

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2106915	(X3) Date Survey Completed 08/25/2021
Name of Provider or Supplier Center For Wellness And Pain Care Of Las Vegas	Street Address, City, State 6930 S Cimarron Rd Ste 260, Las Vegas, NV	
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
D0000	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 25, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) 2019, 2020, and 2021 urine toxicology proficiency testing (PT) records, a review of the CAP 2020, and 2021 Proficiency Testing catalogs, a review of the director approved policy and procedure entitled, "Proficiency Testing Protocols," and an interview with the technical supervisor, the laboratory failed to enroll in the proficiency testing program intended for the quantitative urine drug screen confirmation testing by liquid chromatography-mass spectrometry (LCMS) or provide twice per year verification for all toxicology analytes. Findings include: 1. A review of the CAP proficiency testing records for 2019 urine toxicology events two and three, a review of the 2020 urine toxicology events one, two and three, and a review of the 2021 urine toxicology event one revealed that the evaluation of the submitted results were for qualitative urine drug screen testing. The laboratory performs quantitative confirmatory testing by LCMS for urine drug screens. 2. A review of the CAP 2020 and 2021 Proficiency Testing catalogs revealed, on page 96 of each catalog, that the Urine Toxicology proficiency testing program that the laboratory was enrolled in was not intended for quantitative confirmation of urine drug screen results. The catalog stated that the</p>

Urine Toxicology proficiency testing program was intended for "Screening and/or confirmatory drug analysis WITHOUT quantitation (no quantitation)." 3. The director approved policy and procedure entitled, "Proficiency Testing Protocols," on pages 6 and 7, in the section entitled, "Alternative Performance Assessment," stated, "This laboratory will perform split-sample testing with its reference laboratory for any assay for which CLIA does not require PT testing at least semi-annually to determine the reliability of analytical testing. Store all split-sample testing records in the designated PT manual." 4. There were no records for the twice per year verification of accuracy for the quantitative analysis of the confirmatory urine drug screen testing for amphetamine, methamphetamine, phentermine, alpha-hydroxyalprazolam, alprazolam, diazepam, flurazepam, Lorazepam, oxazepam, temazepam, buprenorphine, norbuprenorphine, 6-monoacetylmorphine (6-MAM), codeine, 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine (EDDP), Fentanyl, hydrocodone, hydromorphone, methadone, morphine, norfentanyl, norhydrocodone, noroxycodone, oxycodone, oxymorphone, Gabapentin, methyphenidate, O-desmethyltramadol, pregabalin, tramadol, benzoylecgonine, 3,4-methylenedioxy-methamphetamine (MDMA), methylenedioxyamphetamine, zolpidem, carisoprodol, meprobamate, and tapentadol. 5. The technical supervisor confirmed the findings during an interview conducted on August 25, 2021 at approximately 12:15 PM. The laboratory performs approximately 91,800 chemistry, urinalysis, and toxicology tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of the director approved policy and procedure for pipette calibration, a review of the director approved policy and procedure for centrifuge calibration and maintenance, a review of the pipette and centrifuge maintenance records, and an interview with the technical supervisor, the laboratory failed to ensure that the annual calibration and maintenance for the automatic pipettes and the annual calibration and maintenance for the centrifuge were performed in accordance with the director approved policies and procedures. Findings include: 1. There was no documentation of the annual calibration for the 0.5-10 microliter (ul) pipette, the 2-20 ul pipette, the 100-1000 ul pipette, and the 20-200 ul pipette during 2019. 2. The director approved policy and procedure entitled "Pipette Calibration," in the section entitled, "Calibration" stated, "Automatic pipettes, re-pipettes and automatic diluters must be checked for accuracy and precision before first put in use, at least annually after first use, and if control (QC) problems develop." 3. There was no documentation of the annual centrifuge calibration and electrical check between the dates of January 1, 2019 and August 27, 2021. 4. The director approved policy and procedure entitled "Centrifuge Calibration and Maintenance" stated, "Frequency of electrical checks should be yearly. Centrifuge must be calibrated yearly." 5. The technical supervisor confirmed the findings during an interview conducted on August 25, 2021 at approximately 1:30 PM. The laboratory performs approximately 91,800 chemistry, urinalysis, and toxicology tests annually.

