Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2240675	05/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
River Valley Obstetrics And Gynecology	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
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based upon a review of proficiency test documentation for 2024 and 2025, lack of documentation, and interview with laboratory staff, the laboratory failed to maintain copies of proficiency test instrument data for six of six proficiency test events surveyed. Survey findings follow: A) Review of proficiency testing documentation for API Microbiology 2024 event 1, API Microbiology 2024 event 2, API Microbiology 2024 event 3, API Microbiology 2025 event 1, API Microbiology 2025 event 2, API Microbiology 2025 event 3, revealed that original instrument result data was not included in the documentation. B) Upon request, the laboratory was unable to produce the instrument data for the events identified above. C) In an interview on 5/13/26 at 10:55 a.m., the laboratory staff member #4, as identified on the CMS 209 form, confirmed that the instrument data for the events identified above was not available.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and,

	when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based upon a review of laboratory policy and procedure, observation, and interview the laboratory failed to label one of six specimen collection containers with patient name and unique patient identifier. Findings follow: A) During a tour of the laboratory on 5/13/26 at 12:02 p.m. one urine specimen container was observed in the laboratory testing area labeled with a patient's last name and first initial only.. B) Review of the laboratory policy and procedure revealed that "patient specimen containers must be labeled with the patient's name and unique identifier". . C) In an interview on 5/13/26 at 12:05 p..m. , the laboratory staff member (#4 on the CMS 209 form) confirmed that the specimen identified above had been analyzed and lacked proper patient identification on the containers as required by policy and procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon review of the laboratory's policy and procedure manual , lack of documentation, and interview with laboratory staff, the laboratory did not have policy and procedure specifying requirements for the preparation and transportation of specimens to be tested for the qualitative presence of Neisseria gonorrhoeae (GC), Trichomonas vaginalis (TV), and Chlamydia trichomatis (CT) performed on the BD Max analyzer. Findings follow: A) Review of the laboratory's policy and procedure manual revealed that the policy and procedure for performing the qualitative testing for the presence of GC, TV, and CT on the BD Max analyzer was the BD Max user's manual which had the statement under paragraph 4.4.1 "specimens should be transported and preparaed according to the instructions in the appropriate BD Max assay package insert". B) When asked for a copy of the requirements for specimen preparation and transportation, the laboratory did not have one available at the time of

	the survey. C) In an interview on 5/13/26 at 11:40 a.m. the laboratory staff member, identified as number 4 on the CMS 209 form, confirmed that no policy and procedure for specimen preparation and transport for qualitative analysis of GC, TV, CT performed on the BD Max analyzer was present in the laboratory policy and procedure manual.