

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468591	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Parkhill Clinic For Women	Street Address, City, State 3215 N North Hills Boulevard, Suite 3, Fayetteville, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Through review of policy and procedure, observation and interview it was determined that one of one urine specimen in the laboratory specimen refrigerator lacked a label of patient identity. Findings follow: A) Review of laboratory policy and procedure revealed that urine collected for testing on the Cepheid GeneXpert system should be removed from the collection cup provided to the patient and placed into a tube and labeled with the patient's name and unique identifier. B) During a tour of the laboratory on 9/7/23 at 10:58 a.m. one of one urine specimen was observed in the laboratory specimen refrigerator without any label of patient identity. C) In an interview on 9/7/23 at 10:58 a.m.the laboratory staff member (number 1 on the CMS 209 form) was asked the patient's identity and was unable to determine the identity of the patient that provided the sample and "just write it up".</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 9/7/23 at 09:00 a.m., two separate rooms (main lab, storage room) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room area. C) During a tour of the laboratory on 9/7/23 at 10:15 a.m. 3 cartons of Gene Xpert CT/NG test cartridges lot # 1000872603 expiration date 2025-04-06 with a storage temperature requirement of 36 degrees F. to 86 degrees F. were observed in the storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored. E) In an interview on 9/7/23 at 10:24 a.m. , the laboratory staff member (# 1 on form CMS 209) stated " no we don't have temperatures for the storage room".

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Through review of the manufacturer's maintenance requirements for the Cepheid GeneXpert analyzer, laboratory's maintenance records for January through August of 2023, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to perform quarterly maintenance as required by the manufacturer. Findings follow: A) Review of the user's manual for the Cepheid GeneXpert analyzer revealed that the laboratory was required to perform "Cartidge Bay and Plunger Rod Cleaning" on a quarterly basis. B) Review of the laboratory's maintenance records of the Cepheid GeneXpert analyzer for the period of January through August 2023 revealed that quarterly cartridge bay and plunger rod cleaning was not documented during the period. C) Upon request, the laboratory was unable to provide records for quarterly maintenance of the Cepheid GeneXpert analyzer. D) In an interview on 9/7/23 at 10:15 a.m., the laboratory staff member (number 1 on the CMS 209 form) confirmed that quarterly maintenance was "missed" on the Cepheid GeneXpert analyzer.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the laboratory developed Individualized Quality Control Plan (IQCP) for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) detection performed on the Cepheid GeneXpert system, observation, review of quality control (QC) records, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to perform required QC procedures on one of two lot numbers of CT/NG test cartridges observed in current use. Findings follow: A) Review of the laboratory's IQCP for CT/NG detection on the Cepheid GeneXpert system revealed that external positive and negative QC is to be performed monthly and with each new lot/shipment of CT/NG cartridges. B) During a tour of the laboratory on 9/7/23 at 10:24 a.m. two different lot numbers (20503 and 35015) of CT /NG cartridges were observed in the laboratory drawer reserved for cartridges "in use" C) Review of QC records for January through August of 2023 revealed that external QC was recorded only once per month and no external QC was recorded for GT/NG cartridges lot number 35015. D) In an interview on 9/7/23 at 10:24 a.m. the laboratory staff member (number 1 on the CMS 209 form) stated that shipments of CT /NG cartridges are received "weekly". E) Upon request, the laboratory was unable to provide external QC results for CT/NG cartirdges lot number 35015. F) In an interview on 9/7/23 at 10:30 a.m., the laboratory staff member (number 1 on the CMS 209 form) confirmed that external QC was not performed for CT/NG cartridges lot number 35015, that lot number 35015 was currently in use and that the laboratory needed to develop a system to ensure that external QC is performed in compliance with the laboratory's IQCP for Cepheid GeneXpert cartridges.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Through a review of patient medical records and an interview with laboratory staff, it was determined the laboratory failed to include all required data on test reports. Survey findings follow: A) Two of Two CT/NG and Trichomonas vaginalis (TV) reports reviewed on the medical record of patient #176991 failed to include the address of the laboratory location where the test was performed and the source of the specimen. B) In an interview, at 10:40 a.m.. on 9/7/23, laboratory staff member

(number 1 on the CMS-209 form) confirmed that there was no laboratory address or specimen source on the report listed above. She further stated that the laboratory "opted to scan reports" from the Cepheid GeneXpert system into the electronic medical record and that no CT/NG or TV reports would list the address of the laboratory or the specimen source. .