Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1075668	11/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rockville Gynecology Llc	15204 Omega Drive, Suite 200, Rockville, MD	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on procedure manual, manufacturer's "Instructions for Use," and record review and interview with the testing personnel (TP) and laboratory director (LD), the laboratory did not follow manufacturer's instructions for performing waived SARS-CoV-2 testing using the Cepheid GeneXpert System. Findings: 1. The "Instructions for Use" for the test, "Xpert Xpress SARS-CoV-2" was reviewed. Section "16.3 Running External Controls" states, "It is recommended that external controls be tested at the frequency noted below. Each time a new lot of Xpert Xpress SARS-CoV-2 kits is received. Each time a new shipment of Xpert Xpress SARS-CoV-2 kits is received even if it is the same lot previously received." 2. Record review showed that the laboratory's "Covid Monthly Control Log" was blank. A review of quality control (QC) records on the instrument from June, 2021 to present showed that no SARS-CoV-2 QC records were recorded. 3. Section "21 Conditions of Authorization for Laboratories" states, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." Procedure manual review showed that the laboratory did not have a procedure for how to report SARS-CoV-2 test results to the appropriate local health department. 4. This section also states, "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." Record review showed that there was no documentation of initial training or competency assessments performed for 4 of 4 TP listed on the "Laboratory Personnel Report (CMS-209)." 5.

	Record review showed that the laboratory validated the instrument and testing system for the "4-Plex" test cartridge (Xpert Xpress SARS-CoV-2/Flu/RSV), however the lab is currently using the "Xpert Xpress SARS-Cov-2" cartridge. There was no documentation that the new cartridge had been validated before use. 6. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not follow manufacturer's instructions for performing waived SARS-CoV-2 testing using the Cepheid GeneXpert System.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the laboratory director (LD), the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. Quality assurance (QA) record review showed that there were no QA records present at the time of the survey. 2. Record review showed that the laboratory did not have documentation that SARS-CoV-2 test results (both positive and negative) were reported to the appropriate health department. 3. During an interview on 10/18 /2021 at 4:00 PM, the LD confirmed that the laboratory failed to retain all analytic systems records for at least 2 years.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and electronic communication with the practice manager and interview with the laboratory director (LD), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. In an email received on 11/08/2021 the practice manager stated that the laboratory began testing with the BD Affirm VPIII Microbial Identification System on 11/30/2020 and with the Cepheid GeneXpert System on 02/03/2021. 2. A review of PT records showed that the laboratory had the results form and the attestation statement for "Q3 Nonchemistry 2021" "Chlamydia/GC/Strep Screen B." The results form was blank and the attestation statement was not signed by the LD or testing personnel. No other PT records were available at the time of the survey. 3. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not retain all PT records for at least 2 years.
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 record review and interview with the laboratory director (LD) the laboratory failed to follow the written procedure manual for all tests, assays, and examinations performed by the laboratory (D5401); failed to provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the BD Affirm Microbial Identification System and the Cepheid GeneXpert System (D5403); failed to define, monitor, and document laboratory refrigerator, room, and heat block temperature and room humidity to ensure proper reagent storage, and accurate and reliable test system operation and test result reporting (D5413); failed to ensure that reagents are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality (D5417); failed to ensure that the laboratory validated all analyzers to demonstrate that they can obtain performance specifications comparable to those established by the manufacturer before being used for patient testing (D5421); failed to ensure that maintenance is performed and documented as defined by the manufacturer and with at least the frequency specified by the manufacturer (D5429); failed to run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (D5445); and failed to 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 (D5791).
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: Based on procedure manual and record review and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to follow the written procedure manual for all tests, assays, and examinations performed by the laboratory. Findings: 1. The procedure "Quality Assessment Program" under "Specimen Collection and Handling" states, "Samples that do not meet acceptable criteria for testing are rejected. Rejected sample documentation includes why a sample was rejected and is maintained on the Sample Rejection Log." During an interview on the day of the survey, TP stated that the laboratory did not have a "Sample Rejection Log." 2. The section titled "Patient Test Management/Record Keeping" states, "A daily specimen accession log is maintained in the lab." The laboratory used a spiral notebook where they wrote patient names but would cross the names off with pen when patient results were entered into the electronic record. The TP stated that the technical consultant was supposed to provide them with a patient log but had not. 3. The section titled, "Proficiency Testing" states, "PT results are reviewed and retained for a period of at least 2 years." Record review showed that proficiency testing records were incomplete. Cross-refer to D3037. 4. The laboratory did not have a policy for reporting all (including positive and negative) SARS-CoV-2 patient results to the

