Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2158018	01/12/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the Laboratory Director (LD) and the Testing Personnel (TP) failed to attest to the routine integration of the proficiency testing samples into the patient workload for 1 (UT-C 2021) of 4 testing events reviewed. Findings include: 1. A review of the College of American Pathologists' (CAP) proficiency testing records revealed a lack of signatures on the attestation statement sheet of the LD and the TP for 1 (UT-C) of 4 testing events in 2020 and 2021. 2. An interview on 1/10/2022 at 3:12 pm, the GS confirmed the LD and TP did not attest to the integration of samples into the patient workload.
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: A - Quantitative Analysis Comprehensive Tox Pain Panel Based on record review and interview with the General Supervisor, the laboratory failed to verify the accuracy of its laboratory testing for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A record review of the "Quantitative Analysis Comprehensive

	Tox Pain Panel" on the patient test requisition revealed the following tests are being performed: a. Buprenorphine b. Norbuprenorphine c. Codeine d. Dihydrocodeine e. Morphine f. Hydrocodone g. Norhydrocodone h. Hydromorphone i. Oxycodone j. Noroxycodone k. Oxymorphone l. Noroxymorphone m. Fentanyl n. Norfentanyl o. Sufentanil p. Methadone q. EDDP r. Merperidine s. Normeperidine t. Naloxone u. Naltrexone v. Tapentadol w. Tramadol x. O-Desmethl-cis-tramadol y. Alprazolam z. Hydroxyalprazolam aa. Clonazepam bb. 7-Amino Clonazepam cc. Flunitrazepam dd. Flurazepam ee. Lorazepam ff. Midazolam gg. Diazepam hh. Nordiazepam ii. Temazepam jj. Oxazepam ll. Triazolam ll. Amphetamine mm. Benzoylecgonine (Cocaine) nn. Cocaethylene oo. Cocaine pp. 6-MAM (Heroin) qq. Methamphetamine rr. MDA ss. MDEA tt. MDMA uu. THC-COOH vv. PCP ww. Gabapentin xx. Methylphenidate yy. Pregabalin zz. Carisoprodol aaa. Meprobamate bbb. Norpropoxyphene ccc. Propoxyphene ddd. Ritalinic Acid eee. Zaleplon fff. Zopiclone ggg. Zalpidem hhh. Amobarbital Pentobarbital iii. Butabarbital jjj. Butalbital kkk. Phenobarbital lll. Secobarbital mmm. Nicotine nnn. Continine 2. The surveyor requested documentation of twice annual verification of accuracy for the toxicology testing listed above at 1:11 pm and it was not made available. 3. An interview on 01/10 /2022 at 1:11 pm, the General Supervisor confirmed the laboratory did not have documentation of twice annual verification of accuracy testing from January 2020 to January 2022 for the toxicology testing listed above. B - Quantitative Analysis Comprehensive Tox Pysch Panel Based on record review and interview with the General Supervisor, the laboratory failed to verify the accuracy of its laboratory testing for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A record review of the "Quantitative Analysis Comprehensive Tox Pysch Panel" on the patient test requisition revealed the following tests are being performed: a. Carbamazepine b. Carbamazepine Epoxide c. Hydroxy-Carbamazepine d. Oxcarbazepine e. Bupropion f. Hydroxybupropion g. Citalopram Escitalopram h. Duloxetine i. Fluoxetine j. Norfluoxetine k. Mirtazapine l. Desmethylmirtazapine m. Paroxetine n. Selegline o. Sertraline p. Trazodone q. Venlafaxine r. O-Desmethylvenlafaxine s. Ariprazole t. Asenapine u. Clozapine v. Fluphenazine w. Haloperidol x. Iloperidone y. Lamotrigine z. Lurasidone aa. Olanzapine bb. Desmethylolanzapine cc. Quetiapine dd. 7-Hydroxyquetiapine ee. Norquestiapine ff. Risperidone gg. 9-Hydroxyrisperidone hh. Ziprasidone ii. Lisdexamfetamine jj. Phentermine kk. Amitriptyline ll. Clomipramine mm. Desipramine nn. Doxepin oo. Imipramine pp. Nortriptyline qq. JWH-018 rr. JWH-073 ss. LSD tt. MDPV uu. Mephedrone vv. Methcathinone ww. Methylone xx. Buspirone yy. Cyclobenzaprine zz. Dextromethorphan aaa. Diphenhydramine bbb. Ketamine ccc. Methylephedrine ddd. Mitragynine eee. 7-Hydroxymitragynine 2. The surveyor requested documentation of twice annual verification of accuracy for the toxicology pysch testing listed above at 1:11 pm and it was not made available 3. An interview on 01/10 /2022 at 1:11 pm, the General Supervisor confirmed the laboratory did not have documentation of twice annual verification of accuracy testing from January 2020 to January 2022 for the toxicology pysch testing listed above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform quality control testing each day of patient testing for 2 (2011080012 and 1953) of 11 patient testing dates reviewed. Findings include: 1. A review of patient test records revealed a lack of acceptable quality control (QC) results for the following tests: a. Patient 2011080012 tested on 11/08/2020 - no acceptable QC for Zaleplon b. Patient 1953 tested on 3/29/2021 - no acceptable QC for Cocaine and Sufentanil 2. A review of the patient testing logs revealed 31 patient were tested on 11/08/2020 and 55 patients on 3/29/2021. 3. A review of the laboratory's "Procedure for "OUT OF CONTROL" Controls" revealed "If the Controls are "Out of Control" the following steps will be followed to correct the problem: 1. Check controls and reagents for contamination, out dating or poor storage. 2. Re-analyze the same control - if results are OK run patient - if they are still out of limits - 3. Use a fresh vial of controls - if they are OK, run patient - if they are still out of limits - 4. Calibrate the instrument (if applicable) and run controls again - if they are OK run patient - if they are still out of limits - 5. Call manufacturers for help or service if problem can be corrected by phone and controls come out - run patient - if not corrected - notify the ordering physician, send specimen out to reference lab for testing - or - specimens may be stored until problem is corrected - if storage is acceptable for test and result is not needed immediately. The decision to send out or store will be made by the ordering physician or laboratory director. 6. Record all QC corrective action and/or maintence on instrument that was needed to correct the control problem on remedial action logs." "NEVER RUN A PATIENT IF THE CONTROLS ARE OUT OF LIMIT!" 4. An interview on 1/10/2022 at 2:10 PM, the GS confirmed the laboratory did not have acceptable quality control documentation available for the dates listed above.
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 record review and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure all proficiency testing final reports were reviewed to evaluate the laboratory's performance for 4 (UT-C in 2020 and UT-A, UT-B, and UT-C in 2021) of 4 events reviewed. Findings include: 1. Record review of the College of American Pathologists' (CAP) proficiency testing records revealed a lack of documentation of review by the LD and the appropriate staff for 4 of 4 events in 2020 and 2021 as follows: a. UT-C 2020 - results not turned into proficiency provider or self grading b. UT-A, UT-B, and UT-C - final results not reviewed by the LD or the appropriate testing personnel staff. 2. An interview on 01/10/2022 at 1:11 pm, the

	GS confirmed there was no documentation of a review by the LD or appropriate staff for the above proficiency testing events.