

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0919777	(X3) Date Survey Completed 06/10/2021
Name of Provider or Supplier Women's Clinic Of Forrest City	Street Address, City, State 902 Holiday Drive, Suite 102, Forrest City, 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
D0000	This is the recertification survey conducted on 6/10/2021. At the time of the recertification survey, the laboratory did not meet the condition of Analytic Systems (493.1250)
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency testing attestation sheets for 2020 and 2021, a review of the proficiency testing policy, and through interviews with laboratory staff, it was determined three of four testing personnel who perform patient testing, did not perform proficiency testing. Survey findings include: A. The laboratory retains attestation sheets for each proficiency testing event. The attestations are signed by testing personnel and laboratory director as documentation that the testing was performed in the same manner as patient samples. The laboratory performed proficiency testing in three testing events in 2020 and one testing event in 2021. All attestation sheets for 2020 and 2021 were signed by laboratory employee #3 (as listed on the form CMS-209). Laboratory employees #2, #4, and #5 never attested to performing proficiency testing during 2020 and 2021 (four events). B. The laboratory policy for proficiency testing states, "Rotate PT events amongst all personnel who test samples and report patient results." C. In an interview, at 11:29 a.m. on 6/10/2021, laboratory employee #3 confirmed that she was the only laboratory employee performing proficiency testing.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p>

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Through a review of proficiency testing attestation sheets for 2020 and 2021, a review of the proficiency testing policy, and through interviews with laboratory staff, it was determined the laboratory quality assessment failed to identify problems in the general laboratory systems. Survey findings follow: A. Monthly QA Checklist for each month in 2020 (12 months) and each month in 2021 (6 months) were photocopied with all answers to quality assurance questions already filled in. Director's signature was photocopied on each monthly sheet. The only items completed each month were the tech signature and date. B. The Monthly QA Checklist includes the following statement: PT samples were tested exactly like patient specimens, i.e., the same number of times, using the same personnel and methods as for patient testing. Every monthly checklist reviewed (18 of 18) had this marked as being done with a "Y" in the blank. C. As cited at D2007, three of four testing personnel who perform patient testing, did not perform proficiency testing E. The Monthly QA Checklist failed to identify failures to follow laboratory policies for external quality control.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Through a review of the laboratory BD Affirm IQCP (Individualized Quality Control Plan), a review of the all quality control records for 2020 and 2021, a review of the "Patient Log" for 2020 and 2021, and interviews with laboratory staff, it was determined the laboratory failed to meet analytic systems requirements or monitor the quality of the analytic systems, as evidenced by: D5445 - the laboratory failed to perform quality control with the frequency required by their quality control plan D5463 - the laboratory failed to rotate testing of control material among all testing personnel D5791 - the laboratory quality assessment failed to identify problems in the analytic systems This is a repeat condition level deficiency from the survey performed on 11/21/2018.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through a review of the laboratory BD Affirm IQCP (Individualized Quality Control Plan), a review of the patient test log for 2020 and 2021, a review of quality control records, and interviews with laboratory staff, it was determined the laboratory failed to perform quality control with the frequency required by their quality control plan. Survey findings include: 1. Quality Control for the BD Affirm was not tested with each new lot or shipment of test kits. A. The laboratory quality control plan, which is part of their IQCP for the BD Affirm states that external quality control will be assayed with each new lot, each new shipment, every 30 days after the lot/shipment is in use, after system maintenance and software upgrades, and to verify device or reagent function before retesting questionable patient results. B. A review of patient test records and quality control records revealed the following new lots of cartridges that were used on patients without first running external quality control: Lot #9247926 started 1/30/2020 and quality control documented on 2/3/2020 (6 patients tested before 2/3/2020); Lot #0008356 started 6/8/2020 and quality control documented on 7/1/2020 (14 patients tested before 7/1/2020); Lot #0077370 started 7/14/2020 and quality control documented on 8/3/2020 (22 patients tested before 8/3/2020); Lot #0031626 started 8/11/2020 with no quality control documented during the use of this lot (31 patients tested with this lot); Lot #0090814 started 8/21/2020 with no quality control documented during the use of this lot (23 patients tested with this lot); Lot #09101120 started 9/1/2020 and quality control documented on 9/2/2020 (6 patients tested before 9/2/2020); Lot #0079624 started 9/14/2020 and quality control documented on 10/5/2020 (32 patients tested before 10/5/2020); Lot #0183296 started 10/22/2020 and quality control documented on 11/4/2020 (19 patients tested before 11/4/2020); Lot #0279326 started 12/7/2020 with no quality control documented during the use of this lot (27 patients tested with this lot); Lot #0248733 started 12/21/2020 and quality control documented on 1/11/2021 (11 patients tested before 1/11/2021); Lot #0295833 started 2/1/2021 and quality control documented on 2/3/2021 (13 patients tested before 2/3/2021); Lot #0303632 started 2/25/2021 and quality control documented on 3/15/2021 (4 patients tested before 3/15/2021); Lot #1018646 started 3/29/2021 and quality control documented on 4/6/2021 (10 patients tested before 4/6/2021); and Lot #1047426 started 5/4/2021 and quality control documented on 6/9/2021 (25 patients tested before 6/9/2021). C. In an interview, at 11:26 a.m. on 6/10/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed there are no additional quality control records and that quality control is not being done when opening a new lot or shipment of test kits. 2. Quality Control for the Cepheid Xpert was not documented per lot or shipment of test cartridges. A. The laboratory quality control plan, which is part of their IQCP for the Cepheid CT/NG test system states that external quality control will be assayed with each new lot, each new shipment, every 30 days after the lot/shipment is in use, after system maintenance and software upgrades, and to verify device or reagent function before retesting questionable patient results. B. At 11:53 on 6/10/2021 the surveyor requested documentation of cartridge lots and dates that the lots were put in use to test patients. Laboratory employee #3 (as listed on the form CMS-209) stated that the laboratory does not track changes in cartridge lots for the Cepheid and does not perform quality control when starting new lots of CT/NG test cartridges. This is a repeat deficiency from the survey performed on 11/21/2018.

