

**New York State Department of Health  
Bureau of Sexually Transmitted Disease Control**

**FAU# 0510280931 Laboratory Testing Services for *Chlamydia trachomatis***

**Questions and Answers**

1. Can you please provide more defined test utilization numbers?

Answer: In 2005, the current laboratory vendor performed 10,559 Chlamydia tests. The Bureau of STD Control supported this testing with funds from the Centers for Disease Control's Infertility Prevention Project (IPP) and the Maternal and Child Health Services Block grants. The Bureau of STD Control used IPP grant funds to support an additional 10,997 Chlamydia tests through sub-contracts with county public health labs or health departments. Consequently, the estimated volume of testing to be supported by this RFP may range from 10,000 – 21,000 tests.

2. Can you please define geographical listing of locations to be serviced?

Answer: The clinical sites that are currently receiving laboratory testing services for Chlamydia trachomatis are located in the following cities (counties) of New York State. The number of sites in each location is also indicated.

<b>City</b>	<b>County</b>	<b># Clinical Sites</b>
Albany	Albany	3
Bronx	Kings	1
Binghamton	Broome	1
Elmira	Chemung	1
Poughkeepsie	Dutchess	1
Buffalo	Erie	4
Watertown	Jefferson	1
Rochester	Monroe	3
Albion	Monroe	1
Westbury	Nassau	1
Utica	Oneida	1
Syracuse	Onondaga	2
Troy	Rensselaer	1
Pomona	Rockland	1
Saratoga Springs	Saratoga	1
Kingston	Ulster	1
New Rochelle	Westchester	1
Valhalla	Westchester	1
Peekskill	Westchester	1

3. Are you looking specifically for DNA (Gen-Probe) or PCR technology? Certain methodologies limit collection sites.

Answer: The requirements of the RFP do not permit the Bureau of STD Control to specify the type of test that will be used. In certain clinical sites where the Bureau of STD Control supports Chlamydia screening, only urine specimens are collected. Consequently, the Bureau of STD Control seeks a vendor that will be able to process urethral and endocervical swab specimens as well as urine specimens. Bidders should take these specifications into consideration when proposing a test technology.

4. We would like to know if you have an estimate of the projected volume for the bid period.

Answer: Please refer to the answer to question 1.

5. Which company is the incumbent contractor?

Answer: Laboratory Corporation of America, Inc.

6. Do the sites currently use a fully functioning electronic laboratory request and result system?

Answer: No.

7. It is obvious that a very important goal of this RFP is consistently high quality and complete data. Because paper based lab requisition systems allow for tests to be processed even though not all data has been provided, will an electronic laboratory request and result system that guarantees all data is provided be preferable or required?

Answer: A laboratory reporting system that promotes the provision of complete, high quality data is preferable but not required.

8. Requirements state sensitivity and specificity of 90% and 95% respectively. Which methodology is currently being used to meet this requirement?

Answer: The current laboratory vendor uses the Gen-Probe Aptima Ct assay.

9. Is the Becton Dickinson ProbeTec CT/GC test acceptable to perform the screening tests?

Answer: A test technology is acceptable if it is FDA-approved and meets the RFP requirements. Bidders are also encouraged to refer to the following resource as listed in the RFP: **Centers for Disease Control and Prevention. Screening Tests to Detect**

***Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002. MMWR 2002; 51 (No. RR-15).** This document provides guidelines for the selection of screening tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

10. Is a non-amplified DNA Probe test acceptable?

Answer: Please refer to the answer to question 9.

11. The result must be reported within 3 days of receipt in the lab. How long do you allow for the specimen to get to the lab? Can it take 5 days?

Answer: The RFP does not specify the number of days allowed for specimen transport, but similar to turnaround time, the number of days elapsed should be minimized to promote early diagnosis and treatment of infected patients and reduce the possibility of transmission to other individuals. Transport requirements may also vary depending on the manufacturer.

12. Must specimens be shipped via overnight courier?

Answer: No.

13. Is US Mail acceptable given the 3-5 extra days it will add to the delivery time?

Answer: US Mail is an acceptable method of specimen transport. Bidders should consider the response to question 11 when determining the method of specimen transport.

14. How many different collection sites will we be expected to collect specimens from?

Answer: Please refer to the response to question 2 which lists the number of sites by city and county that are currently participating in the Bureau of STD Control's Chlamydia screening project. The number of sites is likely to remain the same in 2007 contingent upon the successful bidder's price per test.

15. Can we get the addresses?

Answer: Please refer to the response to question 2.

