Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2158018	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prism Lab Llc	850 Ladd Rd Building B, Walled Lake, MI	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review, observation, and interview, the laboratory failed to have sufficient reagents to perform quantitative urine toxicology testing before specimens were no longer stable (refer to D3007) and failed to retain its documentation for its verification of accuracy (refer to D3031).
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #3, the laboratory failed to have sufficient reagents to perform quantitative urine toxicology testing before specimens were no longer stable for 56 of 56 patient urine specimens observed.

	Findings include: 1. A review of the laboratory's "PSYCH Panel Validation Report Summary" establishment of performance specifications revealed a section stating the following, "Pre-preparative (storage) stability was assessed by preparing multiple sets of samples at low, mid, and high concentrations and storing them at refrigerated temperature (2-8 degrees C) for up to 7 days." 2. A review of the laboratory's "MAIN PANEL Validation Report Summary" establishment of performance specifications revealed a section stating the following, "Storage stability (pre-preparative stability) for the analytes in urine at refrigerated temperatures (2-8 degrees C) was demonstrated for up to 7 days." 3. A review of the laboratory's "Urine Specimen Collection and Patient Instructions Policy" revealed a section stating, "If the samples are not analyzed immediately, specimens may be stored up to 7 days refrigerated and frozen for 30 days." 4. The surveyor observed 56 patient specimens with collection dates of 7/18/23 and 7/19/23 in the refrigerator on 7/31/23 at 10:30 am. 5. An interview on 7/31/23 at 10:30 am with Testing Personnel #3 revealed the specimens collected on 7/18/23 and 7/19/23 had not been tested yet due to a lack of a synthetic urine reagent.
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 record review and interview with the Lab Scientist, the laboratory failed to retain its documentation for its verification of accuracy for 1 (April 2022 Event) of 2 events reviewed. Findings include: 1. A review of the laboratory's April 2022 verification of accuracy testing event revealed a lack of documentation of the reference laboratory reports used to compare the accuracy of its quantitative toxicology testing. 2. The surveyor requested the documentation of the reference laboratory reports used to compare the accuracy of its quantitative toxicology testing on 7/31/23 at 12:17 pm and it was not made available. 3. An interview on 7/31/23 at 4: 20 pm with the Lab Scientist confirmed the laboratory did not have documentation of the reference laboratory reports used to compare the accuracy of its quantitative toxicology testing available.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review, observations, and interviews, the laboratory failed to assess the competency of its General Supervisor (refer to D5209), failed to perform verification of accuracy testing at least twice annually (refer to D5217), failed to follow its policies and procedures for specimen storage, preservation, acceptability, and rejection (refer to D5311), failed to establish policies and procedures for urine quantitative toxicology specimen transportation and calibration (refer to D5403), the

	laboratory failed to label its urine quantitative toxicology reagents with the preparation and expiration dates (refer to D5415 A), failed to label its urine quantitative toxicology control materials with the preparation and expiration dates (refer to D5415 B), and failed to perform corrective action when the urine quantitative toxicology analyte Normeperidine had failed its verification of accuracy criteria (refer to D5781).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to assess the competency of its General Supervisor for 2 (July 2021 to July 2023) of 2 years. Findings include: 1. A review of the laboratory's personnel competency documentation revealed a lack of competency assessments performed for the General Supervisor between July 2021 and July 2023. 2. The surveyor requested the General Supervisor's competency assessments on 7/31/23 at 2:11 pm and they were not made available. 3. An interview on 7/31/23 at 2:11 pm with the General Supervisor confirmed competency assessment documentation for the General Supervisor was not available.
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 record review and interview with the General Supervisor, the laboratory failed to perform verification of accuracy testing at least twice annually for 2 (July 2021 to July 2023) of 2 years for quantitative urine toxicology analytes performed by the laboratory. Findings include: 1. A review of the laboratory's verification of accuracy testing for its April 2022 and November 2022 testing events revealed a lack of documentation of the following analytes: a. Iloperidone b. Methylephedrine c. Zopiclone 2. A phone interview on 8/7/23 at 4:43 pm with the General Supervisor confirmed the laboratory had not verified the accuracy of the analytes listed above. ***This is a repeated deficiency from the 1/12/22 and 2/23/22 surveys.***
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its policies and procedures for specimen storage, preservation, acceptability, and rejection for 3 (Patients 8705, 9277 and 9805) of 3 patient test records reviewed. Findings include: 1. A review of the laboratory's "PSYCH Panel Validation Report Summary" establishment of performance specifications revealed a section stating the following, "Pre-preparative (storage) stability was assessed by preparing multiple sets of samples at low, mid, and high concentrations and storing them at refrigerated temperature (2-8 degrees C) for up to 7 days." 2. A review of the laboratory's "MAIN PANEL Validation Report Summary" establishment of performance specifications revealed a section stating the following, "Storage stability (pre-preparative stability) for the analytes in urine at refrigerated temperatures (2-8 degrees C) was demonstrated for up to 7 days." 3. A review of the laboratory's "Urine Specimen Collection and Patient Instructions Policy" revealed a section stating, "If the samples are not analyzed immediately, specimens may be stored up to 7 days refrigerated and frozen for 30 days." 4. A review of patient test records revealed the following patients had urine quantitative toxicology testing performed on specimens that had exceeded their stability: a. Patient 8705 was collected on 3/7/23 and reported on 4/2/23. b. Patient 9277 was collected on 4/27/23 and reported on 5/28/23. c. Patient 9805 was collected on 6/25/23 and reported on 7/12/23. 5. An interview on 7/31/23 at 4:20 pm with the Lab Scientist confirmed the laboratory had performed testing on specimens exceeding their stability.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Lab Scientist, the laboratory failed to establish policies and procedures for urine quantitative toxicology specimen transportation and calibration for 2 (July 2021 to July 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures for its urine quantitative toxicology testing revealed a lack of policies and procedures for specimen

