Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1068412	02/24/2022
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 review of laboratory's procedures, review of laboratory records and absence of documentation 2/24/22, the laboratory failed to maintain all PT (proficiency testing) records and failed to ensure the laboratory director and testing personnel signed the attestation statements for 4 of 4 testing events in 2020 and 2021. Findings: Review of the laboratory's Proficiency Testing Policy revealed, "Proficiency Testing Procedure and Guidelines"...2.. The individual testing or examining the samples and the Laboratory Director must attest to the routine integration of samples into the patients' workload using the laboratory's routine methods....5. The laboratory personnel will document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory will maintain a copy of all records for a minimum of two years from the date of the proficiency testing event..." Review of laboratory records revealed no documentation on file for the 2020 and 2021 API (American Proficiency Testing) PT events. The laboratory was able to contact API during the survey to obtain a copy of the graded PT results. The laboratory failed to maintain the PT report forms used by

	the laboratory to record PT results, copies of the instrument printouts, the confirmation of the electronic submission of the PT results to the PT vendor, and the review of the graded results by the laboratory director and testing personnel, and failed to ensure the laboratory director and testing personnel signed the attestation statements for the following: a. 2020 API Chemistry Miscellaneous 1st and 2nd events; b. 2021 API Chemistry Miscellaneous 1st and 2nd events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of policies and procedures, review of 2020, 2021, and 2022 laboratory records, observation, and interviews with the laboratory director 2/24/22, the laboratory failed to monitor and evaluate the overall quality of the urine toxicology testing performed on the Siemens Viva-E analyzer and failed to identify problems and implement corrective action. Findings: 1. The laboratory failed to follow manufacturer's instructions for storage and testing of specimens on the Siemens Viva-E analyzer (see D5411). 2. The laboratory failed to monitor and document refrigerator and room temperature and room humidity as required for storage of supplies and operation of the Siemens Viva-E analyzer (see D5413). 3. The laboratory failed to discard reagents and supplies that exceeded their expiration dates (see D5417). 4. The laboratory failed to perform and document 3-point calibration verifications every 6 months for each drug analyte on the Siemens Viva-E analyzer as required (see D5439).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, observation, and interview with the laboratory director 2/24/22, the laboratory failed to follow manufacturer's instructions for the urine toxicology testing performed on the Siemens Viva-E analyzer. Findings: The Siemens Syva Emit II Plus Buprenorphine Assay product insert states "... 5 Specimen Collection and Preparation ... If not analyzed immediately, specimens may be stored refrigerated or unrefrigerated for up to 5 days. After 5 days specimens should be stored frozen at -20 degrees C. ..." Manufacturer's instructions for other analytes such as cocaine, amphetamines, and opiates included storage for 7 days unrefrigerated and 30 days refrigerated. The laboratory's "Specimen Handling and Storage Policy" states "...

	Urine specimens to be tested using the Siemens Analyzer must be tested on date of collection or stored in designated refrigerators (2-8 degrees C) for a maximum of 3 days after collection. ... 5. When the maximum storage limits have been exceeded, then no further testing will be performed on the specimens and the specimens will be discarded per laboratory policy. ..." During tours of the laboratory at approximately 9: 45 a.m. and 10:20 a.m., surveyors observed approximately 300 patient urine specimens on the counter, on carts, and in the refrigerators in the laboratory. The urine specimens were labeled with collection dates from 1/28/22 - 2/21/22. Examples: a. 1 urine specimen labeled 1/28/22 and 17 urine specimens labeled 1/31/22 in a wire basket on the counter; b. 22 urine specimens labeled 2/1/22 in the large refrigerator; c. 22 urine specimens labeled 2/7/22 in the large refrigerator; d. 32 urine specimens labeled 2/8/22 in the small refrigerator; e. 22 urine specimens labeled 2/16/22 in the small refrigerator; f. 23 urine specimens labeled 2/18/22 in the small refrigerator; g. 21 urine specimens labeled 2/21/22 on a metal cart parked in the laboratory. During interview at approximately 9:30 a.m., the laboratory director stated that the lab is not currently testing patient specimens on the Siemens Viva-E analyzer. At approximately 10:00 a.m., the laboratory director stated that all the specimens in the laboratory would be discarded. He stated they kept the specimens because he thought they would be able to start testing again as soon as the new testing personnel was trained and he didn't realize it would take so long.
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 review of manufacturer's operator's manual and instructions for use, review of laboratory records, and absence of documentation 2/24/22, the laboratory failed to monitor and document the temperature of the large refrigerator used to store reagents, calibrators, and controls and failed to monitor and document the room temperature and room humidity of the laboratory where testing was performed. Findings: Review of the manufacturer's instructions for the assays performed on the Siemens Viva-E analyzer revealed a refrigerator storage range of 2-8 degrees C (Celsius) for reagents, calibrators, and controls. For example, the Siemens Syva Emit II Plus Specialty Drug Calibrators/Controls package insert states for Storage, "Always store the calibrators /controls refrigerated at 2-8 degrees C {36-46 degrees F (Fahrenheit)} when not in use. Store upright. Do not freeze or expose to temperatures above 32 degrees C (90 degrees F)." Review of the Viva-E analyzer operator's manual revealed environmental requirements for ambient temperature of 15 to 32 degrees C and for Max. relative humidity of 85% at 32 degrees C. Review of laboratory records revealed there was no documentation that the laboratory had monitored the refrigerator temperatures where reagents, calibrators, and controls were stored and no documentation that the laboratory had monitored room temperature and room humidity where testing was performed since time of last survey in January 2020, a period of approximately 25 months.

