Consultation document

Processing of female genital specimens at Labtests and Northland Pathology Laboratory
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1. INTRODUCTION

Labtests provides microbiology testing to the Auckland and Northland communities (excluding Auckland Regional Sexual Health Service) and receives approximately 500 female genital specimens daily.

Female genital specimens are collected for the diagnosis of the following:

- Bacterial vaginosis (BV)
- *Trichomonas vaginalis* (TV) infection
- Candidiasis
- *Neisseria gonorrhoeae* (NG)
- *Chlamydia trachomatis* (CT)
- Other causes of bacterial vulvovaginitis
- Carriage of group B streptococcus in pregnancy

In addition, specimens are collected for the following testing which is currently done at LabPLUS:

- Herpes simplex virus
- Cervical cytology

Testing methods have changed over the years – most importantly the advent of NAAT has simplified the swab requirement. A self-collect or healthcare worker-collect vaginal swab is usually the only swab required for testing for CT and NG. In the past endocervical swabs were required for culture for NG but this is no longer the case under almost all circumstances. NAAT methodology is now available for TV with increased sensitivity over traditional methods such as microscopy and culture.

Thus, it is timely to review what testing is performed on female genital specimens at Labtests. The aim of the proposed changes is to improve overall health utility by focusing testing on those patients at risk of infection either on the basis of demographic factors and/or clinical presentation, and to ensure that testing methodology is of the highest standard possible.

The detection of group B streptococcus carriage in late pregnancy, testing for herpes simplex virus, and cervical cytology/HPV testing is not part of this review and will not be discussed further in this document.
2. CURRENT SERVICE

All specimens received in an Aptima® collection tube are tested by NAAT for CT and NG

Endocervical bacterial swabs are held and only cultured for NG if an Aptima® specimen is not received

High vaginal swabs (HSV) (bacterial):
   1. Cultured for yeasts/Candida species
      a. If there is a history of recurrent candidiasis speciation +/- sensitivity testing is also performed
   2. Cultured onto blood agar in patients aged ≥ 60 years or on request
   3. Gram stain appearance for BV in patients aged 13 – 60 years
   4. TV culture (micro-broth) in patients aged 13 – 60 years

3. RATIONALE FOR CHANGE

We now have the opportunity to detect TV by NAAT on the same specimens (Aptima®) received for CT/NG testing. Introducing NAAT for TV would enable us to stop TV culture which is time consuming, takes up to five days to report a result, and has poor sensitivity compared with NAAT. However, we are unable (resource-wise) to perform NAAT for TV on all specimens. Interestingly, the routine testing of all specimens for TV is not recommended by national and international guidelines; testing should be done on request on high risk patients. We have performed a study (results in Appendix 1) which describes the demographics of patients in our region with this infection. We believe these data can be used, in conjunction with clinical assessment, to guide referrers into requesting TV testing where it is clinically indicated (as per guidelines).

**STI screening at time of cervical smear – this is not routinely recommended**

We have noted that some GPs and nurses routinely collect specimens for STI testing when they are doing a cervical smear. Often this is not in keeping with guidelines and best clinical practice. In addition, we also notice that the provision of clinical details on request forms is poor and so we do not know if the swab has been collected as part of a ‘screening’ test or if the patient is symptomatic. Without clinical information the interpretation of culture plates is difficult and it is probable that we are reporting organisms that may be colonising the genital tract, rather than infecting.

Another unintended consequence of ‘screening’ for STIs in patients at the time of cervical smear is that women who are low risk for CT/NG are having testing using a methodology with imperfect specificity (all NAAT tests). Even when the specificity is excellent (as it is with the modern assays), where the pre-test probability is low the positive predicative value (PPV) is also low. In other words, a significant proportion of positive tests in this population may be false positives. This can cause a great deal of harm to patients and their families. Tables 1 and 2 of Appendix two demonstrate the impact of prevalence on PPV.
4. PROPOSED NEW SERVICE

- TV NAAT will be performed -
  - On request
  - On specimens received from females aged 13 – 16 years
  - On specimens from females aged 16 – 50 years with appropriate accompanying clinical details
- TV culture will no longer be available
- Vaginal swabs will not be processed without appropriate clinical details
- Vaginal swabs submitted with accompanying relevant clinical details will have the following:
  - Gram stain for BV
  - Gram stain and culture for yeast/candida
  - Culture for other organisms if Gram stain indicates inflammation and/or clinical details include ‘abnormal vaginal discharge’
  - Full Candida identification +/- susceptibility testing if history of recurrent thrush

Appropriate clinical details include: abnormal vaginal discharge, itch, burning, vaginitis, etc.

4.1. IMPLICATIONS OF PROPOSED NEW SERVICE

These proposed changes emphasise the importance of good clinical medicine including taking a sexual history and documenting relevant history and clinical findings on the laboratory request form.

Vaginal specimens not processed on account of absent clinical details will be held at room temperature for seven days before being discarded. In this time, referrers can contact the laboratory to discuss specimen processing.

