Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0942131	03/03/2020
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 insert for Clarity Multistix and an interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the urine Multistix. FINDINGS: 1. The laboratory is using Clarity Multistix on the Urocheck 120 analyzer. The packet insert for the urine Multistix requires that external controls be performed with each new Vial of Multistix opened. 2. On March 3, 2020 at approximately 11:00 AM the technical consultant confirmed surveyor's findings that documentation for the required external control testing was not available for the Multistix from January 2020 through the survey date. 3. Approximately 50 patients specimens were tested and reported for urinalysis using the Multistix.
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: Based on lack of validation records and an interview with the technical consultant, the laboratory failed to perform and document a complete method validation for the new Bio Fire Film Array analyzer prior to patient testing in January 2020. Findings: 1. On March 3, 2020 at approximately 11:30 AM the technical consultant confirmed that Method validation was not performed for Bio Fire Film Array used to test Respiratory Panel prior to patient testing in January 2020. 2. Approximately 50 patient specimens were tested and reported for Respiratory Panel during above time frame.
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 a surveyor's review of endocrinology and virology quality control (QC) records and an interview with the technical consultant, the laboratory failed to ensure that endocrinology and virology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Review of QC records found and it was confirmed with the laboratory director on March 3, 2020 at approximately 11:30 AM during review of QC data that the following level of control materials were out of acceptable range and remediation was not performed: 1. On February 4, 2020 one out of two controls were out of acceptable range for Testosterone and Vitamin D 2. On February 18, 26, 2020 two out of two controls were out of acceptable range for Vitamin D 3. On February 20, 28, 2020 one out of two controls were out of acceptable range for FSH 4. On February 1, 21, 2020 one out of two controls were out of acceptable range for Sensitive Estradiol 2 (Sens E2) and for Folate 5. On February 26, 28, 2020 two out of two controls were out of acceptable range for Testosterone and Sens E2 6. On February 27, 2020 one out of two controls were out of acceptable range for Parathyroid Hormone (PTH) and Progesterone 7. On February 28, 2020 one out of two controls were out of acceptable range for Luteinizing Hormone (LH) 8. On February 20, 25, 2020 one out of two controls were out of acceptable range for Respiratory Panel.
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's findings and an interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. Findings: The laboratory director failed to ensure that the laboratory: 1. Maintained the laboratory's QC program for endocrinology virology and urinalysis. Refer to D6020; 2. The QA program was maintained for all phases of laboratory testing. Refer to 6021.

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 QC records and confirmed in an interview with the technical consultant at the time of this survey, the laboratory director failed to ensure that the QC program for endocrinology, virology and urinalysis testing was maintained to assure the quality of laboratory services. Refer to: D1001, D5421, D5481
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 a surveyor review of the laboratory Quality Assessment (QA) policy and interview with the technical consultant, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5421