Changes to BC Point of Care HIV Test Program Effective January 1, 2016

Effective January 1, 2016, the following changes will come into effect for the BC Point of Care HIV Test Program:

1. **INDETERMINATE Results – are to be reported as REACTIVE**
   - An Indeterminate test interpretation (ring around the test spot rather than a full blue test spot) will be interpreted and reported as a REACTIVE result. An Indeterminate interpretation will no longer exist as a HIV POC test result.
   - **Why?** Indeterminate is a subset of a reactive result and treated identically as any other reactive result. In US and Ontario testing centres, a ring around the test spot is just another appearance of a reactive result, and is not a separate interpretation option. For other HIV tests, an indeterminate result may provide useful information, not so for the POC test.
   - When indeterminate results are reported in the monthly report, we followed up to ask for the confirmatory results and often discovered that the tester saw no spots (“No spots” is the most common type of invalid result). **Testers were confusing invalid and indeterminate results, and some testers were not taking the appropriate action on indeterminate results, i.e., by not requesting a confirmatory test.**

   - The next steps are quite different for invalid vs indeterminate results, with different consequences for the client.
     - If the result is invalid initially (no control spot), the POC test should be repeated, usually a control spot is seen; the results can then be interpreted as reactive or non-reactive. Invalid results often occur because of blood collection challenges. We track invalid test results to identify opportunities to improve testing technique.
     - A ring around a **test spot** area is called an indeterminate result. POC tests displaying an indeterminate result need to be treated as a reactive test result. If the confirmatory test comes back as negative (results not suggestive of HIV infection), then the POC test was a false positive, and further POC testing may not be suitable for this client (ie. future testing should be by blood in the lab).
     - Some testers were interpreting results as “indeterminate”, but treating them as an “invalid” (ie confirmatory testing not done); other testers became concerned over the number of false negatives they saw. Both situations took time to investigate to be certain that a HIV positive result was not missed; often clients were concerned waiting for confirmatory results; testers and clients lose faith in the POC test when the blood result comes back as negative.
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- The above points highlight the reasons for removing Indeterminate as a type of POC test result and for removing this from the monthly inventory report. Please make sure that you use the versions sent by Candice each month so that you are reporting on the most current version.

- During training, please don’t mention indeterminate as a separate interpretation – this is a reactive result and requires confirmatory testing.
  - Results are valid or invalid based on the control spot. Invalid can be repeated by POC.
  - Results are reactive or non-reactive based on the test spot. Reactive requires confirmatory test. Non-reactive requires assessment for early infection.

2. **No longer running the anti-HIV-2 control**
   - The HIV negative and anti-HIV-1 controls will continue to be run per normal practice.
   - Why? Based on the very low incidence of HIV-2 disease in Canada, and in an effort to balance use of kits for quality assurance purposes, the BCCDC Lab Advisory group for the Program reviewed and approved the reduction of quality control expectations to 2 controls, at least once per month.
   - Please continue to store control vials per current recommendations. If you choose to discard the anti-HIV-2 vials, then please use appropriate biohazard disposal practices.

The Program Guidelines and training materials will be changed as soon as possible.

Please share this information with other testers or stakeholders at your site.

Thank you for your assistance as we make these changes.

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BC Point of Care HIV Test Program