

BID SPECIFICATIONS

Chlamydia trachomatis/ Neisseria gonorrhoeae Nucleic Amplification Assay

Trichomonas vaginalis Nucleic Amplification Assay

A. *Chlamydia trachomatis/ Neisseria gonorrhoeae* Nucleic Amplification Assay

1. The assay must utilize nucleic amplification technology (NAAT) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CTGC) in endocervical swabs, male urethral specimens, male and female urines, and vaginal swabs either patient or physician collected.
2. The assay must be approved by the Bureau of Biologics of the Food and Drug Administration (FDA) for *in vitro* diagnostic use with either symptomatic or non-symptomatic patients using either endocervical, male urethral, male or female urine specimens and vaginal specimens.
3. Manufacturer must be able to claim equivalent test performance across all FDA approved specimen collection types.
4. The assay must process all specimen types identically and simultaneously with no specimen segregation or analyst manipulation such as cap removal, swab expression, swab removal or centrifugation.
5. The assay's performance should not be affected by either naturally occurring components in patient samples such as blood, mucous, or bilirubin, nor man-made components such as vitamins or gynecological products.
6. The assay should not cross-react with organisms other than CTGC.
7. The assay must have FDA acknowledged sensitivity (versus patient infected status) of at least 94% (*Chlamydia trachomatis*) and 91% (*Neisseria gonorrhoeae*) with a specificity (versus patient infected status) of at least 97% for both analytes.
8. The assay must be automated such that five hundred (500) combined CTGC samples (patient specimens) can be tested using one analyst in an 8.0 hour period.
9. The Vendor will provide at no additional cost all specimens, specimen collection kits, reagents, test kits, etc., required to verify the assay system to satisfy the current CLIA-88 requirements for verification. Anticipated volume for method verification is 100 tests. Successful completion required for final acceptance.

ESTIMATED USAGE: Montgomery 85,000; Mobile 42,000

B. Trichomonas vaginalis Nucleic Amplification Assay

1. The assay must utilize nucleic amplification technology (NAAT) for the detection of *Trichomonas vaginalis* (TV) in endocervical swabs, male urethral specimens, male and female urines, and vaginal swabs either patient or physician collected.
2. Manufacturer must be able to claim equivalent test performance across all specimen collection types.
3. The assay must process all specimen types identically and simultaneously with no specimen segregation or analyst manipulation such as cap removal, swab expression, swab removal or centrifugation.
4. The assay's performance should not be affected by either naturally occurring components in patient samples such as blood, mucous, or bilirubin, nor man-made components such as vitamins or gynecological products.
5. The assay must be automated such that five hundred (500) combined CTGC samples (patient specimens) can be tested using one analyst in an 8.0 hour period.
6. The Vendor will provide at no additional cost all specimens, specimen collection kits, reagents, test kits, etc., required to validate/ verify the assay system to satisfy the current CLIA-88 requirements. Anticipated volume for method verification is 100 tests. Successful completion of validation/ verification required for final acceptance.

ESTIMATED USAGE: To be determined when and if test is approved by the administration.

Reagents

1. All reagents and equipment must be provided on a reagent rental basis, i.e., reagent purchase/ equipment provided basis.
2. Reagents must be supplied in a form requiring minimal preparation, and in a configuration and package size compatible with the projected user volume.
3. Delivery of reagents must be guaranteed within ten (10) working days after receipt of an order.

4. Test kits must have a minimum of two (2) months of the expiration date remaining at the time they are received in the laboratory.

Collection Kits

1. Specimen collection kits must be offered by the Vendor for use with their CTGC and TV NAAT assays. The Vendor will work with the laboratory and field personnel to ensure that an acceptable plan is in place to replace existing specimen collection kits with new specimen collection kits if necessary.
2. Specimen collection kits should not require refrigerated storage.
3. Specimen collection kits must utilize a penetrable cap for use with automated pipetting instrumentation.
4. Collected specimens must be acceptable for testing at least seven (7) days post collection when shipped or stored under ambient conditions.

