

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628395	(X3) Date Survey Completed 05/09/2023
Name of Provider or Supplier St Charles Madras Laboratory	Street Address, City, State 470 Ne A St, Madras, OR	
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 review of testing personnel (TP) competency records and interview with the Laboratory Manager (MT1) and the North Campus Manager for St. Charles Medical Center (MT2), the laboratory failed to perform bi-annual verification for testing personnel performing microscopic analysis on unregulated analytes. Findings include: 1. During review of TP competencies, bi-annual verification of competency for Potassium Hydroxide (KOH) and other wet mounts could not be produced. 2. An interview with MT1 and MT2 at approximately 3:00 pm on May 09, 2023 confirmed that no bi-annual verification of competency for TP performing wet mounts and KOH preparations since the last survey dated 10/20/2020 had been performed. 3. The laboratory reports performing an average of 263 wet mounts and 1 KOH prep per year. 4. MT2 confirmed the above numbers by email 05/18/23 and 05/19/2023.</p>