Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1047526	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Project Of The Quad Cities, The	4101 John Deere Road, Moline, IL	

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
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 record review, the Laboratory Personnel Report (CMS 209), and an interview with the office staff; the laboratory failed to establish written procedures to assess employees performing Microbiology testing, affecting 1 out of 1 testing personnel (TP1). Findings: 1. The CMS 209, personnel records, and the laboratory's policies and procedures were reviewed. 2. The laboratory's competency policy failed to include the following: *A written competency procedure for Gram Staining; *A written competency procedure for Potassium Oxide (KOH) for fungal identification and *A written competency procedure for Wet Preparation testing. 3. TP1 was listed on the CMS 209 for performing the above tests. 4. The personnel documents revealed that TP1 had not been trained or assessed for competency to perform the above Microbiology tests prior to testing patients. 5. The laboratory failed to establish and implement written competency procedures to assess TP1 before testing patients. 6. On an Initial survey conducted on 03/12/20 at 12:00 PM, the office staff confirmed the above findings.
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 record review and an interview with the office staff, the laboratory's procedures manual failed to include all the applicable requirements specified in 493. 1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory in the specialty of Microbiology. Findings: 1. The laboratory procedures manual was reviewed. 2. The laboratory performs the following staining and organism identification procedures: Gram Stain, Potassium Oxide (KOH) and Wet Preparation (Wet Prep). 3. The procedures manual failed to include the following written policies and procedures: * The Control procedures for KOH and Wet Prep testing. * Corrective action to take when control results fail to meet the manufacturer's criteria or acceptability. * The laboratory's method for entering results in the patients' records and reporting patient results, * Description of the course of action to take, if a test can not be performed on-site. 4. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
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 direct observation, record review and an interview with the office staff, the laboratory failed to obtain signed approval of all procedures from the laboratory director (LD) for tests in the specialty of Microbiology, affecting all patients. Findings: 1. The laboratory procedures manuals were reviewed. 2. The 'Clinical Standard Work' (CSW) manual includes all of the laboratory's preanalytic procedures. 3. Visual review of the CSW manual showed no evidence of the laboratory director's (LD) approval. 4. The laboratory failed to ensure the CSW manual received written approval from the LD before the procedures were implemented in the laboratory. 5. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
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 direct observation, record review, lack of documentation, and an interview with the testing personnel (TP1); the laboratory failed to monitor and document required temperature conditions essential for proper storage of test slides to ensure accurate and reliable test result reporting. Findings include: 1. The laboratory's procedures manual and the manufacturer's package inserts were reviewed. 2. The AlphaTec Gram Stain Control slides package insert stated the slides must be stored in a temperature range of 15 to 30 degrees Celsius (59-86 degrees Fahrenheit). 3. On 03/12/2020 at 10:35 AM, during a tour of the facility, the surveyor observed that the Gram Stain Slides were stored in the patient's examination rooms. Further observation revealed the rooms had thermometers; however, no written evidence that the temperatures in these individual patient rooms were recorded. 4. The laboratory manual failed to include a policy and procedure to ensure the storage room for the slides were documented and monitored as required by the manufacturer. 5. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and an interview with the testing personnel (TP1); the laboratory failed to document each reagent and shipment of reagents, affecting all patients. Findings include: 1. The laboratory's procedures manual and the Project STD Client logbook were reviewed. 2. On 03/12/2020 at 10:35 AM, during a tour of the laboratory, the surveyor observed the following reagents in-use: *Crystal Violet - Used in Gram Stain (GS) procedure; *Iodine - Used in GS procedure; *Decolorize - Used in GS procedure; *Counterstain - Used in GS procedure; *Potassium Hydroxide solution - Used for fungal identification; *Saline solution - Used for Parasite identification 3. The Client logbook revealed that the lot numbers and expiration dates of the above reagents were not recorded with the patients' test information and results. 4. The laboratory failed to document the lot numbers and expiration dates of all it's staining reagents. 5. The laboratory manual failed to establish a procedure for documenting the reagents used for Gram staining, Fungal and Parasite identification. 6. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the TP1 confirmed the above findings.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the testing personnel (TP1); the laboratory failed to document all control procedures performed, affecting 9 out of 9 patients. Findings include: 1. The laboratory's procedures manual, the AlphaTec Gram Stain Control slides, manufacturer's package inserts, and the Project STD Client Logbook were reviewed. 2. The AlphaTec Gram Stain Control slides are used to perform Gram stain procedures on patient specimens. Each slide includes Gram negative organisms (Gr -) and Gram positive organisms (Gr +) for quality control (QC). 3. Review of the laboratory's test logs, patients' slides and result reports revealed the following: *Nine (9) patients were selected from the test log for chart review. *For 9 out of 9 patients' Gram stains, the test date and lot numbers were not written on their respective slides. *The QC results for 9 out of 9 patients were not were recorded. *No documentation was provided to show that the Gram stain QC procedures were performed and met the manufacturer's criteria, prior to reporting patients results. 4. The laboratory manual failed to include a policy and procedure for documenting the Gram Stain slide QC information and results. 5. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the TP1 confirmed the above findings.