	appropriate health department. 5. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the written procedure manual did not accurately reflect the actual practice of the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the BD Affirm Microbial Identification System and the Cepheid GeneXpert System. Findings: 1. Procedure manual review showed that the procedure, "BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure" was a "Sample Procedure" provided by the manufacturer. The "Sample Procedure" stated that it "is not indicated as a substitute for your facility procedure manual, instrument manual, or reagent labeling/package insert. This 'Sample Procedure' is intended as a model for use by your facility to be customized to meet the needs of your laboratory." The procedure was not updated to reflect the current practice in the laboratory. 2. The laboratory did not have a procedure manual or instrument manual for the operation of the Cepheid GeneXpert System, including: step-by-step performance of the procedure, including test calculations and interpretation of results; preparation of calibrators, controls, reagents, and other materials used in testing; calibration and calibration verification procedures; control procedures; and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. This was confirmed by the TP at 10:30 AM on the day of the survey. 3. The laboratory did not have a procedure for performing the validation on the Cepheid GeneXpert System. 4. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory procedure manual did not contain written preanalytical, analytical, and post analytical policies and procedures for performing testing in the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on procedure manual and temperature log record review and interview with the laboratory director (LD), the laboratory failed to define, monitor, and document laboratory refrigerator, room, and heat block temperature and room humidity to ensure proper reagent storage, and accurate and reliable test system operation and test result reporting. Findings: 1. "BD Affirm Microbial Identification Test" "Affirm Temperature/Humidity Charts" were reviewed from September and October, 2021. There were no other temperature records available at the time of the survey. Laboratory staff stated that they thought the technical consultant had taken them offsite/out of the laboratory. 2. The laboratory refrigerator temperature range is 2 - 8C. In October, 2021 the laboratory staff wrote the date instead of documenting the refrigerator temperature on 6 of 12 days that testing was performed. 3. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory failed to document laboratory temperatures and humidity in the laboratory to ensure reliable test system operation.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record and procedure manual review, surveyor observation, and interview with the laboratory director (LD), the laboratory failed to ensure that reagents are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Findings: 1. The laboratory uses the BD Affirm VPIII Microbial Identification System and the Cepheid GeneXpert System to perform laboratory testing. 2. Record review showed that the laboratory had no written documentation of the lot numbers and expiration dates of reagents and quality control (QC) materials used on the Cepheid GeneXpert System. This was confirmed by the laboratory staff at 10:50 AM. 3. A review of the "BD Affirm Microbial Identification Test Reagent Kit Log" showed that 4 kits were documented with "Date Opened/QC'd" between 08/31 /2021 and 10/11/2021. The log did not include the date the kit was received into the laboratory. 4. During a tour of the laboratory it was observed that there were 5 additional kits stored in the cupboard at room temperature (Lot # 1036107, exp. 12/02 /2021; Lot # 1103380, exp. 03/08/2021; and Lot # 1120790, exp. 03/08/2021). These kits were not labeled with the date that they were received into the laboratory. 5. The "BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure" under "Storage of Reagents" states that "The Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8C prior to use.

