



LABORATORY BULLETIN

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To: All Regional Laboratories – Alberta, Northwest Territories, Nunavut

Re: New Syphilis Serology Tests

PLEASE POST OR DISTRIBUTE WIDELY AS APPROPRIATE

In response to the syphilis outbreak in Alberta, as defined by the Provincial Health Officer, the Provincial Laboratory, in collaboration with regional diagnostic laboratories, will be implementing new serological test methods for the diagnosis of **syphilis**, effective **September 4th, 2007**.

Highlights of this change are as follows:

- Syphilis serology algorithm will change September 4th, 2007.
- EIA will replace RPR as the main diagnostic test.
- EIA may be negative very early in infection. If recent infection suspected, repeat serology in 4 weeks.
- RPR will be performed on EIA-positives to document falling titres in response to therapy and to detect re-infections.
- New EIA-positive samples will be tested by confirmatory INNO-LIA.
- INNO-LIA is an immunoblot assay, similar to those used for HIV and HCV.

The Details:

The new test algorithm is summarized briefly in the attached flowchart. The enzyme immunoassay (EIA) is the cornerstone of the new algorithm. Syphilis EIA is similar to the existing TPPA and FTA tests, and detects IgM and IgG antibodies against *Treponema pallidum* but with higher sensitivity and specificity. High volume analyzers will be implemented at ProvLab Calgary and Edmonton, Calgary Laboratory Services and Dynacare Kasper Medical Laboratories. We ask that other regional Laboratories forward their syphilis serology requests to ProvLab for the duration of this outbreak response (Sept 4th, 2007 to March 31st, 2009).

EIA-positive sera will be tested by the Rapid Plasma Reagin test (RPR, similar to VDRL) at ProvLab. This is not for diagnostic purposes, as at present, because RPR is insensitive in primary and late syphilis. Instead, RPR will be used to monitor response to therapy, by

demonstration of falling titres, and to detect re-infection (rising titres). To ensure consistent accuracy of results, supplementary testing on all new cases will be performed using a recombinant immunoblot assay (INNO-LIA). This assay has demonstrated high sensitivity and specificity in the literature, and has performed favourably in ProvLab validation studies.

As outlined in the Canadian Guidelines on STI's, 2006, syphilis serologic testing should be performed on clinically suspect cases, as well as contacts and other high risk individuals, in addition to the prenatal testing program. High risk patients include the following:

- Those who have had contact with a known case of syphilis.
- Men who have sex with men.
- Sex trade workers.
- Those with street involvement.
- Injection drug users.
- Those with multiple sex partners.
- Those with a history of syphilis, HIV and other STIs.
- Those originating from or having sex with an individual from a country with a high prevalence of syphilis.
- Sexual partners of any of the above.

For syphilis serology, please collect 5-10 mL of venous blood in a gold-top serum separator tube, and request "syphilis" on the requisition. Requests for VDRL, RPR, MHA, or FTA will be tested as above. We are also investigating a process at ProvLab whereby follow-up samples on known seropositive cases will just get an RPR titre to monitor response to therapy. This is because Treponemal antibody will persist for life in most cases, so repeat EIA testing is not clinically useful. This process is not yet complete, however, and we will follow up with you later to confirm this.

Syphilis requests on cerebrospinal fluid will continue to be tested by VDRL.

Results will be reported to the ordering physician, clinic, or submitting lab as indicated on the requisition. Positive results will also be reported to public health, who will follow up with the physician to get clinical details. If your laboratory requires a summary or line list of submitted syphilis results, please let us know. We are presently scripting some interpretive comments to go with the results, and will forward these to you for those laboratories that enter our results into their information system.

Due to its increased sensitivity, the EIA will detect cases earlier, and will detect more latent cases than the present RPR test. There will also be a decrease in biological false positive results (RPR-positive, but negative by TPPA and FTA). As with previous tests, the new syphilis serology EIA will not differentiate between primary, secondary, latent and tertiary syphilis, nor will it differentiate treated, cured disease from active disease. These are determined clinically. Serology also cannot differentiate between syphilis and yaws, pinta or bejel. Clinical review, including a thorough sexual and travel history is required. Please be aware that in incubating or early primary syphilis, an antibody response may not yet be present, therefore such cases should be retested in 4 weeks.

We anticipate that the new syphilis serology process will produce more rapid and accurate results, to assist in earlier detection and treatment of cases, and prevention of further

spread. For further discussion on syphilis serology, please feel free to call us at the numbers below or contact the Virologist-on-call or Microbiologist-on-call via:

CLS (403) 770-3757
DKML (780) 451-3702
ProvLab Edmonton (780) 407-7121
ProvLab Calgary (403) 944-1200

Further details will be posted to the Provincial Lab website, the exact hyperlink to follow.

Sincerely,



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Attachment: (1)

The New Syphilis Serology Process

