

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2110388	<b>(X3) Date Survey Completed</b>  01/31/2018
<b>Name of Provider or Supplier</b>  Bolivar Ob/Gyn	<b>Street Address, City, State</b>  1195 N Oakland, Bolivar, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures and interview with the general supervisor the laboratory failed to establish written policy and procedure to assess testing personnel competency. Findings: 1. Review of procedures showed no procedure to assess testing personnel competency. 2. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory failed to establish written policy and procedure to assess testing personnel competency.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of test accuracy and interview with the general supervisor the laboratory failed to verify semen analysis accuracy twice annually in 2017. Findings: 1. Review of verification of semen analysis test accuracy showed test accuracy was not performed twice annually in 2017. 2. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory failed to verify semen analysis accuracy twice annually in 2017.</p>

<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures and interview with the general supervisor the laboratory failed to include a procedure for wright giemsa stain in the procedure manual. Findings: 1. Review of the procedure manual showed no procedure for wright giemsa stain. 2. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory has no procedure for wright giemsa stain.</p>
<p><b>D5435</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation of pipettes and interview with the general supervisor the laboratory failed to perform function checks to verify accuracy of volume dispensed on 2 of 2 pipettes in 2017 to date. Findings: 1. No function check data to verify accuracy of volume dispensed was available for 2 pipettes. 2. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory failed to perform function checks to verify accuracy of volume dispensed on 2 pipettes.</p>
<p><b>D5543</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.1269(a)(d)</p> <p>(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of semen analysis controls and interview with the general supervisor the laboratory failed to complete one control material each 8 hours of operation for semen analysis. Findings: 1. Review of semen analysis controls showed no controls documented. 2. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed no semen analysis controls are performed.</p>

**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:

Based on review of the test report and interview with general supervisor, the laboratory failed to provide positive patient identification and the name and the address of the laboratory on the test report. Findings: 1. Review of test reports showed laboratory did not include positive patient identification. Patient's name and identification number, or a unique identifier and identification number must be included on test report. 2. Review of test report showed the the laboratory did not include the name and address of the laboratory location where the test was performed. 3. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory failed to provide positive patient identification and the name and the address of the laboratory on the test report.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of Bolivar OB/GYN's preanalytical, analytical and postanalytical testing for semen analysis and interview with the general supervisor on January 31, 2018 at 11:30 AM the laboratory director failed to provide overall management and direction for the laboratory (refer to 6103).

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of procedures, competencies, controls, test accuracy, test reports and interview with the general supervisor the laboratory director failed to monitor

preanalytical, analytical and postanalytical phases of testing. Findings: 1. Review of semen analysis procedure revealed no procedure for wright giemsa stain. 2. Review of controls showed semen analysis controls were not completed every 8 hours. 3. Review of test report showed test report did not include positive patient identifiers and name and address of laboratory where test was performed. 4. Observation of pipettes showed no function checks to verify accuracy of volume dispensed. 5. Review of semen analysis test accuracy showed laboratory failed to perform test accuracy two times a year in 2017. 6. Review of competencies showed no competency assessment for testing personnel #1. 7. Interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the laboratory director failed to monitor preanalytical, analytical and postanalytical phases of testing.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

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

This STANDARD is not met as evidenced by:  
Based on review of competencies and interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the technical supervisor failed to evaluate and document the performance for testing personnel #1 semiannually during the first year.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on review of competencies and interview with the general supervisor on January 31, 2018 at 11:30 AM confirmed the technical supervisor failed to evaluate and document the performance for testing personnel #1 annually after the first year.