D5785

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory freezer temperature records for 2019, and 2020, the director approved policy and procedure entitled, "Acceptable Temperature Ranges" and an interview with the technical supervisor, the laboratory failed to ensure that corrective actions were taken and documented when the freezer temperatures exceeded the established acceptable range of -25 to -15 degrees Celsius (C). Findings include: 1. The freezer temperatures exceeded the acceptable range of -25 to -15 degrees C with no documentation of corrective action on three of 20 days in May, 2019, eight of 20 days in June, 2019, ten of 15 days in July, 2019, seven of 22 days in August, 2019, 11 of 20 days in September, 2019, seven of 23 days in October, 2019, eight of 20 days in November, 2019, two of 21 days in December, 2019, five of 21 days in September, 2020, 22 of 22 days in October, 2020, and seven of 21 days in November, 2020. 2. The director approved policy and procedure entitled, "Acceptable Temperature Ranges," in the section entitled, "Corrective Action" stated, "If any of the temperatures are not within the acceptable range, adjust the available controls and document action on the temperature log. Monitor the temperature within 1-3 hours to determine if the adjustment was sufficient to meet the acceptable range. Re-read the temperature and document the results of the adjustment. Document any remedial action on the temperature log. Use the back side of the log if needed." 3. The findings were confirmed during an interview with the technical supervisor during an interview conducted on August 25, 2021 at approximately 12:00 PM. The laboratory performs approximately 91,800 chemistry, urinalysis, and toxicology tests annually.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the 2021 College of American Pathologists (CAP) proficiency testing enrollment records, a review of the CAP proficiency testing records for 2019, 2020 and 2021, a review of the CAP 2020 and 2021 proficiency testing catalogs, a review of the director approved policy entitled, "Proficiency Testing Protocols," and an interview with the technical supervisor, the laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program intended for the quantitative liquid chromatography-mass spectrometry (LCMS) drug screen confirmation testing, and failed to ensure that the laboratory performed twice per year verification of accuracy for all toxicology analytes. Findings include: 1. The laboratory did not enroll in the 2019, 2020 and the 2021 CAP Proficiency Testing Program intended for the quantitative confirmation of urine drug screen test results by LCMS. 2. A review of the CAP 2019 urine toxicology events two and three, a review of the 2020 urine toxicology events one, two and three and a review of the 2021 urine toxicology event one proficiency testing results revealed that quantitative results were not submitted to the proficiency testing program for the events. 3. A review of the CAP 2020 and 2021 Proficiency Testing Catalogs, on page 96 of each catalog,

revealed that the Urine Toxicology program that the laboratory was enrolled in is intended for "Screening and/or confirmatory drug analysis WITHOUT quantitation (no quantitation)." 4. The director approved policy and procedure entitled, "Proficiency Testing Protocols," on pages 6 and 7, in the section entitled, "Alternative Performance Assessment," stated, "This laboratory will perform split-sample testing with its reference laboratory for any assay for which CLIA does not require PT testing at least semi-annually to determine the reliability of analytical testing. Store all split-sample testing records in the designated PT manual." 5. There were no records for the twice per year verification of accuracy for the quantitative analysis of the confirmatory urine drug screen testing for amphetamine, methamphetamine, phentermine, alpha-hydroxyalprazolam, alprazolam, diazepam, flurazepam, Lorazepam, oxazepam, temazepam, buprenorphine, norbuprenorphine, 6-monoacetylmorphine (6-MAM), codeine, 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine (EDDP), Fentanyl, hydrocodone, hydromorphone, methadone, morphine, norfentanyl, norhydrocodone, noroxycodone, oxycodone, oxymorphone, Gabapentin, methyphenidate, O-desmethyltramadol, pregabalin, tramadol, benzoylecgonine, 3,4-methylenedioxy-methamphetamine (MDMA), methylenedioxyamphetamine, zolpidem, carisoprodol, meprobamate, and tapentadol. 6. The findings were confirmed during an interview with the technical supervisor conducted on August 25, 2021 at approximately 1:00 PM. The laboratory performs approximately 91,800 chemistry, urinalysis, and toxicology tests annually.