

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2188990	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Developmental And Neurogenetics Laboratory	Street Address, City, State 8701 Watertown Plank Rd, Milwaukee, WI	
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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form CMS-116, and patient test reports and interview with the general supervisor, the laboratory did not follow quality assurance guidelines to assess and identify problems in the postanalytic system for ten of ten patient test reports. Findings include: 1. Review of Form CMS-116 signed by the laboratory director on July 7, 2021 showed the laboratory's CLIA number is 52D2188990. 2. Review of patient test reports from October 2020 through July 2021 showed the laboratory reported patient test results on CLIA number 52D1043369. 3. Interview with the general supervisor on July 21, 2021 at 12:15 PM confirmed that laboratory did not follow quality assessment guidelines to assess and identify problems in the postanalytic system for ten of ten patient test reports.</p>