Good Specimen Labeling = Patient Safety

Improving patient safety has almost become a daily topic. One easy path to better patient safety is to pay close attention to specimen labeling. Although it is rare, the laboratory does receive unlabeled specimens periodically. We want to remind our clients that the policy of Saint Luke’s Regional Laboratories is to discard any unlabeled specimens and request a new specimen.

How can you ensure that we can accept your specimens? Always label the specimen container clearly with the patient’s first and last name and attach the SLRL requisition label. If you do not have a requisition label, please include the patient’s birth date on the specimen container. The date of collection and phlebotomist initials should also be given.

Blood Bank specimens MUST include the patient’s full name, date of birth, date of collection and the initials of the phlebotomist.

Bordetella Testing

Pertussis or “whooping cough” is most often caused by the bacteria *Bordetella pertussis*, or sometimes by *Bordetella parapertussis*. Small clusters of cases in the Kansas City area have been reported by the Health Department this year, as well as an outbreak in Cass County.

Bordetella infections have traditionally been difficult to detect because the organism cannot be easily cultured. Serology is sensitive and specific, but requires the comparison of acute and convalescent samples collected over a 4-week period to be diagnostic. A recent study reported the following sensitivities for detection of the organism from respiratory specimens: culture 15%, DFA 52%, and PCR 93%.

Mayo Medical Laboratories has developed a rapid PCR method, which detects both *Bordetella pertussis* and *Bordetella parapertussis* with an analytical sensitivity of 1 organism per swab. False negatives may occur due to inhibitory substances in the specimen. Due to the immense improvement in sensitivity of the PCR method, Bordetella culture and DFA have been discontinued. Saint Luke’s Regional Laboratories forwards respiratory specimens submitted for Bordetella testing to Mayo. The preferred specimen is a nasopharyngeal specimen collected using a rayon swab with a wire shaft. Swabs and transport media are available from Microbiology (816-932-2435).

PSA Progress

Men in the U.S. have about one chance in six of eventually being diagnosed with prostate cancer and about one chance in 30 of eventually dying of it. African American men and men with an affected first-degree relative have an even higher risk. Prior to the widespread use of PSA screening in asymptomatic men, prostate cancer was detected by digital rectal exam (DRE) and only 25% of newly diagnosed cancers were organ-confined. Since the advent of PSA testing, the percentage of newly diagnosed prostate cancers that are organ-confined has increased to 80%. Overall, PSA appears to detect cancer 5 to 10 years sooner than DRE.

The American Cancer Society (ACS) and American Urological Association (AUA) have traditionally advised men without specific risk factors to begin having an annual DRE and PSA at age 50. ACS has further recommend that African American males and men with a strong family history of prostate cancer should begin screening at age 45, while AUA has recommended age 40.

The median PSA value for men in their 40s is 0.6 ng/mL and the median for men in their 50s is 0.8 ng/mL. Men who are screened in their 40s and have a PSA value <0.7 ng/mL have a 0.5% rate of developing cancer in the next 5 years, while men with a PSA of 0.7 or higher have a 7% rate. Men who are screened in their 50s and have a PSA of <0.9 ng/mL have a 5 year cancer rate of 0.7%, while those with a PSA of 0.9 or higher have an 8%
rate. Because of this data, the National Comprehensive Cancer Network (NCCN) has recently recommended that men should consider having a PSA baseline value obtained at age 40. If their PSA value is >0.6, they should be reevaluated annually.

One of the most difficult dilemmas that has arisen after widespread PSA testing is deciding the optimal PSA threshold at which prostate biopsy should be performed in asymptomatic patients. Using a PSA value that is too low results in unnecessary biopsies and detects indolent cancers, while using a threshold that is too high misses aggressive tumors. Traditionally, a PSA of 4.0 ng/mL has been recognized as the lower limit for biopsy consideration. Approximately 35% of men with a PSA level between 4 and 10 ng/mL have cancer. However, more recent studies have suggested that a cutoff of 4.0 is too high of a threshold for biopsy because 25% of men with PSA levels in the range of 2.5 to 4.0 have clinically significant cancer. Lowering the threshold to 2.6 would nearly double the rate of detecting cancer in men younger than 60 years old with little loss of specificity. As a result of this new information, the 2004 NCCN guidelines recommend consideration of biopsies for men with PSA in the range of 2.5 to 4.0. The Prostate Cancer Early Detection guidelines from NCCN are available at www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf.

**Fetal Lung Maturity Reference Range Change**

FLM-II has been performed as the initial test for fetal lung maturity since 2001. If a mature or immature result is obtained, no further testing is performed. If an indeterminate result is obtained, a two-dimensional thin layer chromatography fetal lung profile (FLP) is performed. The same cutoff (<40) has been used to indicate immaturity for both diabetic and nondiabetic patients, but a different cutoff for maturity has been used for diabetic (>70) and nondiabetic (>55) patients.

Recently, we have become aware of several patients who had FLM-II values between 35 and 40, but had mature L/S ratios and detectable phosphatidyl glycerol (PG). Therefore, the laboratory has decided to change the cutoff for immaturity from <40 to <35 in order to reduce the incidence of falsely negative FLM-II results. This change will result in the laboratory reflexing a few more indeterminate FLM-II to L/S ratios, but will provide more accurate information for the ordering physician.

The new reference ranges for nondiabetic and diabetic patients are listed in the following table.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Nondiabetic</th>
<th>Diabetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immature</td>
<td>&lt;35</td>
<td>&lt;35</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>35 – 55</td>
<td>35 – 70</td>
</tr>
<tr>
<td>Mature</td>
<td>&gt;55</td>
<td>&gt;70</td>
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</tbody>
</table>

**PTH Reference Range Change**

The laboratory has converted PTH testing from a manual radioimmunoassay to an automated chemiluminescent method. This change has necessitated a change in the reference range from 10 – 65 to 10 – 69 pg/mL. Results will now be available at least one day sooner than before.

**Saint Joe Service Center Closing**

The last day of operation for the Saint Luke’s Regional Laboratory service center in Saint Joseph, MO will be December 30. Please call client services at 816-932-3850 if you have questions about the nearest laboratory service center for your patients.

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