	Alternatively, store at room temperature (up to 30C) for no more than 3 months." There was no way to determine how long the kits had been stored at room temperature or if they were expired and unsuitable for use according to the manufacturer's instructions. 6. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not document the lot numbers and expiration dates of reagents and QC material used for testing to ensure that these items were not used after they had exceeded their expiration date.
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: I. Based on record review and interview with the laboratory director (LD), the laboratory failed to ensure that the laboratory validated the BD Affirm VPIII Microbial Identification System to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before being used for patient testing. Findings: 1. The laboratory performs testing for Candida species, Trichomonas vaginalis, and Gardnerella vaginalis using the BD Affirm VPIII Microbial Identification System. Review of the "Method Validation Worksheet" showed that as part of the validation the laboratory performed split sample testing with 10 patients, testing them on its instrument as well as sending them to a reference laboratory (RL). 2. Record review showed that samples 1 and 2 were negative for all 3 organisms on the laboratory's instrument, but it was not clear if the panel tested at the RL included Garderella vaginalis. 3. Sample 3 tested positive for Gardnerella and Candida on the laboratory's instrument, but the RL reported that the specimen was negative for all 3 organisms. 4. Sample 4 tested positive for Garderella on the laboratory's instrument, but the RL panel ordered reported a "score" of "4", indicating the "presence of bacterial vaginosis." There was no way to determine how to compare the results. 5. Samples 6 and 9 tested positive for Candida on the laboratory's instrument. The RL reported the same results, however the panel ordered did not include testing for Trichomonas. 6. Sample 8 tested negative for all 3 organisms on the laboratory's instrument, but the RL reported that the sample was positive for Gardnerella. 7. Sample 10 tested negative for all 3 organisms on the laboratory's instrument, but the panel ordered from the RL did not include testing for Trichomonas. 8. None of the 10 samples sent for split testing was positive for Trichomonas. 9. Review of validation documents showed that the technical consultant signed off on the validation on 11/23/2021, however the validation was not approved and signed by the LD. This was confirmed during an interview with the LD on 10/18/2021 at 4:00 PM. II. Based on record review and interview with the laboratory director (LD), the laboratory failed to ensure that the laboratory validated the Cepheid GeneXpert System to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before being used for patient testing. Findings: 1. The laboratory performs waived testing for SARS-Cov-2 and moderate complexity testing for Chlamydia trachomatis (CT) and Neisseria

	gonorrhoeae (NG) with the Cepheid GeneXpert System. 2. Record review showed that the laboratory validated the instrument and testing system for the "4-Plex" test cartridge (Xpert Xpress SARS-CoV-2/Flu/RSV), however the lab is currently using the "Xpert Xpress SARS-Cov-2" cartridge. There was no documentation that the new cartridge had been validated before use. 3. Review of validation documents for the CT /NG test cartridge showed that as part of the validation the laboratory performed split sample testing with 10 urine and 10 vaginal swab specimens on its instrument as well as sending them to a reference laboratory. 4. All specimens for both specimen types were negative for CT/NG. There were no positive specimens included in the comparison. 5. The validation was not approved and signed by the LD. This was confirmed during an interview with the LD on 10/18/2021 at 4:00 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on instrument maintenance record review and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to ensure that maintenance is performed and documented as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings: 1. The laboratory uses the BD Affirm VPIII Microbial Identification System and the Cepheid GeneXpert System to perform laboratory testing. 2. Document review showed that no instrument maintenance records were present at the time of the survey for either instrument. 3. During an interview on 10/18/2021, TP were not aware of what maintenance procedures were required to maintain optimum operating characteristics of the analyzers and confirmed that maintenance was not performed and documented as recommended by the manufacturer. This was confirmed by the LD at 4:00 PM on the day of the survey.
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: I. Based on procedure manual and quality control (QC) record review, electronic communication with the practice manager, and interview with testing personnel (TP) and the laboratory director (LD), the laboratory failed to run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for performing testing on the BD Affirm Microbial Identification System.

	Findings: 1. In an email received on 11/08/2021 the practice manager stated that the laboratory began testing with the BD Affirm VPIII Microbial Identification System on 11/30/2020. 2. During an interview at 10:43 AM on the day of the survey, the TP stated that the technical consultant told them that they only had to run QC when a new kit of BD Affirm Microbial Identification tests was opened. 3. QC record review showed that QC was run on 9/22/2021, 10/27/2021, and 11/02/2021. 4. There was no documentation of any other QC runs available at the time of the survey. 5. During an interview the TP stated that they did not know if the laboratory had an IQCP in place to reduce the amount of QC required when performing testing on the BD Affirm. Documentation of an IQCP was not found in the laboratory's records at the time of the survey. 6. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not have an IQCP in place to reduce the amount of QC required when performing testing on the BD Affirm Microbial Identification System. II. Based on procedure manual and quality control (QC) record review, electronic communication with the practice manager, and interview with testing personnel (TP) and the laboratory director (LD), the laboratory failed to run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for performing testing on the Cepheid GeneXpert System. Findings: 1. In an email received on 11/08/2021 the practice manager stated that the laboratory began testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) with the Cepheid GeneXpert System on 02/03/2021. 2. During an interview at 10:43 AM on the day of the survey, the TP stated that the technical consultant told them that they only had to run QC once a month. 3. Review of the "CT/NG Monthly Control Log" for 2021 showed that QC was documented for October, November, and December, 2021. There was no documentation of any other QC runs available at the time of the survey. 4. During an interview the TP stated that they did not know if the laboratory had an IQCP in place to reduce the amount of QC required when performing testing on the Cepheid GeneXpert. Documentation of an IQCP was not found in the laboratory's records at the time of the survey. 5. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not have an IQCP in place to reduce the amount of QC required when performing testing on the Cepheid GeneXpert System.
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 quality assurance (QA) record and procedure manual review and interview with the laboratory director (LD), the laboratory failed to 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. Findings: 1. The procedure, "Quality Assessment Program" states that "As problems in the laboratory surface and are corrected, all actions taken are documented on the appropriate corrective action forms and maintained with all other essential documents pertaining to the problem for a period of two (2) years" and "A QA review is performed each month using the Monthly Quality Assurance Review Form." 2. Record review showed that there were no "corrective action forms" present at the time of the survey and there was no documentation of QA reviews being performed since

