

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2112684	(X3) Date Survey Completed 07/02/2024
Name of Provider or Supplier Wc Health	Street Address, City, State 5412 Boulder Hwy, 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 initial CLIA certification survey conducted at your facility on July 2, 2024. 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>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of April 16, 2024 and June 28, 2024, a review of the FDA test complexity classifications for the tests performed, the laboratory verification studies, a review of the manufacturer's instructions for the tests performed, and an interview with the laboratory supervisor, the laboratory failed to ensure the interpretive guidance was available on the report, or that the interpretive guidance available was appropriate to the testing performed by the laboratory. Findings include: 1. A random patient audit between the dates of April 16, 2024 and June 28, 2024 revealed that three of five final reports generated from the Horiba Pentra C400 analyzer print out included the following interpretive guidance: "Qualitative results are "Presumptive" performed by laboratory developed enzyme</p>

Immunoassay, Clinical considerations and professional judgement should be exercised and further testing by GC/MS or LC/MC/MC (sic) may be required. The performance characteristics of these tests were determined by W-C Health Services. They have not been approved by the U.S. Drug Administration (499.1291(c)(4))" 2. A random patient audit between the dates of April 16, 2024 and June 28, 2024 revealed that two of five final reports generated from the LIS did not include the following interpretive guidance stated in the Thermofisher package inserts: "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 3. A review of the FDA test complexity classifications revealed that the Thermofisher assays in use on the Horiba Pentra C400 analyzer for the following analytes were classified as moderate complexity when performed according to the manufacturer's instructions: Amphetamines, THC (Cannabinoids), Barbiturates, Benzodiazapine, Buprenorphine, Ethanol, and Opiates. 4. A review of the laboratory verification studies revealed that the laboratory did not establish and validate performance characteristics for the analytes as laboratory developed tests. The laboratory verified the manufacturer's performance characteristics for the drugs of abuse panel. 5. The findings were confirmed during an interview with the laboratory supervisor on July 2, 2024 at approximately 1:15 PM. The laboratory performs approximately 4000 routine chemistry, urinalysis and toxicology tests annually.

D5811

TEST REPORT
CFR(s): 493.1291(f)

(f) Except as provided in 493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

This STANDARD is not met as evidenced by:
Based on a random patient audit between the dates of April 16, 2024 and June 28, 2024, and an interview with the laboratory supervisor, the laboratory failed to ensure that name of the ordering provider was on the test reports. Findings include: 1. A random audit of five patients tested for urine drug screens between the dates of April 16, 2024 and June 28, 2024 revealed that two of five final patient reports did not include the name of the ordering provider on the report. The laboratory supervisor stated that the reports were instrument print outs that were issued because the Laboratory Information System (LIS) was not working on the dates of 4/16/24, 5/10/24 and 5/23/24. 2. The laboratory supervisor confirmed the finding during an interview conducted on July 2, 2024 at approximately 1:15 PM. The laboratory performs approximately 4000 routine chemistry, urinalysis and toxicology tests annually.