Equipment/Instrumentation

1. Equipment/Instrumentation is to be provided for use under a reagent purchase plan.
2. The Vendor is responsible for providing no cost preventive maintenance service (PM) per the manufacturer's recommendations and non-routine repair of instrumentation or equipment.
3. Equipment/Instrumentation design requirements should not exceed the area established for the current testing in the laboratory.
4. Equipment/Instrumentation must be compatible with existing electrical supply and environmental conditions; the Vendor is responsible for any required modifications. All work must meet or exceed applicable local building and safety codes; inspection certificates required for final acceptance.
5. The Vendor is responsible for the delivery, unpacking, installation, and set-up of any provided equipment or instrumentation. At the end of the contract period, the Vendor is responsible for the disassembly, packing, removal and shipping of provided equipment or instrumentation.

6. Instrumentation minimum requirements:

- Positive patient specimen identification throughout testing via onboard barcode tracking.
- Automated reagent and specimen pipetting capabilities.
- Liquid level detection for both reagents and patient samples
- Reagent lot number and expiration date tracking
- Onboard destruction of post test amplicons
- Liquid and solid waste monitoring system
- Must be capable of bi-directional interface to the current laboratory information system (LIS). See general requirements below.

LIS

1. The Vendor must provide, at no cost to the BCL, a validated, robust, and functioning bi-directional instrument interface to the BCL LIS within 30 days of installation.
2. Must have a safe memory for programs with a file protection scheme.
3. Software must be menu-driven with a full numeric keypad.
4. The user must be able to protect programs against unauthorized modifications.
5. Must be capable of running Symantec Antivirus 7.5 and above without affecting performance.
6. Must have a Windows XP operating system or equivalent.

Other Requirements

1. In addition to the FDA approved combination assay for CTGC, the Vendor should offer FDA approved individual discriminatory assays which target alternative unique genomic regions on the same instrumentation platform.
2. If test volume increases by 30% or more during the contract period, the Vendor must provide, at no cost to the BCL, additional or updated instrumentation and upgraded data management systems to accommodate the work load increase.
3. The Vendor must comply with applicable HIPPA regulations to maintain the confidentiality of patient demographics and test data. "HIPPA Requirements" below.

Technical Support/Training

1. Vendor technical assistance via telephone must be available within 30 minutes during normal business hours and within 4 hours during non-business hours for reported problems.
2. On-site technical backup must be guaranteed within 24 hours of any reported assay failure for equipment for which in-house troubleshooting was unsuccessful.
3. The Vendor must provide technical training at the Vendor's headquarters for two (2) technologists per instrument provided. Training should be in depth and intensive to include: assay performance, troubleshooting, preventive maintenance, and quality control.
4. The Vendor will also provide on-site technical training to pertinent personnel regarding assay performance, troubleshooting, preventative maintenance, and quality control.

BID ALL OR NONE

HIPPA Requirements

Federal Requirement. This Clause is necessitated by the application of the Health Insurance Portability and Accountability Act, being 42 U.S.C. §§ 1320d-1329d-8 as amended by § 262 of P.L.104-191, 110 Stat. 2020-2031 and § 264 of P.L.104-191 (42 U.S.C. § 1320d-2 as amended) and regulations promulgated thereunder. References in this clause are to the Code of Federal Regulations, hereinafter "CFR."

1. Definitions Terms used, but not otherwise defined, in this Clause shall have the same meaning as in the Department of Health and Human Services' Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") and Security of Electronic Protected Health Information ("Security Rule"), 45 CFR Parts 160 through 164.

a. "Contractor" The Contractor herein. The Contractor is within the definition of a "Business Associate" under the Privacy Rule. Shall refer to Contractor and/or any of its employees.

