

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2005937	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Wadsworth Center - David Axelrod Institute	Street Address, City, State New York State Department Of Health, Albany, NY	
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:</p> <ol style="list-style-type: none"> Based on review of proficiency testing records in Newborn Screening/Genetic & Molecular testing sections, and interview with technical supervisors and section directors, the laboratory failed to verify, at least twice annually, the accuracy of the following analytes/metabolites: Krabbe disease (GALC)-Sanger sequencing; adrenoleukodystrophy (ALD)-Sanger sequencing; hydroxyhexanoylcarnitine (C6OH)-MS/MS; hydroxybutyrylcarnitine (C4OH)-MS/MS; and methymalonylcarnitine (C4DC)-MS/MS. The findings included: a. Krabbe A testing date was 7/3/2019. No other testing date in 2019. The section director stated on 2/11 at around 2 pm the next testing date was on 1/31/2020. b. ALD testing date was 8/24/2018. There was no other testing date in 2018. c. ALD testing date was 12/21/2017. There was no other testing date in 2017. d. C4OH testing date was day 211-2019; C4DC testing date was day 231-2019; C6OH testing date was day 211-2019. The section director verified these testing dates at around 3 pm on 2/12/2020. Based on review of CDC proficiency testing records for Hemoglobin (Hgb) Disorders by high performance liquid chromatography (HPLC), the laboratory failed to verify the accuracy of Hgb F at least twice a year. The section director confirmed 2/11/2020 at around 1:00 pm, the CDC proficiency module did not include samples for Hgb F.