

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0947277	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Laboratory Of Molec Genetics Nidcd-Nih	Street Address, City, State 35a Convent Drive- Room 1f-210 - Msc3729, Bethesda, MD	
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 Centers for Medicare and Medicaid Services (CMS) Philadelphia Regional Office Federal Surveyor conducted an announced routine CLIA recertification survey at Laboratory of Molecular Genetics NIDCD- NIH on November 20, 2020. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. Specific deficiencies includes the following:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's molecular genetics sequencing proficiency testing (PT) events documentation and staff interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for three(3) of three(3) events reviewed for the calendar year 2019 and 2020. Findings Include: 1. Review of the laboratory's College of American Pathologist (CAP) (2019) and (2020) Molecular Genetics Sequencing Events 3 for 2019 and Molecular Genetics Sequencing Events 1 and 2 , a totals three of three events revealed no attestation statement signed by the (LD) for the following testing events a.</p>

December 2, 2019 Kit 32678403 0 01 42 b. January 7, 2020 Kit 32678537 1 01 10 c.
August 6, 2020 Kit 33672261 4 01 25 2. At 12:30 pm during interview with the testing person (TP1) and the Technical Supervisor (TS) for the (PT) records, the surveyor requested documentation of the attestation page electronically or physically. The laboratory provide blank copies in the (CAP)(PT) records binder. 3. At approximately 1:00 PM, the exit interview with the (TS) and the (LD) on November 20, 2020 confirmed the laboratory did not retain signed copies of the PT attestation statements.