Requesting patterns of referrers will be audited to ensure that indiscriminate test ordering is not taking place.
5. CONSULTATION PROCESS

5.1. WHAT ARE WE CONSULTING ON

We are consulting on changes to how female genital swabs are processed at Labtests.

5.2. WHO IS BEING CONSULTED

Referrers to Labtests and Northland Pathology Laboratory:

- General practitioners
- Smear takers
- Midwives
- Nurses
- Obstetrics and Gynaecologists
- Infectious diseases physicians
- Metro Governance Group
- Primary Health Organisations
- Northern Regional Alliance
- Auckland and Northland Family Planning
- Auckland and Northland Regional Sexual Health Services
- Auckland and Northland DHB Chief Medical Officers
- New Zealand Microbiology Network

5.3 CONSULTATION TIMELINE

Consultation document release 7th March 2016

Feedback deadline 5pm Friday 1st April 2015

Decision announcement Friday 8th April 2015

5.4 HOW TO GIVE FEEDBACK

Please give feedback to:

Dr Arlo Upton
Clinical Microbiologist and Medical Director, Labtests and Northland Pathology Laboratory

Arlo.upton@labtests.co.nz

5.5 DECISION

A decision will be made by 5pm on Friday 8th April and communicated to stakeholders and specifically to those who gave feedback.
APPENDIX ONE.

Auckland and Northland *Trichomonas vaginalis* (TV) testing by NAAT

Approximately 3500 samples from female and males aged > 15 years received in Jan/Feb 2016 for CT/NG NAAT testing were also tested for TV (Ethics approval was obtained). Age, gender, ethnicity, and NZ deprivation score data were collected.

Please note: these data are somewhat incomplete as total population is not presented and so the data reflect prevalence among patients tests, not the entire population.

TV (green lines) is clearly an infection of females; infection among males is rare.

The data for men aged 61-65 years is biased by only four samples being tested in that age group.

Ethnicity and NZ deprivation data demonstrate significantly different rates of infection among different ethnicities. Infection of TV is more common among patients from higher deprivation than those from areas of minimal or low deprivation.
APPENDIX TWO.

Tables 1 and 2 – Impact of infection prevalence on the positive predictive value (PPV) of a test

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>0.3%</th>
<th>1%</th>
<th>5%</th>
<th>10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population number</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Number with infection</td>
<td>3</td>
<td>10</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Number without infection</td>
<td>997</td>
<td>990</td>
<td>950</td>
<td>900</td>
</tr>
<tr>
<td>True positives (assuming 100% sensitivity)</td>
<td>3</td>
<td>10</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>False positives (assuming 99% specificity)</td>
<td>9.97</td>
<td>9.9</td>
<td>9.5</td>
<td>9</td>
</tr>
<tr>
<td>Total numbers test positive</td>
<td>12.97</td>
<td>19.9</td>
<td>59.5</td>
<td>109</td>
</tr>
<tr>
<td>Positive predictive value (PPV)</td>
<td>23%</td>
<td>50%</td>
<td>84%</td>
<td>92%</td>
</tr>
</tbody>
</table>

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<tr>
<th>Prevalence</th>
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</tr>
<tr>
<td>False positives (assuming 99.9% specificity)</td>
<td>0.997</td>
<td>0.99</td>
<td>0.95</td>
<td>0.9</td>
</tr>
<tr>
<td>Total numbers test positive</td>
<td>3.997</td>
<td>10.99</td>
<td>50.95</td>
<td>100.9</td>
</tr>
<tr>
<td>Positive predictive value (PPV)</td>
<td>75%</td>
<td>91%</td>
<td>98%</td>
<td>99%</td>
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</tbody>
</table>
APPENDIX THREE.

Table 3. Screening and diagnostic testing for genital infections in women aged 13-50 years

<table>
<thead>
<tr>
<th>Organism</th>
<th>Screening</th>
<th>Diagnostic testing</th>
<th>Specimen type</th>
<th>Laboratory Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT/NG</td>
<td></td>
<td>APTIMA collection</td>
<td>Vaginal swab</td>
<td>NAAT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>device</td>
<td>*(preferred)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>First catch urine</td>
<td></td>
</tr>
<tr>
<td>TV</td>
<td>Recommended only for high risk groups as per local epidemiology</td>
<td>Vaginal discharge</td>
<td>APTIMA collection device</td>
<td>NAAT</td>
</tr>
<tr>
<td>BV</td>
<td>Not recommended</td>
<td>Vaginal discharge, odour</td>
<td>Orange topped swab</td>
<td>Gram stain Gram, Sab/Blood agar</td>
</tr>
<tr>
<td>Candidiasis</td>
<td>Not recommended</td>
<td>Vaginal discharge, itch</td>
<td>Orange topped swab</td>
<td>Gram, Sab/Blood agar if clinical details of ‘abnormal vaginal discharge, itch, burning, etc.</td>
</tr>
<tr>
<td>Other</td>
<td>Not recommended</td>
<td>Vaginal discharge, odour, itch</td>
<td>Orange topped swab</td>
<td>Gram Sab/Blood agar if clinical details of ‘abnormal vaginal discharge’</td>
</tr>
</tbody>
</table>