Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520943	(X3) Date Survey Completed 11/03/2020
Name of Provider or Supplier Obgyn Associates Of Idaho Falls	**Street Address, City, State** 2065 E 17th St #D, Idaho Falls, ID	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory testing person on November 3, 2020, the individual testing or examining the samples and the laboratory director failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods of the BD Affirm for the 2019 Microbiology 3rd event. Findings: 1. A PT record review revealed that the laboratory director failed to sign the attestation statement for 2019 Microbiology 3rd event from the American Proficiency Institute (API). 2. A PT record review revealed that the individual testing or examining the samples failed to sign the attestation statement for 2019 Microbiology 3rd event from API. 3. An interview with the laboratory testing person, on November 3, 2020, at 2:00 pm, confirmed that the API 2019 Microbiology 3rd event PT attestation statement was not signed by the individual testing the samples or the laboratory director.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the testing person on November 3, 2020, the laboratory failed to 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. Findings: 1. Record review of the laboratory procedure manual revealed the laboratory failed to establish and follow a written quality assurance policy and procedure. 2. An interview with the testing person on November 3, 2020, at 2:45 pm, confirmed that the laboratory failed to establish and follow a written quality assurance policy and procedure.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of BD Affirm IQCP and an interview with the testing person on November 3, 2020, the current laboratory director failed to approve, sign, and date before use. Findings: 1. A procedure review of the BD Affirm IQCP revealed that the current director has not approved, signed and dated the procedure before use. 2 An interview with the testing person on November 3, 2020, at 2:25 pm, confirmed that the laboratory director had not signed the IQCP for BD Affirm. 3. The facility tests approximately 420 BD Affirm tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing person on November 3, 2020, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: accuracy and precision, before reporting patient test results. Finding: 1. A record review for the BD Affirm revealed that they had received a new instrument on May 31, 2018 from McKesson but had not performed a verification of performance, before reporting patient test results. 2. An interview with the testing person on November 3, 2020, at 3:00 pm, confirmed that the laboratory had not preformed a verification of performance on the new BD Affirm analyzer before reporting patient test results. 3. The facility tests approximately 420 BD Affirm tests annually.
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: Based on an interview with the testing person on November 3, 2020, and a Quality Control (QC) record review the laboratory failed to include a negative and positive control material for each analyte tested. Findings: 1. Based on QC record review, the laboratory failed to run all three organism types: Candida albicans, Gardnerella vaginalis and Trichomonas vaginalis, and a negative control for their BD Affirm tesing system. The records showed that only Candida albicans was being used for QC. 2. An interview with the testing person on November 3, 2020, at 2:30 pm, confirmed that the laboratory was only testing Candida albicans QC for their BD Affirm testing system. 3. The facility tests approximately 420 BD Affirm tests annually.