Impact of Prevalence on STD Testing

Nucleic acid amplification tests, such as PCR, have been shown to greatly improve the detection of both symptomatic and asymptomatic *Chlamydia trachomatis* (CT) infections. PCR tests for *Neisseria gonorrhoeae* (NG) are convenient to perform simultaneously with CT, since testing can be done from the same sample swab. Although the sensitivity and specificity of both tests are high (98% and 99%), the positive predictive value (PPV) is significantly impacted by the prevalence of disease in the population being tested.

PPV for CT is approximately 90%. However, the prevalence of NG infections is generally lower than for CT, resulting in a lower positive predictive value. Prevalence of NG in PCR testing performed by SLRL is 1 to 2%, which corresponds to a positive predictive value of only 60%, making clinical correlation essential.

Specificity of PCR tests for NG is affected by cross-reactivity with other non-gonococcal Neisseria species. These Neisseria species are not frequently recovered from urogenital sources, but do represent normal respiratory tract flora. Therefore, throat swabs are unsuitable for NG testing by PCR.

Although non-gonococcal Neisseria species generally have an equivocal signal, which is resulted as negative, occasionally a signal above the positive cut-off for the assay occurs, causing a false-positive result. Specificity can be improved by testing a second specimen, or by an alternative method such as NG culture. SLRL offers both PCR and culture for NG.

A recent publication by the CDC recommends that all positive screening tests for CT and NG should be considered presumptive evidence of infection. Additional testing should be considered after a positive screening test when the PPV is <90%, or when there are significant adverse social or psychological consequences from a positive screening result (MMWR 2002; 51,No.RR-15). Recently, SLRL added the following comment to all positive results, “False positive results should be considered when patients have an unexpected positive screening test for Chlamydia trachomatis or Neisseria gonorrhoeae, especially when clinical findings are not supportive.”

Platelet Antibody & Prognosis of ITP

In recent years, the diagnosis of ITP has been based on history, physical examination, CBC, peripheral smear exam, and exclusion of other causes of thrombocytopenia. This approach has been recommended by the American Society of Hematology, which stated that other diagnostic tests (including platelet antibody assays) are generally unnecessary, unless atypical findings are present suggesting other etiologies. Several studies have indicated that platelet antibody testing is useful in the diagnosis of ITP, and may be associated with disease severity, nonetheless the clinical utility of platelet antibody tests has remained controversial.

A recent prospective study analyzed the association between the presence or absence of platelet antibodies and the clinical course of ITP (Blood, 2004;103:4562). Fifty consecutive adult patients with ITP (both acute and chronic) were tested, using a modified ELISA assay for detection of serum autoantibodies against specific platelet glycoproteins (GP IIb/IIIa, GP Ib/IX, and GPIa/IIa). Fifty percent of the patients had detectable antibody and the other 50% did not. Patients were followed clinically for at least 6 months, and monitored for evidence of clinical worsening, defined as the need for starting or modifying therapy because of platelet counts lower than 10,000/uL, or admission for bleeding.

Antibody-negative patients had a significantly lower incidence of clinical worsening (32%) compared with antibody-positive patients (72%). The degree of thrombocytopenia and duration of disease also affect the outcome in ITP, however the relationship of detectable platelet antibody to incidence of clinical worsening also existed for patients with moderate to severe ITP (platelet count < 50 X 10^3...
/uL), and duration of disease greater than 6 months (chronic ITP). The median time to clinical worsening was 2.1 months for antibody-positive and 27.7 months for antibody-negative patients. Specificity of antibodies did not correlate with clinical outcome.

In conclusion, this study provides evidence that the presence of platelet antibodies in patients with ITP may be a useful prognostic indicator. Serum platelet antibody testing is available through SLRL using a method similar to that described in this study. Specimen requirement is one 5ml plain red-top tube of blood.

