Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0875952	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a lack of proficiency testing records and reports, the laboratory failed to have complete documentation of American Proficiency Institute (API) Proficiency Testing (PT) records to include the attestation statement for a minimum of two years. Findings Include: It was confirmed with the laboratory testing person on July12, 2018 at approximately 12:20 pm that the laboratory failed to have documentation of handling, preparation, processing, examination and each step in the testing and reporting of results and the attestation for all PT samples for 2016 second & third events, 2017 all three events and the first event in 2018 along with the signed attestation statements.
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's API PT score reports and confirmed in an interview with the laboratory testing person, the laboratory failed to satisfactorily participate in a CMS-approved PT program for Bacteriology. The following score was assigned: 2016 second event = 40% 2018 first event = 40% Both are considered unsatisfactory PT performance test events.
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 surveyor's review of the laboratory policies/procedures, annual competency records and an interview with the laboratory testing person, the laboratory failed to have a complete policy and procedure for personnel competency and perform annual competency. Finding Include: 1) It was confirmed by the laboratory testing person on July 12, 2018, at approximately 12:00 pm that the laboratory failed to have a complete written procedure for annual competency to include direct observation for testing personnel number one for calendar year 2017 and 2018. 2) The laboratory failed to perform annual competency for testing personnel number two in the calendar years 2017 and 2018.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of API PT reports and an interview with the laboratory testing person, the laboratory did not evaluate, perform and document remedial action for the PT score that was less than 100% for the 1st event in 2017 for bacteriology testing. Findings Include: It was confirmed with the laboratory testing person on July 12, at approximately 12:20 pm that the laboratory failed to evaluate the results received for: 2017 first event Bacteriology = 80%
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on reviewing proficiency testing results from API the second event for 2016 and first event for 2018, and lack of documentation, the laboratory failed to document the evaluation of three of five unsatisfactory test results for the bacteriology samples.

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 a review of procedures and an interview with the laboratory testing person, the laboratory failed to have a procedure explaining how they are documenting the results of throat culture when not using the bacitracin disk. Findings Include: 1) It was confirmed with the laboratory testing person on July 12, 2018 at approximately 11:30 am that the laboratory no longer uses the bacitracin disk for throat cultures and continues to document "Pos for Strep A". 2) The laboratory failed to have a procedure indicating that throat cultures are now read and documented for Beta hemolysis or no Beta hemolysis. 3) Approximately 300 patient specimens have been read and test results released during this time period. This is a recitation of the last survey of July 21, 2016.
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 a lack of refrigerator and incubator temperature records and an interview with the laboratory testing person, the laboratory failed to have available for review temperature records for the storage refrigerator and the incubator used to incubate throat cultures.
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 surveyor's observation of vacutainer blood tubes and an interview with the laboratory testing person, the laboratory failed to discard the expired blood tubes used for patient testing. Findings: It was confirmed with the laboratory testing person on July 12, 2018 at approximately 11:45 am that the laboratory retained and used the following expired vacutainer blood tubes: Grey top - Lot #7016716, expired 6/30/18 Navy Blue Top Lot #7157861, expired 6/30/18 Yellow Top - Lot #4156881, expired 6 /16 Turquoise Top - Lot #6253984, expired 6/30/18 Turquoise Top - Lot #7180816, expired 4/30/18
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the laboratory testing person, the laboratory failed to check each new batch or lot number of Strep Select Agar (SSA) for sterility. Findings Include: It was confirmed with the laboratory testing person at the time on July 12, 2018 at approximately 10:30 am that the laboratory failed to perform the sterility check for SSA plates. Approximately patient specimens were tested for throat cultures from July 2016 through the date of this survey. This is a recitation from the survey of July 21, 2016.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) policy, records and confirmed in an interview with the laboratory testing person, the laboratory failed to

	identify, take corrective action and revise policies necessary to prevent the recurrence of failing to perform throat culture sterility checks from August, 2016 through the date of this survey.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of the test reports and confirmed in an interview with the laboratory testing person, the laboratory failed to have the address of the laboratory documented on five of five patients test charts reviewed.
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 surveyor findings and interview with the laboratory testing person, the director failed to provide overall management and direction for the laboratory. Findings Include: The director failed to ensure that: 1. Plan of correction from the survey conducted on July 21, 2016 was implemented and maintained. 2. A corrective action plan for PT was performed. Refer to D6019 3. The QC program for bacteriology was maintained. Refer to D6020 4. The QA program for bacteriology was maintained. Refer to D6021 5. Training for the new testing person was documented. Refer to D6029 6. Semi-annual and annual competency was documented. Refer to D6053 & D6054
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on a review of API PT reports, and an interview with the laboratory testing person, the laboratory director failed to ensure that an approved corrective action plan is followed when proficiency testing results are found to be unsatisfactory. Refer to D2015, D2020 & D5211
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: Based on a review of QC records, and confirmed in an interview with the laboratory testing person at the time of this survey, the laboratory director failed to ensure that the QC program for throat culture testing was maintained to assure quality of laboratory services. Refer to: D5413 and D5477 This is a recitation from the survey of July 21, 2016.
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 surveyor's review of laboratory procedures and an interview with the laboratory testing person, the laboratory director failed to: 1. Have a complete procedure for performing sterility checks for the SSA agar. 2. The laboratory failed to discard expired blood tubes. 3. The laboratory failed to perform corrective action when identified. Refer to: D5403, D5417 and D5793
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 a review of personnel records and an a telephone interview with the laboratory director, the laboratory director failed to ensure that appropriate training was documented for the new testing person who began testing in late 2016 and performs the moderately complex testing for throat cultures.
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 a review of the personnel records and an interview with the laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation for the new testing personnel during the first year of patient testing in calendar year 2017. Refer to D5209.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a lack of competency records and an interview with the laboratory testing person, the director, acting as the technical consultant, failed to ensure that annual competency for one of two laboratory testing personnel was performed in 2017 and 2018. Refer to D5209