16. Must each site's specimens be picked up 5 days per week?

Answer: No, not all of the participating sites have clinic hours 5 days a week. Specimen pick up will be determined by the hours of clinic operation.

17. Requirements state that the lab should perform supplementary/confirmation testing to verify a positive screening test. Which method is currently used to confirm positive results and achieve this requirement?

Answer: The current laboratory vendor repeats the test on the same specimen using the same test technology (Gen-Probe Aptima Ct Assay).

18. We currently have a fully functioning electronic laboratory request and result system which is used by each site to request tests and enter patient demographic information. The system is specifically designed to provide data collection for the IPP Project. The system is currently used by over 400 sites such as the US Department of Labor, US Department of Interior and the PA department of Health and provides data for the CDC IPP project. Do your sites have computers that this program can be run on or should we plan on providing, installing, training and maintaining computers and build this cost into our per test cost?

Answer: Each of the Bureau of STD Control's IPP clinical sites has a computer, however, it is unknown if these individual computers are compatible with your system. The current laboratory vendor uses a paper based requisition slip system for reporting patient information from the site to the lab. If the bidder intends to build the costs associated with establishing this system into the per test cost, it is recommended that these costs are clearly defined in the "breakdown of bid amount component" section on the Bid Form (Attachment 4).

19. For the electronic transmission of patient demographic information either from the site to the lab or from the lab to the NYDOH, will the use of a 3DES, Blowfish encryption algorithm over an HTTPS session using a 128 bit key from Verisign be considered secure and HIPAA compliant for this contract?

Answer: Yes.

20. Questions about Attachment 3

- a. Clinic code: What is the size and format of code?

Answer: The Region II IPP code book specifies a variable of length=15 that may be numeric or character.

- b. Patient ID: What is the size and format of code?

Answer: This varies according to clinic.

- c. Clinician: Is this the person's name or Id number/code? If a number, what is the size and format of code?

Answer: The clinician's name.

21. Could you please expand on the definition of DIRECT TESTING (as per mentioned at the last paragraph of page 4)?

Answer: The laboratory is responsible for testing the specimens in their facility and not through a subcontract with another laboratory vendor.

22. As per indicated at paragraph 3 of page 5, the Bureau of STD Control supported Chlamydia screening of more than 38,000 women and their sexual partners in 2005. Could you please specify whether that amount corresponded to SINGLE Chlamydia testing or whether it corresponded to a COMBINATION of Chlamydia and Gonorrhea testing? Also, did the 38,000 screening tests include the women AS WELL AS their partners or does it reflect testing for the women ONLY?

Answer: The 38,000 tests reflect screening women AS WELL AS their sexual partners and a stand-alone Chlamydia test was used for all but 8,577 tests that were tested by a dual Chlamydia/gonorrhea test.

23. Can information be provided about designated or potential CLINIC SITES (as per mentioned on page 6)?

Answer: The locations and number of sites by location are listed in the response to question 2. Clinical sites that currently participate in the Chlamydia screening project include the following types of providers: STD clinics, adolescent health centers, college/university health centers, community health centers, county jails, and county juvenile detention centers.

24. Will confirmatory/supplemental testing be performed to verify ALL positive screening test results (as per *vii.* on page 6)?

Answer: Yes. Currently, the Bureau of STD Control follows the recommendations listed in the resource: **Centers for Disease Control and Prevention. Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002. MMWR 2002; 51 (No. RR-15)** that recommends additional testing after a positive screening test.

25. Must patient identifiers be PATIENT NAMES or CODES/NUMBERS as per *xiv.* of page 6)?

Answer: Patient identifiers may include both patient names and patient specific identification numbers as both are required for data reporting purposes (see Attachment 3). The specific reference to patient identifiers on page 6 relates to the requirement for

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maintaining the confidentiality of patient information therefore any patient specific data that might result in revealing the identity of the patient, e.g. name, medical record number, date of birth, patient identification number, must be kept confidential.

26. Could we please be provided with the total COST of last year's winning proposal?

Answer: The total amount of the contract with the current laboratory vendor for the January 1 – December 31, 2006 period is \$231,701.

27. Should we factor CLINICIAN TRAINING into the proposed test cost (as per *viii.* of page 6)?

Answer: Any costs associated with the provision of laboratory testing services per the specifications of the RFP may be incorporated into the per test cost or reflected as in-kind. On the Bid Form (attachment 4), a breakdown of the components that comprise the per test cost should be clearly delineated.