Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1077790	07/05/2022
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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interviews, the laboratory failed to follow manufacturer's instructions for proper specimen storage (See D5311), failed to have an effective quality assurance (QA) plan that identified manual data entry errors (See D5391), and failed to document quality assurance activities for preanalytic systems when specimens were rejected for testing (See D5393).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to have an effective quality assurance (QA) plan that identified issues with data entry during the pre-analytic phase of testing for 9 of 117 patient specimens tested for one (01/30/2022) out of eight days (01/30/2022, 02/20/2022, 03

	/05/2022, 03/22/2022, 04/02/2022, 04/25/2022, 05/08/2022, and 06/20/2022) that testing was performed. Findings Included: Record review of the laboratory's procedure "Quality Assurance" revealed the laboratory believes in a strong QA program. The entire laboratory staff will review potential problems and document all corrective actions taken. The QA system encompasses pre-analytical, analytical, and post analytical factors that can influence analytical results. It is the intention of this QA program to minimize laboratory error whether it is caused by pre-analytical, analytical, or post analytical factors. Record review of patient test results tested by the Medical Technologist on 01/30/2022 and signed as reviewed by the Laboratory Director revealed: Patient #2 had a "Draw Date" of 11/16/2022 Patient #3 had a "Draw Date" of 11/19/2022 Patient #4 had a "Draw Date" of 11/19/2022 Patient #5 had a "Draw Date" of 11/19/2022 Patient #6 had a "Draw Date" of 11/23/2022 Patient #7 had a "Draw Date" of 11/23/2022 Patient #14 had a "Draw Date" of 12/15/2022 Patient #15 had a "Draw Date" of 12/17/2022 Patient #17 had a "Draw Date" of 12/21 /2022 Observation during the recertification survey conducted on 01/06/2022 at 9:30 a. m. revealed the same Patients' urine specimens were in the refrigerator labeled with the following draw dates: Patient #2 - 11/16/2021 Patient #3 - 11/19/2021 Patient #4 - 11/19/2021 Patient #5 - 11/19/2021 Patient #6 - 11/23/2021 Patient #7 - 11/23/2021 Patient #14 - 12/15/2021 Patient #15 - 12/17/2021 Patient #17 - 12/21/2021 Telephone interview on 07/01/22 at 2:00 PM with the Laboratory Director revealed he did not notice that the data entry for the draw dates were incorrect and showed the year 2022 instead of 2021 when he signed the test reports.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the General Supervisor, the laboratory failed to document quality assessment for preanalytic systems when the laboratory rejected 9 specimens (#1, #8, #9, #10, #11, #12, #13, #16, #18) out of 18 specimens (#1-#18) that were found in the refrigerator during the recertification survey conducted on 01/06/22. Findings included: Observation during the recertification survey conducted on 01/06/2022 at 9:30 a.m. revealed urine specimens awaiting testing for urine pH, cannabinoids, and opiates were observed in the refrigerator for Patients #1, #8, #9, #10, #11, #12, #13, #16, and #18. Record review on 06/30/22 revealed none of these patients had test results. On 06/30/22 at 11:25 AM, the General Supervisor/Testing Personnel stated that the 9 specimens were rejected for testing per Laboratory Director instructions, but the specimen rejection steps were not documented. Review of the laboratory policy titled "Job Assessment" for the Laboratory Consultant signed by the General Supervisor/Testing Personnel on 9/10/13 revealed job duties included: "7. Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur... 9. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified..."

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the Laboratory Director failed to ensure overall compliance of the laboratory (See D6079) and failed to establish an effective preanalytical quality assurance program to ensure quality and accuracy of laboratory services (See D6094).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure overall compliance of the laboratory for two out of two years reviewed (2021-2022). Findings Included: Review of the delegation of Laboratory Director duties to the General Supervisor document revealed the Laboratory Director and the General Supervisor had not signed the document. On 06/29/22 at 2:15 PM, the Laboratory Director stated he had not reviewed the Statement of Deficiencies for the recertification survey conducted on 01/06/22 or the Allegation of Compliance signed by the Laboratory Director on 01/30/22 and submitted to the State Agency (SA). Continued interview with the Laboratory Director revealed he also had not reviewed the second Allegation of Compliance submitted to the SA via fax on 02/04/22 and signed by the Laboratory Director on 1/4/22 (before the recertification survey had occurred). When attempting to interview the Laboratory Director via telephone on 07/01/22 at 2:00 PM to discuss possible Immediate Jeopardy related to testing of patient specimens past the manufacturer's instructions for proper refrigerator storage requirements for opiates and cannabinoids (THC), he stated that the surveyor should be contacting the General Supervisor because she was in charge.