

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2149322	(X3) Date Survey Completed 08/03/2021
Name of Provider or Supplier Pioneer Central Medical Laboratory Llc	Street Address, City, State 15230 Levan Road Level B, Livonia, 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
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 record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of toxicology testing at least twice annually for 2 (August 2019 to August 2021) of 2 years of testing. Findings include: 1. A record review of the laboratory's test menu and list of drugs tested on the College of American Pathologist proficiency testing (PT) reports, the records revealed a lack of documentation of verification of accuracy testing for 13 toxicology analytes for 2 (August 2019 to August 2021) of 2 years of testing as follows: a. Norhydrocodone b. Noroxymorphone c. Naloxone d. Naltrexone e. Tapentadol f. Secobarbital g. Sufentanil h. Hydroxalprazolam i. Midazolam. j. Triazolam k. Ritalinic Acid l. MDEA m. Methathinone 2. An interview on 8/03/2021 at 11:53 am, the LD confirmed the laboratory did not perform verification of accuracy testing for all analytes not included in the PT program for 2 years.</p>
D6151	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4)</p> <p>(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the general</p>

supervisor (GS) failed to evaluate the competency of 1 (#1) of 3 Testing Personnel (TP) at least annually after the first year. Findings include: 1. A record review of the competency documentations revealed a lack of documentation for the annual competency evaluations for 1 (TP#1) of 3 TP in 2020 and 2021. 2. An interview on 8 /03/2021 at 10:19 am, the LD confirmed the GS did not perform annual competency evaluation for TP#1 in 2020 and 2021.