August 7, 2013

AHS Laboratory Services
Laboratory Integration, Standards & Initiatives
Edmonton General
Room 13R21, 11111 Jasper Ave
Edmonton, AB T5K 0L4

Dear Physicians,

Re: Transition of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) Testing to Calgary Laboratory Services (CLS)

This letter is directed to all physicians and healthcare staff in South Zone East who currently submit samples for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) testing to the Medicine Hat Diagnostic Laboratory using Starplex sterile, screw-capped container or the cobas 4800 CT/NG Female Collection Kit.

We would like to inform you that as part of a provincial standardization and consolidation initiative; as of September 23rd, 2013 testing will be performed at Calgary Laboratory Services. Since the method that will be used; GEN-PROBE APTIMA COMBO2® Chlamydia/GC method is different than what is currently performed at Medicine Hat Diagnostic Laboratory, a change in the collection kit is required.

**** Please note: Urine samples must come already transferred in the urine specimen transport tube. Swab specimens must be collected with the blue shaft collection swab. Samples not collected properly will not be processed. ****

**** Please note as this assay is extremely sensitive, all individuals handling patient samples must ensure they avoid introducing contamination by changing gloves after each patient they come in contact with or after each patient sample they contact. ****

Included are the AHS/CLS Laboratory Bulletin, CLS utilization Memo and Newsletter, CLS Microbiology Requisitions, and Collection instructions.

If you have any questions, please contact Medicine Hat Diagnostic Laboratory or Calgary Laboratory Services.

Sincerely,

[Signature]

Alberta Health Services
Basil Elyas, BSc, PMP, CSSBB
Business Support Manager,
Laboratory Integration, Standards & Initiatives
Enc. 10
TO: All Physicians
FROM: Dr. Dan Gregson, Division Head, Microbiology, CLS
DATE: AUGUST 7, 2013
RE: Testing of Women ≥ 35 years of Age for Genital *Chlamydia trachomatis/Neisseria gonorrhoeae* Cervicitis

As per the attached Calgary Laboratory Services (CLS) Microbiology Newsletter (August 2013), women ≥ 35 years of age will no longer be routinely tested for genital *Chlamydia trachomatis/Neisseria gonorrhoeae* cervicitis effective September 23, 2013 when CLS assumes responsibility for testing Medicine Hat patients.

CLS will routinely test women in this age group in the following clinical situations:

1) Woman meets the **risk factors** outlined by Health Canada which include:
   - Recent contact with a known case of sexually transmitted infection (STI) and/or
   - Sexually active with new or > 2 partners within the past 6 months **and/or**
   - Street involvement **and/or**
   - Substance abuse
   - Approval by Microbiologist-on-Call

2) Woman has symptoms suggestive of cervicitis and/or urethritis

3) Pregnant – prenatal screening. Public Health requires routine screening of pregnant women for genital *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infection. CLS will therefore continue to routinely screen pregnant women, regardless of age.

Physicians should complete the clinical history on the CLS Microbiology requisition, indicating why a woman ≥ 35 years of age is being tested as outlined above. If the clinical reason for testing is not provided, the sample will not be analyzed.

CLS holds all genital specimens from women ≥ 35 years of age for 7 days that are initially rejected for testing because a clinical history is not provided on the requisition. In these cases, the Medical Microbiologist-on-Call should be contacted at 403-770-3757 to have the testing approved.

If you have any questions or concerns, please contact the Medical Microbiologist on call at: 403-770-3757.
Calgary Zone – Epidemiology of Genital *Chlamydia trachomatis* (CT) Infection in Women and Rationale for Restricted Testing in Those ≥ 35 Years of Age

Calgary Laboratory Services (CLS) currently performs simultaneous routine testing for both genital CT and *Neisseria gonorrhoeae* (GC) infection from urethral and endocervical swabs or urine from females using an automated nucleic acid amplification test called the APTIMA COMBO 2® Assay, which is run on the TIGRIS instrument (Hologic, Gen-Probe, San Diego, CA). This assay has a reported sensitivity and specificity of 94.2% and 97.6% respectively for both swabs and urine samples ([http://www.gen-probe.com/products-services/aptima-combo](http://www.gen-probe.com/products-services/aptima-combo)).

