Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0878705	08/09/2019
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
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 record review and interview with the testing personnel and technical consultant, the laboratory did not check each batch of selective strep throat culture agar and urine culture agar for sterility, the ability to support growth and inhibit growth of specific organisms prior to using for patient testing. Findings: 1. Review of the laboratory worksheets for 2018 through August 2019 showed that the laboratory did not perform a risk assessment for the media purchased from an outside vendor. The laboratory did not check the throat agar and urine culture agar for sterility, the ability to support growth and inhibit growth of specific organisms prior to using for patient testing. 2. During the survey on 08/09/19 at 12:30 PM the testing personnel and technical consultant confirmed that the throat culture agar and urine culture were not checked for sterility, the ability to support growth and inhibit growth of specific organisms prior to using for patient testing. The laboratory had not completed an Individual Quality Control Plan (IQCP) and risk assessment to eliminate the need for the end user quality control requirements.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)

	(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment (QA) program did not include a postanalytical system to ensure that the laboratory director and testing personnel were informed of QA reviews conducted by the technical consultant (TC). Findings: 1. At the time of the survey the QA reviews were not available for 2018 and 2019. 2. When interviewed the TC stated that the QA reviews were not available in the laboratory at the time of the survey and that the laboratory director was not evaluating (initialing and dating) the reviews performed by the TC. 3. During the survey on 08/09/19 at 12:30 PM the TC confirmed that the QA plan did not include a system for communicating the findings of the monthly QA review to the laboratory director and the testing personnel to ensure that problems and corrective actions are discussed with the staff members as a part of an ongoing in-service program.
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 interview with the technical consultant (TC), the laboratory director failed to ensure that the TC was documenting a regular review of the laboratory worksheets, quality control (QC) records and maintenance records. Findings: 1. The laboratory QC records for 2018 and 2019 were reviewed. The records did not include documentation of the on-site visits performed by the TC to verify compliance with the CLIA regulations. 2. The duties and responsibilities of the TC states that a monthly review of the QC logs is to be performed. Review of the daily instrument QC print-outs show that the TC initialed the printout but there was no date of the review. The monthly QC graphs did not include a signature or date showing that the review was performed in a timely manner. 3. The duties and responsibilities of the TC states that a review of all proficiency testing and QC logsheets are also done on a quarterly basis. There were no records showing a quarterly review. 4. The TC is responsible for performing the annual evaluations of the testing personnel. The records that were available for 2018 and 2019 did not include the original signature of the TC verifying the evaluation was performed by the TC. 5. During the survey on 08/09/19 at 12:30 PM the TC confirmed that there was no documentation showing the times that the TC visited and reviewed laboratory records at the time of the survey.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: The technical consultant was not documenting a regular review of the laboratory worksheets, quality control (QC) records and maintenance records that included the date of the review. Cross refer to Tag D6022 for details.
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 evaluation documentation and interview with the technical consultant (TC), the TC did not ensure that all testing personnel received an initial and semiannual competency review. Findings: 1. The laboratory currently has eleven testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)". 2. The testing personnel evaluation records for 2017, 2018 and 2019 were reviewed. Two of the eleven files for the testing persons showed only an annual evaluation and did not include documentation of the initial and semiannual evaluations. 3. During the survey on 08/09/2019 at 12:30 PM the TC confirmed that there were no records in the file documenting the initial and semiannual evaluation of two of the eleven testing persons listed on the CMS-209.