Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2205647	02/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Asap Labs And Care, Llc	2002 New Garden Road Unit 205, Greensboro, NC	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory calibration records and interview with the laboratory owner 2/21/23, the laboratory failed to retain calibration records for the testing performed on the Diatron Pictus 500 analyzer from July 2022 through December 2022, a period of approximately 6 months. Findings: Review of laboratory calibration records revealed no documentation of calibrations performed from July 2022 through December 2022. Interview with laboratory owner at approximately 2:30 p.m. confirmed the laboratory failed to retain calibration records from July 2022 through December 2022.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records, the absence of records, and interview with the laboratory owner 2/21/23, the laboratory failed to verify the accuracy of their urine toxicology testing at least twice during 2022. Review of API PT records revealed the laboratory was enrolled for urine toxicology testing during 2021 and participated in the 2021 1st and 2nd Chemistry

	Miscellaneous test events. Review of API PT records revealed the laboratory was also enrolled for 2023. There were no records of enrollment or participation in API PT for 2022. During interview at approximately 11:20 a.m., the laboratory owner stated she did not think PT was ordered for 2022. She stated that messages from API were sent to the personal email of a former employee, so she was unable to track the messages. She stated that they had not been able to locate any documentation of participation in PT or other activities to verify the accuracy of the urine toxicology testing during 2022.
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 laboratory procedure, review of 2020, 2021, 2022, and 2023 calibration and calibration verification records 2/21/23, the laboratory failed to perform a three point calibration verification every 6 months for the quantitative potential hydrogen (PH) and Urine Creatinine testing 3 of 4 required verifications since testing began 12/30/20. Findings: Review of laboratory procedure "Calibration and Quality Control Testing for the Pictus 500" revealed "Calibration verification: This is performed every six (6) months for analytes that are reported out quantitatively and have less than 3-point calibration.". Review of 2020, 2021, 2022 and 2023 calibration records for quantitative PH and Urine Creatinine testing revealed the laboratory performs a 2-point calibration for PH and Urine Creatinine. Review of 2020, 2021, 2022, and 2023 calibration verification records revealed the laboratory performed calibration verifications for PH and Urine Creatinine in December 2021, 12 months after testing began, and February 2023, 14 months after last calibration verification was performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken

	when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of performance specification records for the Diatron Pictus 500 analyzer and review of random patient test reports 2/21/23, the laboratory failed to ensure that corrective action was taken and documented for patient Urine Creatinine test results which exceeded the reportable range of 1.3-23.0 milligrams per deciliter (mg/dL) established by the laboratory for the Urine Creatinine testing from 12/30/20 - 2/21/23, a period of approximately 26 months. Findings: Review of laboratory procedure "Performance Specification Verification" revealed "Reportable Range: (Linearities). To verify the manufacturer's established reportable range for a test, choose samples with known values at the highest and lowest levels that the manufacturer claims accurate results can be produced by the system (5 - 6 levels).". Review of performance specification records, EP Evaluator dated 12/18/20, for the Urine Creatinine testing, revealed the laboratory did use 5 levels of samples, 1.3 mg/dL, 2.0 mg/dL, 7.5 mg/dl, 20.0 mg/dL and 23.0 mg/dL. The highest level established was 23.0 mg/dL. Review of 3 random patient test reports revealed Urine Creatinine test results were reported above the established reportable range of 23 mg /dL. For example: a. Sample Id 15480, resulted 2/1/23 - 95.6 mg/dL b. Sample Id 1260, resulted 2/1/23 - 115.5 mg/dL c. Sample Id 1261, resulted 2/1/23 - 131.1 mg /dL. The laboratory failed to recognize that the patient Urine Creatinine values exceeded the established reportable range, and failed to take any corrective action prior to reporting the patient results. The surveyor was unable to determine the number of patients affected from 12/30/20 - 2/21/23.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2020, 2021, 2022, and 2023 laboratory records, the laboratory director failed to ensure the establishment of an effective quality assessment plan designed to identify and correct problems and prevent their recurrence. Findings: Review of the laboratory's quality assessment plan revealed "... RESPONSIBILITY The lab service is under the jurisdiction of the Lab Director. It is the responsibility of the Technical Supervisor to implement the plan. The Laboratory Director and Technical Supervisor will be responsible either directly or by delegation for the following: ... 6. Assuring the prompt, accurate, and reliable reporting of test results. 7. Assuring the adequacy and competency of staff. 8. Maintaining required enrollment in Proficiency testing programs, with appropriate review and actions. 9. Overseeing the quality control

	program. ..." . The laboratory had documentation of routine quality assessment reviews by the general supervisor, but the reviews failed to identify the following problems identified during the survey: 1. The laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the urine toxicology testing during 2022. See D5217. 2. Patient urine creatinine test results were reported above the laboratory's established reportable range for approximately 26 months since testing began 12/30/20. Surveyor was unable to determine the number of patients potentially affected. See D5781. 3. The laboratory director failed to perform and document a competency evaluation for the general supervisor during 2022. See D6128.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and telephone interview with the general supervisor (GS) 2/21/23, the technical supervisor (TS) failed to perform and document a competency evaluation for the GS during 2022. Review of personnel records revealed the TS had evaluated the competency of the laboratory's former GS during 2021. There was no documentation of a competency evaluation for the former or the current GS during 2022. During telephone interview at approximately 11:00 a.m., the GS confirmed that she did not have a competency evaluation during 2022.