Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1020157	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
San Marcos Ob Gyn	2003 - B Medical Parkway, San Marcos, TX	

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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.801 Condition: Enrollment and testing of samples 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; technical consultant 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; testing personnel 493.1250 Condition: Analytic Systems
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory testing records, CMS 155 report, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for the specialty of Bacteriology and the subspecialties of Parasitology and Mycology. The findings were: 1. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program between 2016 and 2018. The laboratory started testing patient specimens using the BD Affirm VPIII Microbial Identification Panel in October 2016. 2. Review of the CMS 155 report found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 3. An

	interview with testing personnel conducted on March 27, 2018 at 09:27 AM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for Bacteriology. 4. According to the Annual Test Volume recorded in the CMS 116 application obtained during the inspection, the laboratory performs 300 BD Affirm VPIII Microbial Identification Panels annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of laboratory records and interview of facility personnel it was revealed that the laboratory failed to have a procedure to assess the competency of all consultants and testing personnel . Findings were: 1. There was no procedure available for review for assessing the competency of the consultants or testing personnel. Personnel files were requested but not provided. 3. Interview of the Testing personnel conducted on February 27, 2018 at 09:25 AM confirmed there were no competency assessment records or a procedure for assessing the competency of consultants or testing personnel.
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 laboratory records and interview of facility personnel, the laboratory failed to have a quality assessment program to identify and correct problems in general Lab systems. The laboratory failed to enroll in a proficiency testing program for Bacteriology in 2016, 2017 and 2018. (See D 2000)
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory policies and procedures, manufacturer instructions, BD Affirm quality control records, patient test records, and staff interview, the

	laboratory failed to meet the applicable requirements in analytic systems. The findings included: 1. The laboratory failed to have a written procedure available to testing personnel for testing the BD Affirm VPIII Microbial Identification Test. (See D5401) 2. The laboratory failed to label BD Affirm reagent kits with new expiration dates when storing the reagents to room temperature. (See D5415). 3. The laboratory failed to test quality controls each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to reduce the frequency of testing of quality control when using the BD Affirm VPIII Microbial Identification Test. . See D5445.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Review of policies and procedures, observations, review of laboratory test records and interview of facility personnel found that the laboratory failed to have a written procedure for BD Affirm VPIII Microbial Identification Test. the findings Included: 1. Review of policies and procedures found no written procedure available to testing personnel for the performance of the BD Affirm VPIII Microbial Identification Test. The laboratory was requested to provide a copy of the manufacturer's package insert that was provided with the BD Affirm VPIII Microbial Identification test kit but was unable to find one. 2. Observations made in the laboratory found no manufacturer's instructions available to testing personnel. 3. Interview of testing personnel listed on the CMS Report 209 Laboratory Personnel Report conducted on February 27, 2018 at 10:16 AM confirmed that the laboratory did not have a written procedure for performing the BD Affirm VPIII Microbial Identification Test, or a copy of the manufacturer's Instructions for use.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the BD Affirm VPIII Microbial Identification test manufacturer instructions, surveyor observation, and staff interview, the laboratory failed to label the BD Affirm reagent kit in use with an opened expiration date when storing the kit at room temperature. The findings included: 1. Review of the manufacturer's instructions for the BD Affirm VPIII reagent package (670160JAA(02), 2015-04), under Storage of Reagents, states: "The Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8 C. Alternatively, store at room temperature (up to 30 C) no more than 3 months. 2. At 09:19 AM on February 27, 2018 in the laboratory, the surveyor observed 21 tests from a 25 test kit BD