**Correction of Prolonged Protime with FFP**

Occasionally, vitamin K deficient patients or patients receiving warfarin require immediate reversal of their anticoagulation by transfusion of FFP because they are scheduled for an invasive procedure, their INR is supratherapeutic or they are bleeding. Published guidelines often recommend transfusing 15 mL/kg to an adult, which usually calculates to be 2 to 4 units of FFP. However, actual data using current coagulation instruments and sensitive Protime (PT) reagents does not exist. Ideally, each laboratory should develop their own guidelines based on their coagulation tests and FFP source.

Saint Luke’s Regional Laboratories published guidelines in July 1999. However, the laboratory has changed PT reagents several times since then. Therefore, a new study involving 116 patients transfused with FFP for a prolonged PT between March 25 and August 18, 2004 was undertaken. Patients were included in the study if the PTT was normal and no other blood components were transfused at the time of the FFP infusion.

<table>
<thead>
<tr>
<th>Pre-transfusion Protime &amp; INR</th>
<th>Correction per FFP unit Mean &amp; Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT 16.0 – 19.9 sec</td>
<td>0.8 (0 – 1.9) sec</td>
</tr>
<tr>
<td>INR 1.3 – 1.7</td>
<td>0.1 (0.1 – 0.2) sec</td>
</tr>
<tr>
<td>PT 20.0 – 24.9 sec</td>
<td>1.7 (0.6 – 2.7) sec</td>
</tr>
<tr>
<td>INR 1.7 – 2.3</td>
<td>0.2 (0.1 – 0.3) sec</td>
</tr>
<tr>
<td>PT 25.0 – 29.9 sec</td>
<td>3.0 (0.9 – 5.6) sec</td>
</tr>
<tr>
<td>INR 2.4 – 2.9</td>
<td>0.4 (0.1 – 0.7) sec</td>
</tr>
<tr>
<td>PT 30.0 – 39.9 sec</td>
<td>5.4 (2.8 – 11.1) sec</td>
</tr>
<tr>
<td>INR 3.0 – 4.3</td>
<td>0.7 (0.2 – 1.5) sec</td>
</tr>
<tr>
<td>PT 40 – 130 sec</td>
<td>20.7 (7.2 – 50.5) sec</td>
</tr>
<tr>
<td>INR 4.4 – 20.0</td>
<td>3.5 (1.1 – 8.4) sec</td>
</tr>
</tbody>
</table>

The longer the pre-transfusion PT or INR, the greater the correction achieved with a single unit of FFP. An INR of 10 (PT sec) can usually be corrected to between 2.0 and 2.5 with only two units of FFP. However, 2 to 4 units of FFP may be required to correct an INR of 2.0 to 1.5. It is seldom necessary to correct the INR below 1.5 prior to an invasive procedure.

**How to Find Laboratory Letter On Line**

Issues of the Clinical Laboratory Letter from 2000 to the present are available on the Saint Luke’s Health System website. A variety of options are available for searching the available archives.

**Search by Topic:**
- Go to saintlukeshealthsystem.org
- Enter a topical search word (for example: SARS) in the Search box and click the arrow
- A page will present with the topic you request.
- Click that topic and the Laboratory Letter that addresses that topic will be presented in a PDF format.

**Search by Date:**
- Go to saintlukeshealthsystem.org
- Enter “SLRL” in the Search box and click the arrow
- The Saint Luke’s Regional Lab home page will present
- Select the date of the Laboratory Letter you would like to read from the right hand navigation.
- You can also select Request a Search from right hand navigation. Complete and submit this form. Laboratory personnel will investigate your request and get the necessary information back to you.

**See all Topics:**
- Go to saintlukeshealthsystem.org
- Enter “SLRL” in the Search box and click the arrow
- The Saint Luke’s Regional Lab home page will present
- Select Search by Topic from right navigation
- You can page through all the topics addressed in the Lab Letters

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- Overview of available lab services
- Sign up to receive the monthly Lab Letter
- Lab & drawing station locations including maps and contact information.