CLS implemented a new policy in the Calgary Zone in March 2003 that restricted routine testing of genital samples for CT and GC infection in women ≥ 35 years of age. The Microbiology requisition was changed so that physicians had to provide a history for genital samples from women ≥ 35 years to be automatically tested as follows:

- Symptoms
- At Risk
- Pregnant

This newsletter outlined the rationale for implementing the age-restricted testing policy for women ≥ 35 years of age.

1) **Who is at risk for acquiring genital CT infection?**

Guidelines have been published by Health Canada that outline who is at risk for acquiring genital CT infection[^1]. The following patients have a high risk for acquiring genital CT infection and should be routinely tested for the presence of infection: 1) sexually active males and females <25 years of age, and/or 2) recent contact with a known case of any sexually transmitted infection (STI), and/or 3) sexually active with new or >2 partners in the past 6 months, and/or 4) street involved, and/or 5) involved in any substance use.

2) **Demographics and prevalence of genital CT infection in women being tested for genital CT infection by CLS:**

Figure 1 shows the number of negative versus positive genital CT tests done by CLS for women during the years of 2001-02 and according to age groups before testing was restricted to women ≤ 35 years of age. Figure 2 shows that after the age of 30-years, the overall rate of genital CT infection in women falls to an almost negligible rate of 0.5%. The peak overall prevalence of genital CT infection in women occurs in those between the ages of 21-30 years, and confirmed genital infection sharply decreased in women older than 30 years of age. Although much less prevalent than genital CT infection, the demographics of genital GC infection are similar (data not shown). This data confirmed that CLS was unnecessarily routinely testing many older women without any risk prior to the implementation of the age-restricted testing policy[^2],[^3]. A recent review of the testing data in our region from last year showed that the prevalence of CT infection amongst women has not changed, except more testing is now being done in girls and teens ≤ 15 years of age.

[^1]: Guidelines have been published by Health Canada that outline who is at risk for acquiring genital CT infection.
[^2]: CLS implemented a new policy in the Calgary Zone in March 2003 that restricted routine testing of genital samples for CT and GC infection in women ≥ 35 years of age.
[^3]: A recent review of the testing data in our region from last year showed that the prevalence of CT infection amongst women has not changed, except more testing is now being done in girls and teens ≤ 15 years of age.
3) What is the Risk Factor Profile of women being tested for genital CT infection in Calgary?

Several regional studies were also done prior to implementation of our age-restricted testing policy to determine the reasons why women in Calgary were being tested for genital CT infection\textsuperscript{2,3}. Women aged 15 to 75 years were enrolled at various patient care locations in the Calgary Health Region. Pertinent risk factors for genital CT infection were recorded and a gynecological examination was performed. Two endocervical swabs and a first-void urine sample were collected for CT detection using two different nucleic acid amplification methods\textsuperscript{2}. Five hundred and four women with a mean age of 28.1 ± 8.22 years were enrolled from the Provincial STI clinic, the family planning clinic, the infertility clinic, and at the Emergency Departments and physicians’ office practices. Two hundred ninety-one women (57.8%) were at high risk for acquiring genital CT infection. Twenty-eight (5.6%) tested positive for CT infection and almost all of these women (26 of 28.9%) had risk factors for acquiring infection. Of the high-risk women, 9.8% were CT positive versus only 1.3% of the women were at low risk (P=0.0001). Only two of 152 (1.3%) of the women >30 years had genital CT infection. Although most women were asymptomatic, those with laboratory-confirmed CT infection were more likely to have genitourinary symptoms. Three hundred forty-three of 476 (72%) of the women who did not have genital CT infection had no risk factors, and screening was done as part of a routine gynecological examination for other purposes (prenatal visit, Pap smear)\textsuperscript{3}.

