

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2230858	(X3) Date Survey Completed 06/08/2023
Name of Provider or Supplier Chrom Medical Labs, Llc	Street Address, City, State 201 W Main St, Ste 101a, Jenks, OK	
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	The intital survey was performed on 06/08/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
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 review of records, urine drug assay package inserts, and interview with the technical consultant, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 06/08/2023 at 09:20 am, the technical consultant stated Urine Drug Screen testing, which included the analytes Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Ecstasy, Opiates, Oxycodone, Methadone, Methamphetamines, and Phencyclidine, was performed using the Diatron Pictus 700 analyzer; (2) A review of the manufacturer's instructions contained in the assay package inserts for each analyte stated, "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 judgement should be applied to any drug of abuse test</p>

result, particularly when preliminary positive results are used" (3) A review of one patient report with Urine Drug Screen test results reported on 06/02/2023 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the technical consultant who stated on 06/08/2023 at 10:00 am, the patient report did not include the disclaimer.