| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D0465556 | 10/19/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| South Arkansas Women's Clinic | 706 West Grove Street, El Dorado, 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 |
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| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of the "BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure" and a review of the patient and quality control logs for 2022 it was determined the laboratory failed to document the internal positive and negative controls for the BD Affirm III with each patient. Survey findings include: A. A review of the "BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure" revealed the procedure stated, "The Affirm VPIII Microbial Identification Test includes two internal controls on each PAC: a Positive Control bead and a Negative Control bead. These control beads are tested simultaneously with each patient specimen, ensuring the proper performance of PAC, Reagent Cassette (RC) and Processor. The Positive Control also ensures the absence of specimen interference. The Negative Control also ensures the absence of non-specific binding from the specimen. B. Through a review of the patient and quality control logs for January through October of 2022 it was determined Positive and Negative internal control results were not reported for any patient tests performed in 2022. The laboratory reported an annual test volume of 5,112 patient Affirm tests. C. In an interview at 10: 40 on 10/19/2022, the laboratory technical consultant (as listed on the form CMS-209) stated that the internal quality control is not reported. |

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| **D6011** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<br><br>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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.<br><br>This STANDARD is not met as evidenced by:<br>Through observations made during a tour of the laboratory, it was determined the laboratory director failed to provide a safe environment in which employees were protected from chemical and biological hazards. Survey findings include: During a tour of the laboratory, at 11:26 on 10/19/2022, the surveyor observed two packages of crackers in the laboratory drawer, next to the blood drawing chair. |