- b. “Department” The Department herein. Department is within the definition of a “Covered Entity” under the Privacy Rule.
- c. “Improper disclosure” means actual disclosure (including mailing or e-mailing protected information to the wrong physical or e-mail addresses and posting of protected information to unauthorized websites), or loss of control of the protected information (including loss of records in transit, physical burglary, electronic record intrusion), and other events indicating that the protected information actually was disclosed to unauthorized parties or there is a reasonable likelihood that it may have been disclosed to unauthorized parties.
- d. “Individual” shall have the same meaning as the term "individual" in 45 CFR. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- e. “Privacy Rule” Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR. Part 160 and Part 164, Subparts A and E.
- f. “Proper notification” to ADPH means sending an electronic message to Sharon P. Massingale, Ph. D. and Marian M. Woodman at the following email addresses, sharon.massingale@adph.state.al.us and marian.woodman@adph.state.al.us and a written letter to Sharon P. Massingale, Ph. D. and Marian M. Woodman at the following, Bureau of Clinical Laboratories, P.O. Box 244018, Montgomery, AL 36124-4018, within 48 hours of the improper disclosure event. In the case that Contractor has reason to believe that receipt by neither of these parties was actually accomplished Contractor will notify John R. Wible at the following email address jwible@adph.state.al.us, as soon as possible after recognizing the failure of the original notification.
- g. “Protected Health Information” shall mean individually identifiable health information and Electronic Protected Health Information as found in the Security Rule, 45 CFR ' 160.103, except for that information in (a) education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. ' 1232g, (b) records described at 20 U.S.C. ' 1232g (a) (4) (B) (iv), and (3) employment records held by Department in its role as employer, or as the term may otherwise be defined in 45 CFR ' 164.501.
- h. “Protected individuals” means ADPH’s patient , or clients, or employees, former employees, their spouses, dependents, or other individuals whose protected information was provided by or on ADPH’s behalf to Contractor or its subcontractors in connection with Contractor’s services under this Contract.
- i. “Protected Information” means individuals’ Social Security Numbers; credit, banking, and other financial information; and protected health information, or information from an employee or former employers personnel or health information file.
- j. “Required By Law” shall mean any mandate contained in law that compels Department to make a use or disclosure of Protected Health Information and that is enforceable in a court of

law, including, but not limited to, court orders and court-ordered warrants, subpoenas or summons, a civil or an authorized investigative demand, Medicare conditions of participation (if applicable), statutes or regulations requiring the production of information, or as the term may otherwise be defined in 45 CFR ' 164.501.

k. “Secretary” The Secretary of the United States Department of Health and Human Services or his designee.

l. “Designated Record Set” Means the medical and billing records maintained by or for Department about a Department patient, or any other group of records used by or for Department to make decisions about the patient.

m. “Security Rule” shall mean the Security Standards for the Protection of Electronic Health Information at 45 CFR Part 160 and part 164, Subparts A and C.

2. Obligations and Activities of Contractor

a. Use and Disclosure of Protected Health Information. Contractor agrees not to use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required By Law.

b. Safeguards. Contractor shall use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

c. Mitigation of Damages Contractor shall mitigate, to the extent practicable, any harmful effect that is known to of a use or Contractor disclosure of Protected Health Information by Contractor in violation of the requirements of this Contract.

d. Reporting Violations Contractor shall within (5) days of becoming aware of a use or disclosure or security incident in violation of this Contract, report the use or disclosure to Department

e. Agents and Contractors Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Contractor on behalf of Department agrees to the same restrictions and conditions that apply through this Contract to Contractor with respect to such information.

f. Access to Protected Health Information If Contractor maintains a PHI Designated Record Set, Contractor shall, within five (5) days of a request by Department for access to a patient’s PHI make available to Department the requested PHI that Contractor maintains in Designated Record Sets, in accordance with 45 CFR 164.524.

g. Amendment of Protected Health Information If Contractor maintains a PHI in Designated Record Set, Contractor shall, within 10 days of receiving a request from Department for the amendment of a patient’s PHI, incorporated the amendment into the information that

Contractor maintains in a Designated Record Set in order to meet the requirements under 45 CFR 164.526.

h. **Books and Records** If Contractor maintains a Designated Record Set, Contractor agrees to make its facilities, internal practices, books, accounts, other sources of information and records relating to the use and disclosure of Protected Health Information received from, or created or received by Contractor on behalf of Department available to the Department, or at the request of the Department to the Secretary, during normal business hours or as otherwise directed by the Secretary for purposes of determining the parties' compliance with the applicable standards, implementation specifications and other requirements of the Privacy Rule.

i. **Accounting of Disclosures** Contractor shall within ten (10) days of receiving notice from Department that it has received a request from a patient for an accounting of disclosures of PHI, provide to Department or, if so directed, to the patient or the patient's personal representative, information relating to disclosures of the PHI made, including (i) the date of the disclosure, (ii) the name of the entity or person who received the information, (iii) a brief description of the information disclosed, and (iv) a brief statement of the purpose of the disclosure which includes an explanation of the basis for the disclosure, pursuant to 45 CFR 164.528.