	transportation and calibration procedures. 2. An interview on 7/31/23 at 10:16 am with Testing Personnel #3 indicated specimens are collected offsite and brought to the laboratory. 3. The surveyor requested the laboratory's policies and procedures for urine quantitative toxicology specimen transportation and calibration on 7/31/23 at 2: 08 pm and they were not made available. 4. An interview on 7/31/23 at 2:15 pm with the Lab Scientist confirmed the laboratory had not established policies and procedures for urine quantitative toxicology specimen transportation and calibration procedures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . A. Based on observation and interview with Testing Personnel #3, the laboratory failed to label its urine quantitative toxicology reagents with the preparation and expiration dates for 3 of 3 reagents on board the AB Sciex Triple Quad 5500 urine toxicology analyzer. Findings include: 1. The surveyor observed the laboratory's AB Sciex Triple Quad 5500 urine toxicology analyzer on 7/31/23 at 10:25 am with three glass reagent bottles labeled "Needle Rinse", "MP A", and "MP B" without the preparation and expiration dates. 2. An interview on 7/31/23 at 10:25 am with Testing Personnel #3 confirmed the laboratory's reagents on board the AB Sciex Triple Quad 5500 urine toxicology analyzer had not been labeled with the preparation and expiration dates. B. Based on observation and interview with Testing Personnel #3, the laboratory failed to label its urine quantitative toxicology control materials with the preparation and expiration dates for 11 of 11 control materials observed. Findings include: 1. The surveyor observed the laboratory's urine quantitative toxicology control materials on 7/31/23 at 10:36 am and revealed a lack of preparation and expiration dates for the control materials. 2. An interview on 7/31/23 at 10:36 am with Testing Personnel #3 confirmed the laboratory's urine quantitative toxicology control materials had not been labeled with the preparation and expiration dates.
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 record review and interview with the Lab Scientist, the laboratory failed to

	perform corrective action when the Normeperidine had failed its verification of accuracy criteria for 1 (November 2022) of 2 twice annual verification of accuracy testing events reviewed. Findings include: 1. A review of the laboratory's "Competency Study" verification of accuracy documentation revealed a section stating, "This study generates clinical competency results between two laboratories, Prism Labs LLC and Hazel Park by virtue of a 5-sample comparison of select analyte results, in which both laboratories that the same samples and compare results obtained. The ideal scenario is to obtain results that have a percent difference of less than or equal to 25% between each of the analytes." 2. A review of the laboratory's raw data for the verification of accuracy study revealed the laboratory's result for Normeperidine was 558 ng/mL and the reference laboratory received a result of 414 ng /mL, making the percent difference 29.6%. 3. An interview on 7/31/23 at with the Lab Scientist confirmed the percent difference for Normeperidine's verification of accuracy testing had exceeded the laboratory's acceptability criteria and the laboratory had not performed and documented corrective action for the failed result.
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 interviews and record review, the laboratory failed to have a laboratory director for 4 years and 9 months since the laboratory submitted their initial Form CMS-116 on November 13, 2018. Findings include: 1. The surveyor requested the phone number of the Laboratory Director listed on Form CMS-116 from the Technical Supervisor on 8/16/23 at 11:10 am and a phone number was provided. 2. An interview on 8/16/23 at 11:15 am with the individual listed as the Laboratory Director revealed they had never performed laboratory director services for this laboratory and never signed a contract with this laboratory to provide director services. 3. An interview on 8/16/23 at 12:03 pm with the owner of the laboratory revealed the contract for laboratory consultation services was made with the Technical Supervisor and confirmed no contract for laboratory director services had been entered with the individual indicated as the Laboratory Director. 4. A review of the laboratory's previous CMS-116 forms revealed the individual listed as the Laboratory Director had been listed as the laboratory director on the laboratory's initial application that was received on November 13, 2018.