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 observation 2/24/22, the laboratory failed to discard reagents and supplies that had exceeded their expiration dates. Findings: 1. During a tour of the laboratory approximately 9:40-9:55 a.m., the surveyors observed the following reagents located in the large laboratory refrigerator, available for use: a. Open bottle of Syva Emit II Plus Specialty Drug Calibrator/Control level 2, lot #10872298-N1, expiration date: 10/7/21; b. Syva Emit Calibrator/Control level 2, lot #P1, expiration date: 12/29/21; c. 1 unopened bottle of Siemens Syva Emit II Plus Specialty Drug Calibrator/Control Level 2, lot #N1, expiration date: 10/7/21; d. Siemens Syva Emit II Plus Opiate Antibody/Substrate Reagent 1, lot #9B318UL-P4, handwritten expiration date: 1/26/22; e. Siemens Syva Emit II Plus Opiate Enzyme Reagent 2, lot #9B348UL-P4, handwritten expiration date 1/26/22; 2. During a tour of the laboratory approximately 12:10-12:15 p.m., the surveyors observed the following supplies in the cabinets under the counter, available for use: a. 1 unopened package of yellow top tubes (no additive), lot #7256796, expiration date: 9/30/19; b. 1 partial package of yellow top tubes (no additive), lot #9004545, expiration date: 1/31/21; c. 12 Multi-Drug Urine Test Panels, lot #W51291109, expiration date: 11/20/21.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of 2020 and 2021 calibration records, review of laboratory records and absence of documentation 2/24/22, the

	laboratory failed to perform 3-point calibration verifications every 6 months for each drug analyte on the Siemens Viva-E analyzer as required in 2020 and 2021. Findings: Review of the laboratory's procedure for 6-month Calibration Valdiation/linearity check revealed, " Every six months (June, December) a calbration validation/linearity check will be performed by running 10 replicates of the low control (0), high control (5), and one mid-point calibrator (run as a control) for a 3 point validation..." Random review of the 2020 and 2021 calibration records revealed the laboratory performs a one-point calibration weekly or as required after maintenence for each drug analyte on the Siemens Viva-E analyzer. Review of laboratory records revealed there was no documentation that the laboratory had performed the 3-point calibration verifications that were due in June and December in 2020 and 2021.
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 review of laboratory records, observation, and interview with the laboratory director, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure that 2020 and 2021 proficiency testing results were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action (see D6018). 2. The laboratory director failed to ensure the maintenance of an effective quality assessment program (see D6021). 3. The laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for the Siemens Viva-E analyzer (see D6023).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory records, the absence of proficiency testing records, and interview with the laboratory director 2/24/22, the laboratory director failed to ensure that 2020 and 2021 proficiency testing results from 4 of 4 testing events were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Review of laboratory records revealed no documentation on file for the 2020 and 2021 API (American Proficiency Institute) proficiency testing events. The laboratory was able to contact API during the survey to obtain a copy of the graded proficiency testing results for the 4 testing events. During interview at approximately 10:50 a.m., the laboratory director stated he was unsure whether they

	had received any graded proficiency testing reports from API for 2020 or 2021. He stated he had seen some reports from API periodically and signed off on them, but he was unsure where they might be.
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 review of the laboratory's quality assessment plan, the absence of records, and interview with the laboratory director 2/24/22, the laboratory director failed to ensure the maintenance of the quality assessment program to identify and correct problems and monitor and evaluate the ongoing and overall quality of the urine toxicology testing performed. Findings: The laboratory's "Quality Assessment Policy" states "... The laboratory director and technical personnel are responsible for the ongoing systematic quality assessment monitoring system ... The assessment will be derived from studies of all aspects of the laboratories operation, which will include: 1. General Laboratory Procedures 2. The Pre-Analytic Phase of testing 3. The Analytic Phase of testing 4. The Post-Analytic Phase of testing ... Quality indicators for this environment have been defined as: GENERAL: ... D. Monitoring patient and specimen identification, labeling and integrity of the specimen ... F. Evaluation of Proficiency Testing ... PRE-ANALYTIC PHASE: ... B. Specimen handling, collection and labeling ... ANALYTIC PHASE: ... B. Monitoring supply and storage of reagents, test equipment, instruments, and materials C. Verification of calibration, QC and maintenance records ... POST-ANALYTIC PHASE: ... B. Documentation of critical values and turn around time evaluation ... Each quality indicator will be reviewed according to the calendar established and documented on a quality assessment report form. Included will be pertinent data collected, interval for review, a summary and analysis of the findings, the acceptable threshold for those findings, the corrective action to be taken, date action will be completed and a follow-up review. All data, corrective action and follow-up will be approved by the Lab Director and will become part of the QA records to be retained. ..." There were no quality assessment records available for review during the survey. There was no documentation of routine reviews of pre-analytic, analytic, or post-analytic systems, and there was no documentation of problems identified by the laboratory or corrective actions taken since the last survey on 1/15/20. During the exit interview at approximately 2:20 p.m., the laboratory director confirmed that there were no quality assessment records available. He stated he thought some quality assessment activities had been performed, but he was unsure what might have happened to the documentation.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory records and the absence of records 2/24/22, and the deficiencies cited at D5413 and D5439, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for the Siemens Viva-E analyzer. Findings: 1. The laboratory failed to monitor and document the temperature of the large refrigerator used to store reagents, calibrators, and controls for the Siemens Viva-E analyzer and failed to monitor and document the temperature and humidity of the laboratory where the Siemens Viva-E analyzer is located (see D5413). 2. The laboratory failed to perform 3-point calibration verifications every 6 months for each drug analyte on the Siemens Viva-E analyzer as required (see D5439).