4) References:


IF YOU HAVE ANY QUESTIONS OR CONCERNS

PLEASE CONTACT:

Dr. Dan Gregson, Clinical Section Chief, Microbiology at: 403-770-3762, Sandra Corbett, Manager of Microbiology at: 403-770-3215 or the Microbiologist-on-Call at CLS at: 403-770-3757
Microbiology Requisition Requirements:
Chlamydia trachomatis/Neisseria gonorrhoeae Testing

Benefits of providing CLS with COMPLETE and LEGIBLE information:
- Promotes patient safety through reduced transcription errors
- Ensures samples are processed for the correct patient and tests are sent to the correct provider
- Reduces turn around time when processing patient samples

Ordering physician is required for laboratory standards.
Please stamp all requisitions with the physician’s stamp provided by CLS.

If additional “COPY TO” reports are needed – last name, first name and location are required.

Dr. Fred Smith
All Smiles Med Clinic
222-456 Happy Dr. SW

Dr. Fred Smith
All Smiles Med Clinic
222-456 Happy Dr. SW

Cole Jonathan Market Mall

The two letter province code and Personal Health Number ensure accurate patient identification and registration.

Patient’s full legal name, complete address, gender, date of birth, and phone number ensure accurate patient ID.

Always indicate specimen site and source where applicable.
Include patient history when requested on the requisition to ensure appropriate testing is performed.

Always indicate specimen site and source where applicable.
Include patient history when requested on the requisition to ensure appropriate testing is performed.

Date and time the specimen was collected is required.

2013 - August
<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Organism/Site</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>Bacterial</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Blood</td>
<td>Fungal</td>
<td>Fungal Culture</td>
</tr>
<tr>
<td>Urine</td>
<td>Bacterial</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Urine</td>
<td>Fungal</td>
<td>Fungal Culture</td>
</tr>
<tr>
<td>Stool</td>
<td>Bacterial</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Stool</td>
<td>Fungal</td>
<td>Fungal Culture</td>
</tr>
<tr>
<td>Bronchoalveolar lavage (BAL)</td>
<td>Bacterial Culture (C &amp; S)</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Bronchial Wash (BW)</td>
<td>Bacterial Culture (C &amp; S)</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Nasopharyngeal aspirate</td>
<td>Group A Strep (GAS)</td>
<td>Group A Strep (GAS)</td>
</tr>
<tr>
<td>Nasopharyngeal aspirate</td>
<td>Mycoplasma/Ureaplasma</td>
<td>Mycoplasma/Ureaplasma</td>
</tr>
<tr>
<td>Bronchoalveolar lavage (BAL)</td>
<td>Mycoplasma/Ureaplasma</td>
<td>Mycoplasma/Ureaplasma</td>
</tr>
<tr>
<td>Cerebral spinal fluid (CSF)</td>
<td>Mycobacterium</td>
<td>Mycobacterium</td>
</tr>
<tr>
<td>Rectal Adult (13 yrs or older)</td>
<td>Bacterial Culture (C &amp; S)</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Rectal Adult (13 yrs or older)</td>
<td>Anaerobic culture</td>
<td>Anaerobic culture</td>
</tr>
<tr>
<td>Vaginal/Rectal - pregnant only</td>
<td>Bacterial Culture (C &amp; S)</td>
<td>Bacterial Culture (C &amp; S)</td>
</tr>
<tr>
<td>Vaginal/Rectal - pregnant only</td>
<td>Anaerobic culture</td>
<td>Anaerobic culture</td>
</tr>
</tbody>
</table>

**URINOGENITAL**

- For surgical/traumatic urogenital wounds/abscesses
- Complete surgical wound section
- Chlamydia/GC - Symptomatic/At Risk
- Pregnant
- Planning Pregnancy
- Mycoplasma/Ureaplasma
- Malaria: History form required www.calgarylabservices.com
- Contact Microbiologist on Call 403-770-3757 before collection
- Cerebral spinal fluid (CSF):
  - Lumbar puncture
  - Indwelling CNS Shunt
  - External ventricular drain
  - Other - specify:
- Peritoneal dialysis fluid (dialysate):
- Peritoneal fluid
- Pleural fluid
- Synovial fluid
- Fluid - other specify:
PATIENT SERVICE CENTRES – APPOINTMENTS ARE STRONGLY RECOMMENDED.

