

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0947277	<b>(X3) Date Survey Completed</b>  06/22/2022
<b>Name of Provider or Supplier</b>  Laboratory Of Molec Genetics Nidcd-Nih	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centers for Medicare and Medicaid Services (CMS) Federal Surveyor conducted an announced routine CLIA recertification survey at Laboratory of Molecular Genetics - NIDCD/NIH on June 22, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The following deficiencies were found during the announced routine CLIA recertification survey:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, laboratory procedures and interview with laboratory staff, the laboratory failed to establish a competency assessment policy to assess the competency for one of one clinical consultant (CC), five of five technical supervisors (TS), seven of seven general supervisors (GS) and testing personnel (TP). Findings Include: 1. One the day of survey, June 22, 2022 around 10:35 am, the laboratory could not provide a competency assessment policy that assesses the competency for CC, TS, GS and TP. 2. The laboratory could not provide competency assessment records for one of one CC, five of five TS and seven of seven GSs. 3. During the exit conference on June 22, 2022 around 11:45 am, the laboratory staff and the laboratory Director confirmed a competency assessment policy had not been established and that the CC, TS, GS were not assessed for competency.</p>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on lack of maintenance records and interview with laboratory staff, the laboratory failed to establish protocols for one of one Synene NuGenius/NuGenius plus imaging system. Findings Include: 1. The Synene NuGenius/NuGenius+ user manual states, "The system does not require regular maintenance or calibration other than occasional checking and cleaning." 2. On the day of survey, June 22, 2022 around 11:00 am, laboratory staff could not provide maintenance protocols established by the laboratory for one of one Synene NuGenius/NuGenius plus imaging system. 3. The laboratory staff and laboratory director confirmed at the exit conference around 11:45 am, that the Synene NuGenius/NuGenius plus imaging system has not been maintenance and that a maintenance protocols for the imaging system has not been established.

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on review of The College of American Pathologist (CAP) proficiency testing (PT) records and interview with laboratory staff, the laboratory failed to establish corrective action plans for unacceptable or unsatisfactory CAP PT scores in 2020 and 2021. Finding Include: 1. On the day of survey, June 22, 2022 around 11:30 am, the laboratory could not provide a corrective action plan for unacceptable or unsatisfactory PT scores. 2. Review of the following CAP PT records revealed, the following unacceptable scores did not have documented corrective actions: CAP SEC1-B 2020 DNA Sequencing - two of four specimen were unacceptable - Grade 50%. CAP SEC1-B 2021 DNA Sequencing Challenge - one of four specimen were unacceptable - Grade 75%. 3. The laboratory staff and laboratory director confirmed at the exit conference around 11:45 am, that CAP PT personnel were contact in regards to the unsatisfactory scores, but corrective actions were not documented.