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 an interview with the office staff, the laboratory failed to have a director who provide overall management and direction in accordance with 493. 1407 for testing performed in the specialty of Microbiology. Findings: 1. The LD failed to ensure quality control and quality assessment programs are established and maintained. See D6022. 2. The LD failed to ensure all personnel have appropriate education and training for the Microbiology testing performed, and have demonstrated their competency. See D6029. 3. The LD failed to specify in writing the authorization of each individual engaged in testing, prior to testing patients. See D6032.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on record review and an interview with the office staff, the laboratory director (LD) failed to ensure quality control and quality assessment programs are established and maintained to identify failures in quallity as they occur in the specialty of Microbiology. Findings Include: 1. The procedures manuals were reviewed. 2. The manual failed to establish the following policies and procedures: *Quality control (QC) procedures for the Fungal and Parasite identification tests; *Procedures for documenting QC information and results for ;the Gram stain, Fungal and Parasite identification tests; *Quality assessment policies and procedure to monitor and identify pre-analytic, analytic, and post-analytic phases of the laboratory processes. 3. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
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, the Laboratory Personnel Report (CMS 209), and an interview with the office staff; the laboratory director (LD) failed to ensure that prior to testing patients' specimen, all personnel have appropriate education and training for the Microbiology testing performed, and have demonstrated that they can perform the testing reliably to provide and report accurate results for 1 out of 1 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and patients' test logs were reviewed. 2. TP1 was performing Gram Staining, Potassium Hydroxide (KOH) and Wet preparation testing on patients. 3. The LD failed to ensure TP1 met the education criteria and was trained and assessed for competency to perform the above tests, prior to testing patients. 4. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
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: Based on the Laboratory Personnel Report (CMS 209), the laboratory's records and an interview with the office staff; the laboratory director (LD) failed to specify in writing the authorization of each individual engaged in the performance of the analytic phase of testing, prior to reporting patient test results for 1 out of 1 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and the procedures manual were reviewed. 2. The personnel files of TP1 performing Gram Staining, Potassium Hydroxide (KOH) testing and Wet mount Preparations (Wet Preps) revealed the following: a). The LD failed to have written authorizations for TP1 to perform patient testing and report results. b). The LD failed to specify in writing for TP1, whether supervision is required for test performance or results reporting, and whether a consultant or director review is required. 3. The requirement for authorizing laboratory personnel to test patients was not included in the laboratory's competency policies and procedures manual. 4. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.
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 record review and an interview with the office staff; the laboratory failed to ensure individuals meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the complexity of tests performed in the specialty of Microbiology for 1 out of 1 testing personnel (TP). Findings: 1. The laboratory failed to ensure that laboratory personnel meet the education requirement for moderately complex testing, prior to testing patients. See D6065.
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: Based on record review, the Laboratory Personnel Report (CMS-209) and an

	interview with the office staff; the laboratory failed to ensure laboratory employees meet the qualification requirements for performing moderately complex testing in the specialty of Microbiology for 1 out of 1 testing personnel (TP). Findings: 1. The CMS 209 and the employee files were reviewed. 2. The CMS 209 lists TP1 performing Gram Stain and Fungal and parasite identification. 3. The personnel education credentials revealed that TP1 had education documentation from a foreign country. These documents had not been evaluated for United States equivalency. 4. The laboratory failed to ensure the foreign documents of TP1 met the education requirements for moderately complex testing, prior to testing patients. 5. On an Initial survey conducted on 03/12/2020 at 12:00 PM, the office staff confirmed the above findings.