	the laboratory began testing in November, 2020. 3. During an interview on 10/18 /2021 at 4:00 PM, the LD confirmed that the laboratory did not 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.
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 record review and interview with the laboratory director (LD), the LD failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the BD Affirm VPIII Microbial Identification System and the Cepheid GeneXpert System (D6013) and failed to ensure that the laboratory has documentation that all testing personnel have the appropriate education, experience, and training to perform laboratory testing (D6029).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the BD Affirm VPIII Microbial Identification System and the Cepheid GeneXpert System. Cross-refer to D5421.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the LD failed to ensure that the laboratory has documentation that all testing personnel have the appropriate education, experience, and training to perform laboratory testing. Findings: 1. The laboratory currently has 4 testing personnel (TP) listed on the "Laboratory Personnel Report (CMS-209)" form. 2. Record review showed that there was no documentation of TP credentials (diplomas/school transcripts/training) for 4 of 4 TP at the time of the survey. 3. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the laboratory did not have documentation showing that TP were qualified to perform testing in the laboratory.
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: Based on record review and interview with testing personnel (TP) and the laboratory director, the technical consultant failed to verifiy the test procedures performed and establish the laboratory's test performance characteristics, including the precision and accuracy of each test and test system (D6040); failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure 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 (D6042); failed to ensure that each individual performing tests received training and education appropriate for the type and complexity of the laboratory services performed (D6045); and failed to perform and document the competency reviews on all TP (D6046).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: The technical consultant failed to verifiy the test procedures performed and establish the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. Cross-refer to D5421.
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: The technical consultant failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure 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. Cross-refer to 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 record review and electronic communication with the practice manager and interview with the laboratory director (LD), the technical consultant (TC) failed to ensure that each individual performing tests received training and education appropriate for the type and complexity of the laboratory services performed. Findings: 1. In an email received on 11/08/2021 the practice manager stated that the laboratory began testing with the BD Affirm VPIII Microbial Identification System on 11/30/2020 and with the Cepheid GeneXpert System on 02/03/2021. 2. The laboratory currently has 4 testing personnel (TP) listed on the "Laboratory Personnel Report (CMS-209)." Record review showed that there was no documentation of initial training on the BD Affirm for 2 of the 4 TP (TP #2 & #4); and 3. There were no training records for the Cepheid GeneXpert System for 4 of 4 TP available at the time of the survey. 4. During an interview on 10/18/2021 at 4:00 PM, the LD confirmed that the TC failed to ensure that all TP were trained to perform testing in the laboratory.
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 record review and electronic communication with the practice manager and interview with the laboratory director (LD), the technical consultant (TC) failed to perform and document the competency reviews on all testing personnel (TP). Findings: 1. The laboratory currently has 4 TP listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." 2. In an email received on 11/08/2021 the practice manager stated that the laboratory began testing with the BD Affirm VPIII Microbial Identification System on 11/30/2020 and with the Cepheid GeneXpert System on 02

	/03/2021. 3. Record review showed that there was no documentation that competency assessments were performed on 4 of 4 TP. This was confirmed during an interview with the LD on 10/18/2021 at 4:00 PM.