Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0928381	06/05/2018
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
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 surveyor's review of the manufacturer's packet inserts for the Siemens Multistix and interview with the laboratory director/testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the Siemens Multistix 10SG. FINDINGS: 1. The packet insert for the Siemens Multistix requires that external controls be performed with each new Vial of Multistix opened. On June 4, 2018 at approximately 11:00 AM the laboratory director/testing person confirmed surveyor's findings that documentation for the required external control testing was not available for calendar years 2016 and 2017. 2. Approximately 20 patient's specimens were tested and reported for urinalysis.
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 a surveyor's observation of the 0.04 bacitracin disc used for identification of Streptococcus A and an interview with the laboratory director/testing person, the

	laboratory failed to discontinue the use of the expired testing materials. FINDINGS: 1. On June 4, 2018 at approximately 11:30 AM the laboratory director/testing person confirmed surveyor's findings, that the laboratory failed to discontinue the use of the expired 0.04 bacitracin disc for the following lots: #5078770 expiration date 6/17/15 and #5310860 expiration date 5/31/17. 2. Approximately 120 patient's were tested and reported for throat cultures.
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: laboratory failed to check each new batch, lot number and shipment of the bacitracin disks and failed to check each new batch, lot number and shipment of Selective Strep Agar (SSA) Media for positive and negative reactivity from February 2016 to survey date. FINDINGS: 1. On June 4, 2018 at approximately 11:30 AM the laboratory director/testing person confirmed surveyor's findings that the laboratory failed to check each new batch, lot number and shipment of the bacitracin disks and failed to check each new batch, lot number and shipment of Selective Strep Agar (SSA) Media for positive and negative reactivity from February 2016 to survey date. Following lots for SSA media were not tested: Lot numbers/expiration dates 5309946/ 2/05/16 5321732/ 2/16/16 6244544/ 1/11/17 6314523/ 2/07/17 8005582/ 4/11/18 8068547/ 6/7/18 Following lots for bacitracin disc were not tested: Lot numbers/expiration dates 5078770/ 6/17/15 2. Approximately 120 patient's specimens were tested and reported for throat culture.
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 a surveyor's review of the laboratory's policy and procedure manuals and confirmed in an interview with laboratory director/testing person, the laboratory failed to follow their QA policy and identify and correct QC problems in the general laboratory system for bacteriology testing. FINDINGS: The laboratory director/testing person confirmed on June 5, 2018 at approximately 11:30 AM. that the laboratory failed to identify the quality control issues for bacteriology testing. a. Use of expired 0.04 bacitracin discs, refer to D5417 b. Failure to perform and document QC for the SSA media for its ability to support growth, refer to D5477

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 a surveyor's findings and interview with the laboratory director/testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. Bacteriology QC program was maintained, refer to D6020; 2. QC problems were identified and corrective action was taken, refer to D6024.
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 surveyor's review of the laboratory records, and confirmed in an interview with the laboratory director/testing person, the laboratory director failed to ensure that the laboratory's QC program was maintained to assure quality of laboratory services. Refer to: D5417 and D5477.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on the surveyor's review of bacteriology records, observation of SSA media & 0.04 bacitracin disc and confirmed in an interview with the laboratory director/testing person, the laboratory director failed to ensure that bacteriology problems were identified and remedial action was taken. Refer to D5791.