

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2158018	(X3) Date Survey Completed 11/07/2019
Name of Provider or Supplier Prism Lab Llc	Street Address, City, State 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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Technical Supervisor (TS) and General Supervisor #2 (GS2), the laboratory failed to ensure the test requisition had the tests to be performed indicated for 5 (patients #1, #5, #6, #7, and #8) of 8 patient charts audited. Findings include: 1. A patient chart audit revealed the following patients had test requisitions without the tests to be performed indicated on the requisition for the following dates: a. Patient #1 had testing performed on 4/24/19 b. Patient #5 had testing performed on 10/12/19 c. Patient #6 had testing performed on 10/18/19 d. Patient #7 had testing performed on 10/26/19 e. Patient #8 had testing performed on 11/3/19 2. An interview on 11/7/19 at 2:50 pm with the TS and GS2 confirmed the patients listed above did not have the tests to be performed indicated on the corresponding test requisitions. B. Based on record review and interview with the Technical Supervisor (TS) and General Supervisor #2 (GS2), the laboratory failed to</p>

ensure the test requisition indicated the patient's name or unique identifier, sex, and age or date of birth for 1 (patient #5) of 8 patient charts audited. Findings include: 1. A patient chart audit revealed patient #5 had a test requisition on file for 10/12/19 when testing was performed. 2. A review of the test requisition for patient #5 revealed it was missing the patient's name or unique identifier, sex, and age or date of birth. 3. An interview on 11/7/19 at 2:50 pm with the TS and GS2 confirmed the information listed above was missing from the test requisition for patient #5.

D5309

TEST REQUEST
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Supervisor (TS) and General Supervisor #2 (GS2), the laboratory failed to enter test requisitions accurately for 8 (#1 - #8) of 8 patients reviewed. Findings include: 1. Record review of patient #1-#8 test requisitions and final reports from April to November 2019 revealed the following discrepancies: Patient #1 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 04/15/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflyrazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethytpentadol, Tricyclic Antidepressant - Amtryptiline, Nortryptline, Doxepin, Desipramine, and Imipramine." Patient #2 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 9/18/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflyrazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethytpentadol, Tricyclic Antidepressant - Amtryptiline, Nortryptline, Doxepin, Desipramine, and Imipramine." Patient #3 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 9/25/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates

- Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflynazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethylnapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." Patient #4 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 10/07/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflynazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethylnapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." Patient #5 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 10/11/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflynazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethylnapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." Patient #6 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel signed by the ordering physician on 10/14/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflynazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyedone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethylnapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." Patient #7 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel was not dated by the ordering physician but collected on 10/22/19 that included the following tests that were not on the final

report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflyrazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyeodone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethyltapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." Patient #8 a. The test requisition revealed a "Comprehensive Quantitative Analysis" panel was ordered. b. The tests indicated in the "Comprehensive Quantitative Analysis" panel not dated by the ordering physician but collected on 10/25/19 included the following tests that were not on the final report: "Alcohol - ETG and ETS, Methylphenidate, Anticonvulsant - Gabapentin and Pregabalin, Barbiturates - Secobarbital, Phenobarbital, and Butalbital, Benzodiazepine - 2-Hydroxyethyl, Desalkflyrazepam, Midazolam, Alpha-Hydroxymidazolam, and Chlordiazepoxide, Naloxone, Cathinones (Bath Salts) - MDPV, Methedrone, Methylone, and Pentedrone, Muscle Relaxant - Carisoprodol and Meprobamate, Nicotine Metabolite - Cotinine, Opiates - Norhydrocodone and Dihydrocod, Oxycodone - Noroxyeodone, Sleep aid - Zaleplon and Zolpidem, Synt. Marijuana (SPICE) - JWH-073 N-(5Hydroxybutyl, JWH-250 5-Hydroxypentyl, JWH-018 N-4Hydroxypentyl, and JWH-018 Pentanoic Acid, N-Desmethyltapentadol, Tricyclic Antidepressant - Amitriptyline, Nortriptyline, Doxepin, Desipramine, and Imipramine." 2. During the interview on 11/7/19 at approximately 3:15 pm, TS and GS2 acknowledged the discrepancies between the test requisitions and test reports.

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:
The laboratory failed to meet applicable analytic system requirements in 493.1251 - 493.1283 and correctly identify problems specified in 493.1289. Findings include: 1. The laboratory failed to establish performance specifications for the laboratory information system (LIS). Refer to D5423 A. 2. The laboratory failed to establish and verify the performance specifications of analytic specificity for toxicology testing. Refer to D5423 B. 3. The laboratory failed to follow established performance specifications in the verification of Alprazolam and Hydromorphone testing. Refer to D5423 C.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed

in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. A. Based on procedure review, document review, and interview with the Technical Supervisor (TS) and the General Supervisor #2 (GS2), the laboratory failed to establish performance specifications for the laboratory information system (LIS) for 7 (April to November 2019) of 7 months testing patient specimens. Findings include: 1. Review of the laboratory procedure manual revealed a section labeled "Laboratory Information System" which stated the system is "validated with 2-5 specimens and monitored semiannually." 2. Document review revealed a lack of documentation for the validation of the LIS system and the semiannual review. 3. On 11/7/2019 when queried at 2:15 pm, GS2 was unable to provide the surveyor the documentation of the LIS system validation prior to reporting patient test results and the semiannually review. 4. During the interview on 11/7/2019 at 2:15 pm, GS2 acknowledged the documentation for the validation of the LIS system was not available on the day of the survey. B. Based on record review and interview with the Technical Supervisor (TS) and General Supervisor #2 (GS2), the laboratory failed to establish and verify the performance specifications of analytic specificity for toxicology testing for 7 (April 2019 to November 2019) of 7 months reviewed. Findings include: 1. A review of the laboratory's "Prism Lab LLC Rochester Hills, MI Performance Validation Approval" book revealed a lack of documentation of an analytic specificity study for toxicology testing performed on the Sciex Triple Quad 5500 analyzer. 2. A review of the laboratory's procedure manual revealed a procedure titled "Initial Method Verification" did not include specifications for analytic specificity. 3. An interview on 11/7/19 at 1:42 pm with the TS and GS1 confirmed performance specifications of analytic specificity for toxicology testing were not available. C. Based on record review and interview with the Technical Supervisor and General Supervisor #2 (GS2), the laboratory failed to follow established performance specifications in the verification of Alprazolam and Hydromorphone testing for 7 (April 2019 to November 2019) of 7 months reviewed. Findings include; 1. A review of the laboratory's "Prism Lab LLC Rochester Hills, MI Performance Validation Approval" book revealed a section stating, "Review the Calibration curves for each primary transition to ensure that the R value of the regression is >0.9." 2. A review of the laboratory's "Prism Lab LLC Rochester Hills, MI Performance Validation Approval" book revealed the following analytes with the corresponding regression values: a. Alprazolam had a regression value of 0.84 b. Hydromorphone had a regression value of 0.89. 3. An interview on 11/7/19 at 1:17 pm with the TS and GS2 confirmed the laboratory did not adhere to the established performance specifications for the analytes listed above. 41759