

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2240675	(X3) Date Survey Completed 10/14/2022
Name of Provider or Supplier River Valley Obstetrics And Gynecology	Street Address, City, State 2500 W Main St, Russellville, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Through review of the manufacturer's user manual for the BD Max microbiology instrument, lack of documentation and interview it was determined that the laboratory failed to monitor the humidity level required for the operation of the BD Max microbiology system. Findings follow: A) Review of the manufacturer's user manual for the BD Max microbiology instrument revealed an operating humidity requirement of 20% to 80%. B) Review of the environmental records of the laboratory room in which the BD Max microbiology systems is used contained no records of the room humidity level. C) In an interview on 10/14/22 at 11:37 am, the laboratory staff member (#4 on the CMS 209 form) confirmed that the humidity level in the room in which the BD Max system was used had not been monitored.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through</p>

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 review of the Individualized Quality Control Plan (IQCP) for the BD Max microbiology system and interview with laboratory staff it was determined that the IQCP plan for the BD Max system lacked the specific identification of the external quality control material used. Findings follow: A) Review of the "BD Max IQCP" revealed that "External quality control containing a positive and negative control will be analyzed with each new lot number of reagents or at least once a month" but the identification of the control material was not specified. B) In an interview on 10/14/22 at 12:12 pm, the laboratory staff member (#4 on the CMS 209 form) confirmed that the IQCP, identified above, lacked the specific identity of the QC material to be used.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the Individualized Quality Control Plan (IQCP) for the BD Max microbiology system, review of QC results from March 2022, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to run negative QC material when performing monthly QC. Findings follow: A) Review of the IQCP for the BD Max microbiology system revealed that positive and negative external control material is to be performed "at least monthly". B) Review of the QC results from March 2022 to the date of survey revealed positive external control results for each month reviewed but no negative results were presented. C) Upon request, the laboratory was unable to provide monthly negative external QC results for each month since March 2022. D) In an interview on 10/14/22 at 12:12 pm, the laboratory staff member (#4 on the CMS 209 form) stated that no negative external control was performed from March 2022, when testing was begun, until the date of the survey.

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 randomly selected medical records, lack of documentation, and interviews with staff, it was determined test reports failed to include the date of collection and source of the specimen submitted. Survey findings follow: A) The surveyor reviewed test reports from randomly selected medical records of patients who had tests performed in the laboratory . . B) In an interview, at 12:15 pm on 10/14/22, employee #4 (as listed on the CMS 209 form) confirmed the lack of date of collection and specimen source on all records reviewed.