j. **Implementing Safeguards for Electronic PHI** (1) Contractor shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of Department as required by the Security Rule. (2) Contractor agrees to ensure that any agent, including a, Contractor to whom it provides this information agrees to implement reasonable and appropriate safeguards to protect the electronic protected health information.

k. **Confidentiality** In addition to any other protections provided for in this Contract, Contractor agrees to properly notify ADPH within 48 hours of learning of the event of any improper disclosure or suspected improper disclosure of protected information that Contractor or Contractor's subcontractors receive, store, create, or transmit related to ADPH's protected individuals.

Contractor further agrees to use its best efforts to determine how the improper disclosure of the protected information occurred and to take reasonable remedial action to prevent a recurrence. In addition, Contractor will remediate improper disclosures made by Contractor or its subcontractors by covering the expenses related to timely notifying the affected protected individuals about the disclosure; and in the event of actual disclosure to cover the expenses related to procuring commercial monitoring of the affected protected individuals' security for a period of one year, unless ADPH consents that such monitoring is unnecessary in the particular circumstances surrounding the event. ADPH will not unreasonably withhold such consent.

3. Permitted Uses and Disclosures by Contractor

a. **Permitted Uses and Disclosures by Contractor** Except as otherwise limited in this Contract, Contractor may use or disclose Protected Health Information on behalf of Department,

or to perform functions, activities, or provide services to, Department or patients or clients of Department for the purposes of providing health care to patients and clients in accordance with Department's Confidentiality Policy, if such use or disclosure of Protected Health Information would not otherwise violate the Privacy Rule if such disclosure is made by Department.

b. **Uses for Management and Administration Purposes** Except as otherwise limited in this Contract, Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

c. **Disclosures for Management and Administration Purposes** Except as otherwise limited in this Contract, Contractor may disclose Protected Health Information for the proper management and administration of the Contractor, provided that disclosures are required by law, or Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

d. **Data Aggregation Services.** Except as otherwise limited in this Contract, Contractor may use Protected Health Information to provide Data Aggregation services to Department as permitted by 42 CFR § 164.504(e)(2)(i)(B).

4. Obligations of Department

a. **Notification of Elected Limitations** Department shall provide Contractor with Department's Privacy Notice which Department produces in accordance with 45 CFR § 164.520, as well as any changes to such notice.

b. **Notification of Changes in Authorization** Department shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Contractor's permitted or required uses and disclosures.

c. **Notification of Restrictions** Department shall notify Contractor of any restriction to the use or disclosure of Protected Health Information that Department has agreed to in accordance with 45 CFR § 164.522.

5. Permissible Requests by Department Department shall not request Contractor to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Department except that if the Contractor will use or disclose protected health information for data aggregation or management and administrative activities of Contractor, such information may be requested.

6. Return of Information and Survival of the terms of this Clause The provisions of this paragraph shall survive the termination of this Contract and may constitute a continuing duty in perpetuity

a. Except as otherwise provided, upon termination of this Contract for any reason, Contractor shall delete, return or destroy all Protected Health Information maintained in a designated record set received from Department, or created or received by Contractor on behalf of Department or as a result of this Contract. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Contractor. Where such information is deleted or destroyed, Contractor shall provide Department with an assurance of the deletion or destruction of such.

b. Except in accordance with normal business practices, Contractor shall retain no copies of the Protected Health Information.

c. In the event that Contractor determines that returning or destroying the Protected Health Information is infeasible, Contractor shall provide to Department notification of the conditions that make return or destruction infeasible. Upon mutual Contract of the Parties that return or destruction of Protected Health Information is infeasible, Contractor shall extend the protections of this Contract to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such Protected Health Information.

7. Administrative Provisions

a. A reference in this Contract to a section of the Privacy Rule shall mean that section as it is most recently amended.

b. The parties hereto agree to take necessary action as is necessary to amend this Contract from time to time to maintain compliance with the Privacy Rule.

c. Interpretation. Any ambiguity in this Contract regarding the application of the Privacy Rule shall be resolved in favor of a meaning which permits the parties hereto to comply with the Privacy Rule.