	Affirm kit lot: 7317769 (Expiration: 2018/10/25) present at room temperature (25.3 C). 3. Interview of testing personnel conducted on February 27, 2018 at 10:16 AM in the laboratory found that the laboratory did not change the expiration date of reagents stored at room temperature. Testing personnel stated that the reagent kit had been at room temperature "about a week".
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. This STANDARD is not met as evidenced by: Based on review of policies and procedures, quality control records for the BD AFFIRM VPIII Microbial Identification test system, observations, review of patient test logs and interview of facility personnel, the laboratory failed to perform and document quality control testing at least once each day of testing for the organisms Candida,Gardnerella and Trichomonas when tested using the BD Affirm. Findings included: Review of policies and procedures found no procedure available to testing personnel defining the number and frequency of testing quality control materials when using the BD AFFIRM VPIII Microbial Identification test system for testing patient specimens 2. Review of quality control records between August 31, 2016 and February 27, 2018 found the laboratory documented quality control procedures on 4 of 546 days. Quality control procedures were documented on: August 31, 2016 October 3, 2016 October 10, 2016 December 13, 2016 Additional quality control records were requested but not provided. 2. Observations made during the tour of the facility found no quality control materials available for use to ensure the quality of results tested using the BD AFFIRM VPIII Microbial Identification test system. 3. Review of patient test logs found the laboratory tested 248 patient specimens between September 8, 2016 and February 21, 2018 without testing quality control materials each day of patient testing. 4. Interview of testing personnel conducted on February 27, 2018 at 09:16 AM in the laboratory confirmed that quality control materials were not tested each day of patient testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, observations, review of test records and interview of facility personnel found the laboratory failed to have a

	written policy to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. 1. The laboratory failed to have a written procedure available to testing personnel providing instruction for the step by step procedure for testing patient specimens using the BD Affirm VPIII Microbial Identification test. The laboratory did not have a package insert available for the BD Affirm VPIII Microbial Identification test . 2. The laboratory failed to detect that the BD Affirm VPIII Microbial Identification test kit stability was decreased when stored at room temperature. The laboratory did not document the date of opening the kit to ensure that it was not used beyond the three month stability when stored at room temperature. (see D5415) 3. The laboratory failed to detect that quality control procedures were not performed each day of patient testing when using the BD Affirm VPIII Microbial Identification test or develop an IQCP to reduce the frequency of quality control testing. (see D 5445
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient test records, and confirmed in interview with laboratory staff, the Laboratory Director failed to provide overall management and direction to the laboratory. 1. The laboratory Director failed to ensure that testing personnel were performing test methods as required. (see D 6014) 2. The laboratory Director failed to ensure that the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program for Bacteriology. (see D 6015) 3. The laboratory Director failed to ensure that a quality control program had been established and maintained to ensure the accuracy and reliability of results obtained when using the BD Affirm VP III Microbial Identification Test. (See D 6020) 4. The laboratory Director failed to ensure that a Quality Assessment program had been established to ensure the quality of results obtained when using the BD Affirm VP III Microbial Identification Test. (See D 6021) 5. The laboratory Director failed to ensure that Testing personnel had received the appropriate education and training prior to performing non waived testing. (See D 6028) 6. The laboratory Director failed to ensure that procedures had been established to assess the competency of individuals performing moderate complexity procedures. (see D6030) 7. The laboratory Director failed to ensure that an approved procedure manual was available to all testing personnel responsible for patient testing. (see D 6031) 8. The laboratory Director failed to specify in writing the duties of each consultant, supervisor and testing person. (See D 6032)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: The Laboratory director failed to ensure that reagent test kits were stored at an appropriate temperature to prevent degradation of the BD Affirm VPIII Microbial Identification Test kits used for patient testing .(See D5415)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for Bacteriology in 2016, 2017 and 2018. (See D 2000)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that quality control procedures were done each day patient specimens were tested for Bacteriology procedures using the BD Affirm VPIII Microbial Identification test, or develop an IQCP. (see D5445)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies and staff interview, it was revealed the laboratory director failed to ensure quality assessment programs were established and maintained (see D5291 and D5791).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel performing Bacteriology testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D 6066)
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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: The Laboratory director failed to ensure that the laboratory had a procedure to assess the competency of all testing personnel and the technical consultant responsible for patient testing to include Direct Observation,Monitoring the recording and reporting of test results,Review of quality control and proficiency testing, instrument maintenance, Assessment of test performance , and Assessment of problem solving skills. (See D 5209)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the manufacturer's instructions for the BD Affirm VPIII Microbial Identification Test , and staff interview, it was found that the laboratory director failed to ensure that a written procedure was available to all testing personnel outlining the step by step performance of the test. (see D 5401)
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review of personnel records, policies and procedures and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties of personnel responsible for all phases of patient testing Findings included: 1. Review of personnel records found no written job descriptions or delegation of duties for the technical consultant, laboratory director, clinical consultant or testing personnel. 2. Review of policies and procedures found no written job descriptions or delegation of duties for the technical consultant, laboratory director, clinical consultant or testing personnel. 3. Interview of testing personnel conducted on February 27, 2018 at 09:16 AM confirmed that there were no written job descriptions or delegation of duties for all positions.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: 05/25/2017 Based on surveyor observations, review of laboratory records, quality control records, and patient test records, the Technical Consultant failed to provide technical oversight of the laboratory. 1. The Technical Consultant failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for Bacteriology. (see D 6041) 2. The Technical Consultant failed to ensure that a quality control program had been established and maintained. (see D 6042) 3. The Technical

