1.0 PURPOSE:
1.1 Appropriate and consistent Public Health management of chlamydia and gonorrhea results that are identified as potentially false positive

2.0 SCOPE and GOAL:
2.1 Applicable to Public Health and Clinic Liaison Nurses working with the Healthy Sexuality and Harm Reduction team
2.2 Outline a clear and consistent process for chlamydia and gonorrhea results that are identified as potentially falsely positive

3.0 DEFINITIONS:
3.1 False-positive: test result that is erroneously classified in a positive category due to imperfect testing methods or procedures
3.2 Sensitivity: The proportion of individuals in a population that will be correctly identified as positive when administered a test designed to detect a particular disease, calculated as the number of true positive results divided by the number of true positive and false negative results.
3.3 Specificity: probability that an individual who does not have the particular disease being tested for will be correctly identified as negative, expressed as the proportion of true negative results to the total of true negative and false positive results

4.0 BACKGROUND:
4.1 There are a number of reasons why a result may not be accurate. E.g.:
   4.1.1 Mislabeling lab specimens at source of collection
   4.1.2 Contamination of the specimen from another source
   4.1.3 False identity given by client
   4.1.4 Sensitivity/specificity of the specimens. Summary of sensitivity and specificity data for GenProbe Aptima Combo 2 test:

<table>
<thead>
<tr>
<th></th>
<th>Specimen type</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chlamydia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>Swab</td>
<td>94.2</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>94.7</td>
<td>98.9</td>
</tr>
<tr>
<td>Males</td>
<td>Swab</td>
<td>95.9</td>
<td>97.5</td>
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<tr>
<td></td>
<td>Urine</td>
<td>97.9</td>
<td>98.5</td>
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<tr>
<td><strong>Gonorrhea</strong></td>
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</tr>
<tr>
<td>Females</td>
<td>Swab</td>
<td>99.2</td>
<td>98.7</td>
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<tr>
<td></td>
<td>Urine</td>
<td>91.3</td>
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</tr>
<tr>
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<tr>
<td></td>
<td>Urine</td>
<td>98.5</td>
<td>99.6</td>
</tr>
</tbody>
</table>
Limitations of this data:
The above data is based on information published by GenProbe (http://www.genprobe.com/products/aptima.aspx) and specific details on the gold standard against which the results have been compared are not stated on the website. The above data is based on controlled evaluation studies and does not necessarily reflect the sensitivity and specificity values that may be found following implementation in a diagnostic laboratory.
As per all diagnostic tests with less than 100% sensitivity and specificity, positive and negative predictive values will vary depending on disease prevalence in a given area.

4.2 Cadham Provincial Lab (CPL) doesn’t have a case definition for false positive chlamydia or gonorrhea results. This lab does not routinely do a second test on chlamydia and gonorrhea specimens. However, if the sample is a low positive they repeat the test (per verbal communication Dr. John Wylie, CPL scientist)

5.0 PROCEDURE:

5.1 If the testing practitioner indicates that the client has a false positive chlamydia or gonorrhea result, verify with testing practitioner that client was actually tested that day; rule out possible mix-up with another client’s specimen and that correct identification was used

5.1.1 Check if client has since been given an antibiotic that has potential to clear the infection (e.g. zithromax/amoxil). E.g. client treated day of testing, or since or given an antibiotic for any other infection such as respiratory or strep infection

5.1.2 If client has not been treated yet, recommend repeat testing, doing sexual history with the client and screening of partner(s) which may support the false positive result

5.1.2.1 If the 2nd result is positive, recommend management as per positive results for the chlamydia or gonorrhea

5.1.2.2 If the result is negative, the testing practitioner may:

- Choose to still treat with appropriate antibiotic as the 2nd result may be false negative and there is minimal potential for harm with treatment
- Choose not to treat

5.1.2.3 Advise testing practitioner that the NSTD (Notification of Sexually Transmitted Disease form) still needs to be completed/sent. Advise that the provider can attach the explanation such as “consider result false positive; second testing negative”, therefore no treatment and no interview; or treatment given but considered false positive therefore no
5.1.2.4 If medical practitioner/health care provider refuses to fill out NSTD, nurse should document on STI cover sheet that doctor considers results to be false positive therefore no treatment, no interview or no interview but treated and include any partner testing and results

5.1.3 Document in chart that doctors office repeated testing and negative or verify with CPL if necessary and document (correct lab slip not required unless mix up with specimens in doctors office or CPL or false identity used or person never tested)

5.1.4 Have Admin update database with “Dr indicates false positive as repeat testing negative”

5.2 If the testing practitioner indicates the false positive result was due to mix up with another client’s specimen, recommend:

5.2.1 Re-test client who had positive result. If result is positive, manage as per positive result. If result is negative, no recommended treatment but the NSTD must be filled out with explanation that client actually negative and specimen’s originally mixed up

5.2.2 PHN/CLN to fill out STI cover with same information, if health care provider refuses to fill out NSTD

5.2.3 Advise health care provider to call CPL and issue a corrected lab slip for the “original positive case”

5.2.4 Document sequence of events in the chart

5.2.5 Give file to Admin to remove positive case from database

5.2.6 Testing practitioner re-call for re-testing her/his other patients that were tested for same organism on same day

5.3 If testing practitioner indicates that false positive result due to use of false identity: e.g. client tested positive but used a friend’s or stolen id, recommend:

5.3.1 Testing practitioner retests the client who used false identification under correct name and regardless of result of treatment or interview, fill out NSTD

5.3.2 Testing practitioner call CPL to advise that false identity used and to issue corrected lab slip for that false identity that was never tested.

5.3.3 Give file to Admin to remove false identity name from database

5.3.4 Admin to add to database name of person who actually tested positive
VALIDATION:
