information is gathered from the daily log book.

Note: There are several different ways a kit may be used in error.

Kit Usage and the Monthly Summary

The Inventory Management portal requests the information you have captured.

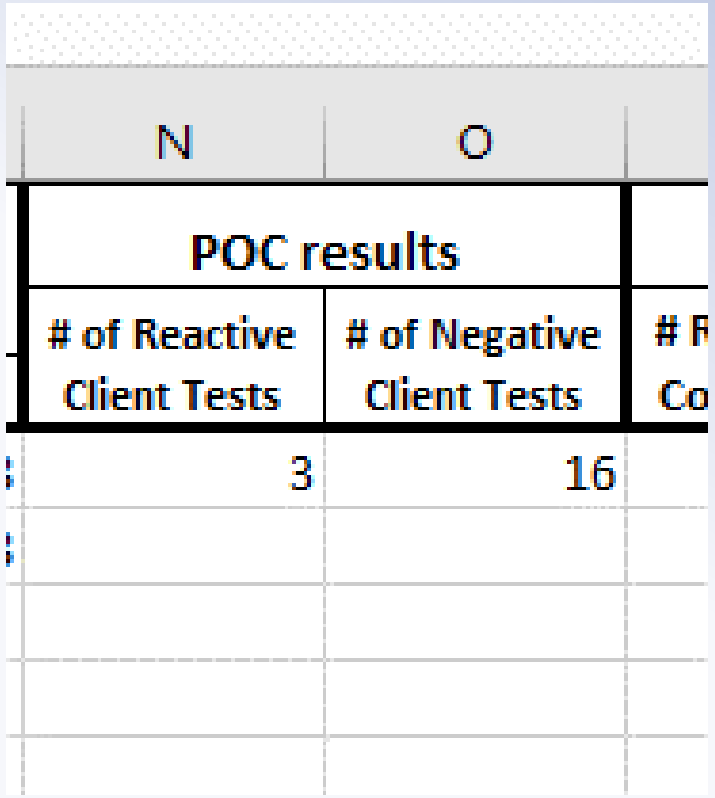


The Monthly Summary: POC Testing Results

The second section of the monthly report summarizes POC results at your site. This helps lets you reflect on the number of negative and positive results at your site.

Are you reaching the most at-risk people in your community?

- Some sites use this information in annual reports about their services or clinical reports to supervisors.
- HIV and Hepatitis C Program staff may also want to review it during an audit.



N	O	
POC results		
# of Reactive Client Tests	# of Negative Client Tests	# R Co
3	16	

The Monthly Summary: Parallel Testing

There are a number of situations where follow-up standard HIV testing by the provincial laboratory is recommend following a POC result:

- A POC test is reactive
- A client is testing early in the window period
- A POC test result is invalid twice and clarification is needed
- A client wishes the reassurance of more than one type of test

Follow-up standard testing is always at the discretion of the client, and is done to provide clear results for the client. However, when parallel tests occur, they are an opportunity to ensure that testing and testing procedures are working well at your site. One element of the monthly summary report is to review any parallel tests done at your site and look for discrepancies.

The Monthly Summary: Parallel Testing

This section of the monthly summary looks at those parallel testing results. Most sites will have a relatively small number of parallel tests each month:

Tests sent to PHOL							Discrepancies			
# Reactive for Confirmation	# Non-Reactive Window	# Invalid to clarify	POC Reactive Confirmed		PHL Results for POC Invalids		POC Reactive, PHL Neg		POC Neg, PHL Reactive	
			#	%	PHL Reactive	PHL Negative	#	%	#	%
3	1		2	67%			1	33%		0%

Why was parallel testing done? In this example, 4 parallel tests were sent to PHOL, three to confirm reactive tests.
(Client requests where the window period is unclear, can be captured in # non-reactive window.)

2/3 reactive tests confirmed.
The template automatically calculates the %.
The INSTI test is highly accurate. In most cases this number will be 100%. A percentage less than 100 indicates a discrepancy.

Record the discrepant test in this section (the % is automatically calculated.)

The Monthly Summary: Parallel Testing

Tests sent to PHOL							Discrepancies			
# Reactive for Confirmation	# Non-Reactive Window	# Invalid to clarify	POC Reactive Confirmed		PHL Results for POC Invalids		POC Reactive, PHL Neg		POC Neg, PHL Reactive	
			#	%	PHL Reactive	PHL Negative	#	%	#	%
3	1		2	67%			1	33%		0%

Discrepancies in HIV testing results may be indicator of a problem with the performance of the test kits. Notify the HIV and Hepatitis C Program if:

- Any false negative test was recorded (POC Neg/PHL Reactive); the manufacturer must legally report such results to Federal regulators.
- There are more than 1% false reactive POC tests or invalid POC tests in a month. This may indicate a problem with test kit performance.

The Monthly Summary

This report is an important part of quality assurance at your site. It is an opportunity for you to reflect on practices at your site, and where improvements could be made:

- Are too many kits expiring or being damaged?
- Are sufficient numbers of quality controls being performed on the test kits?
- Is your clinic seeing an increase (or decrease) in positive tests? Why? Should this change how you reach out to vulnerable people in your community? Is your testing program focused on priority populations?
- Are avoidable errors happening at your site? How could you stop them?

In Summary: Notifying Ministry Staff

This unit described two circumstances were the supervisor or quality assurance lead should notify HIV and Hepatitis C staff Program about an issue. Ministry staff should be notified when any of the following occurs:

- Two invalid tests on the same specimen (or >1% of tests in a one month period)
- Two unexpected quality control results
- Any negative POC test, followed by a positive laboratory test (even if the client was in the window period; the manufacturer is legally required to report this outcome)
- More than one false reactive POC test (or >1% of tests done in a month)
- Damage to a significant number of newly shipped kits (>5% of the order)

The best way to notify Ministry staff is by email to: poct@Ontario.ca