	Consultant failed to ensure that all testing personnel received the appropriate training for moderate complexity procedures. (see D 6045) 4. The Technical Consultant failed to assess the competency of all testing personnel responsible for testing patient specimens. (see D6046 and D 6053)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel the technical consultant failed to ensure the laboratory was enrolled in a proficiency testing program for Bacteriology in 2016, 2017 and 2018. (See D 2000)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: TheTechnical Consultant failed to ensure that quality control procedures were done each day patient specimens were tested for Bacteriology procedures using the BD Affirm VPIII Microbial Identification test. (see D5445)
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of the CMS-209 laboratory personnel report, review of personnel records, and staff interview, the Technical Consultant failed to have documentation of training for two of two testing personnel performing moderate complexity testing in Bacteriology. The findings included: 1. Based on review of the CMS-209 laboratory personnel report the laboratory had two testing personnel performing moderate complexity testing. 2. Personnel records were requested for review but not provided. 3. Interview of Testing personnel listed on the CMS report 209 conducted on February 27, 2018 at 09:25 AM confirmed that there were no education and or training records available for review.

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, it was revealed the technical consultant failed to perform competency assessments in 2016, 2017 and 2018 for two of two testing personnel performing the BD Affirm VP III Microbial Identification Test The findings included: 1. A review of the laboratory records found that the laboratory started testing patients using the BD Affirm VP III Microbial Identification Test in September 2016 with no documentation of competency assessments for testing personnel . 2. Interview of the Testing personnel listed on the CMS Report 209 conducted on February 27, 2018 at 09:25 AM confirmed that there were no competency assessments performed for testing personnel between September 2016 and February 27, 2018. Testing person one confirmed a hire date of June 22, 2015 for herself, and a hire date of December 2016 for testing person two.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 the laboratory records, the CMS-209 Laboratory Personnel report, and confirmed in interview, the Technical Consultant failed to evaluate and document the performance of two of two testing personnel at least semiannually during the first year of patient testing. The findings included: 1. Based on review of laboratory records found no documentation of semi annual competency assessment in the first year of testing using the BD Affirm VP III Microbial Identification Test. 2. Interview of testing personnel conducted on February 27, 2018 at 09:25 AM confirmed that competency assessments were not performed annually and had not been performed semiannually during the first year of patient testing. Testing Person One provided a hire date of June 22, 2015 for herself and a hire date of December 2016 for testing person Two.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 laboratory personnel report, and staff interview, the laboratory failed to have documentation of education and training to qualify two of

	two testing personnel performing testing using the BD Affirm VP III Microbial Identification Test (a moderate complexity procedure). (See D6065 and D6066).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Review of laboratory records and interview of facility personnel found that two of two testing personnel listed on the CMS Report 209 had no documentation of education prior to testing patient specimens using the BD Affirm VP III Microbial Identification Test. Findings included: 1. Review of laboratory records found no documentation of education for two of two testing personnel listed on the CMS Report 209. Education records were requested but not provided. 2. Interview of testing personnel conducted on February 27, 2018 at 09:25 AM confirmed that education records were not available for review. Testing Person One provided a hire date of June 22, 2015 for herself and a hire date of December 2016 for testing person Two.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Review of laboratory records and interview of facility personnel found that two of two testing personnel listed on the CMS Report 209 had no documentation of training prior to testing patient specimens using the BD Affirm VP III Microbial Identification Test. Findings included: 1. Review of laboratory records found no documentation of training for two of two testing personnel listed on the CMS Report 209. Training records were requested but not provided. 2. Interview of testing personnel conducted on February 27, 2018 at 09:25 AM confirmed that no training records were available for review. Testing Person One provided a hire date of June 22, 2015 for herself and a hire date of December 2016 for testing person Two.