WEBSITE BOOKING: www.calgarylabservices.com OR CALL 403-770-5136

General Information or Inquiries: www.calgarylabservices.com or call Lab Information Centre 403-770-3600

Medical Staff: For test information, specimen collection instructions, etc. see www.calgarylabservices.com

Physicians may contact the Laboratory Information Centre (L.I.C.) for test results and related inquiries.

For Calgary Rural Laboratory locations and hours of operation, visit http://www.calgarylabservices.com/lab-patient/lab-locations/rural-lab-locations.aspx

Alberta Health Care or other form of government issued I.D. must be presented at each visit.

CALGARY REGION HOSPITAL LABORATORY LOCATIONS

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Mon-Fri Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta Children's Hospital</td>
<td>7:30 am - 5:00 pm</td>
</tr>
<tr>
<td>Peter Lougheed Centre</td>
<td>7:00 am - 5:00 pm</td>
</tr>
<tr>
<td>Rockyview General Hospital</td>
<td>6:30 am - 5:00 pm</td>
</tr>
</tbody>
</table>

FOOTHILLS MEDICAL CENTRE

<table>
<thead>
<tr>
<th>Location</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Services Building</td>
<td>7:30 am - 4:00 pm</td>
</tr>
<tr>
<td>Womens Health Centre</td>
<td>127 North Tower</td>
</tr>
<tr>
<td>Ground Floor</td>
<td>7:00 am - 4:00 pm</td>
</tr>
<tr>
<td>Room AGC72C</td>
<td>127 North Tower</td>
</tr>
</tbody>
</table>

Microbiology Tests Available STAT

- Gram stain
- Malarial Smear
- Pneumocystis jiroveci (PCP)

Other tests ordered STAT require the approval of a Microbiologist. Contact: MICROBIOLOGIST ON CALL 403-770-3757 (Physicians Only)

For General Laboratory tests available STAT refer to the yellow Community General Requisition (9012PSC), or the Acute Care Requisition (9011RRL)
Collection for Male and Female Urine Specimens

*Patient should not have urinated for at least 1 hour prior to specimen collection.*

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.

2. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.

3. Re-cap urine specimen transport tube tightly. This is now known as the “processed urine specimen.”

Specimen Transport and Storage

1. After collection, transport and store the processed urine specimens in the APTIMA urine specimen transport tube at 2°C to 30°C until tested. Processed urine specimens should be assayed with the APTIMA Assay for CT and/or GC within 30 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 90 days after collection.

2. Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer urine sample into APTIMA urine specimen transport tube within 24 hours of collection. Store at 2°C to 30°C and test within 30 days of collection.
Collection for Endocervical Swab Specimens

1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard this swab.**

   A large-tipped cleaning swab (not provided) may be used to remove excess mucus.

2. Insert specimen collection swab (blue shaft swab in package with green printing) into endocervical canal.

3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.

4. Withdraw swab carefully; avoid any contact with vaginal mucosa.

5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.

6. Carefully break swab shaft at scoreline; use care to avoid splashing contents.

7. Re-cap swab specimen transport tube tightly.

Collection for Male Urethral Swab Specimens

*Patient should not have urinated for at least 1 hour prior to specimen collection.*

1. Insert specimen collection swab (blue shaft swab in package with green printing) 2 to 4 cm into urethra.

2. Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.

3. Withdraw swab carefully.

4. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.

5. Carefully break swab shaft at scoreline; use care to avoid splashing contents.

6. Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

After collection, transport and store swab in swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the APTIMA Assay for CT and/or GC within 60 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 90 days after collection.
Improper Sample Collection Results In Sample Rejection

STOP!

Collect and Send to the Lab... One (1) BLUE Swab Only.