<p>D5463</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Through a review of the "QC (EQC) LOG" for 2020 and 2021, a review of the "Patient Log" for 2020 and 2021, and interviews with laboratory staff, it was determined the laboratory failed to rotate testing of control material among all testing personnel. Survey findings include: A. Through a review of the "QC (EQC) LOG" for 2020 and 2021, the surveyor determined that all quality control (21 of 21) was performed and initialed by laboratory employee #3 (as listed on the form CMS-209). B. During a review of the "Patient Log" for 2020 and 2021 it was revealed that five different testing personnel had initialed the patient log to indicate that they had performed the patient testing. The CMS-209 form provided to the surveyor lists four current testing personnel. C. In an interview at 11:29 a.m. on 6/10/2021, employee #3 (as listed on the form CMS-209) confirmed that she is the only testing personnel who performs external quality control.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Through a review of the "Monthly QA Checklist", a review of quality control records, a review of the patient test logs, a review of the form CMS-209, and interviews with laboratory staff, it was determined the laboratory quality assessment failed to identify problems in the analytic systems. Survey findings follow: A. Monthly QA Checklist for each month in 2020 (12 months) and each month in 2021 (6 months) were photocopied with all answers to quality assurance questions already filled in. Director's signature was photocopied on each monthly sheet. The only items completed each month were the tech signature and date. B. The Monthly QA Checklist includes the following statement: QC was run according to our written policy. All testing personnel performed QC on a rotating basis. Every monthly checklist reviewed (18 of 18) had this marked as being done with a "Y" in the blank. C. As cited at D5445 the laboratory failed to perform quality control with the frequency required by their quality control plan. D. As cited at D5463 the laboratory failed to rotate testing of control material among all testing personnel. E. The Monthly QA Checklist failed to identify failures to follow laboratory policies for external quality control.</p>
<p>D6032</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Through a review of personnel records, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for one of four testing personnel listed on the form CMS-209, to perform testing without direct supervision. Survey findings include: A. During a review of personnel records for the four testing personnel listed on the CMS-209, it was determined the personnel record for personnel #2 (as listed on the form CMS-209) failed to include authorization to perform testing without direct supervision. B. In an interview at 10:06 a.m. on 6/10/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of written authorization for employee #2 to perform testing without direct supervision.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Through a review of personnel records for four employees listed as testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the technical consultant failed to perform annual competency evaluations on one of four laboratory testing personnel. Survey findings include: A. Through a review of personnel records for laboratory employee #3 (as listed on the form CMS-209), it was determined that employee #3 was hired on 8/5/2016 and that the last two competency assessments documented were dated 8/29/2019 and 7/30/2021. There was no documented competency assessment in 2020. B. In an interview at 10:06 a.m. on 6/10/2021, laboratory employee #3 confirmed the lack of documented 2020 competency assessment.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Through a review of the policies and procedures for the BD Affirm test system, a review of personnel records for four employees listed as testing personnel on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the technical consultant failed to perform semiannual competency evaluations during the first year of employment on one of four laboratory testing personnel. Survey findings include: A. The policies and procedures for the BD Affirm test system state that personnel are evaluated at six months after beginning patient testing. B. Through a review of personnel records for laboratory employee #5 (as listed on the form CMS-209), it was determined that employee #5 was hired on 9/10/2019 and that the only competency assessments documented were dated 9/11/2019 and 9/1/2020. There was no documentation that competency was assessed at six months after employee #5 started patient testing as required by the laboratory policies and procedures. C. In an interview at 10:06 a.m. on 6/10/2021, laboratory employee #3 confirmed the lack of documented semiannual competency assessment for employee #5.