

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0947274	<b>(X3) Date Survey Completed</b>  02/04/2021
<b>Name of Provider or Supplier</b>  Claia Molecular Diagnostics Laboratory	<b>Street Address, City, State</b>  8560 Progress Drive Atrf C3023, Frederick, 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>	An announced CLIA recertification survey was conducted by a CMS CLIA Philadelphia Regional Surveyor at CLIA Molecular Diagnostics Laboratory on February 4, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. Specific deficiencies cited are as follows:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 proficiency testing records and interview, the laboratory failed to document and maintain copies of the handling, preparation, processing, and examination of each step in the testing for all proficiency testing samples. Findings include: Record review of proficiency testing (PT) events for Mutation Detection and Sanger Sequencing from December PT 2018 event and Saliva DNA Exaction from December PT 2020 revealed the laboratory failed to document how the laboratory handled, prepared, processed and examined each step for all testing samples. 1. a. CLIA Molecular Diagnostics Laboratory PT- Mutation Detection and Sanger Sequencing December 2018 document states, "In November 2018, 1 DNA sample randomly chosen and aliquoted by Kristen Pike. This specimen had been previously tested. The sample ID</p>

was blinded to lab staff" b. CLIA Molecular Diagnostic Laboratory PT- Saliva DNA Extraction December 2020 document states, "In December 2020, Todd Young provided his own saliva sample. This was due to the Covid-19 pandemic. The sample had DNA extracted from it. Upon analysis, it was confirmed that the sample met required criteria." 2. During an interview on February 04, 2021 at approximately 12:00 pm the federal surveyor asked the Technical Supervisor (TS)#1, "How does the laboratory document the handling and preparation of samples?" TS#1 stated, "There is an email stating competency is in fridge. There is not a form that has bullet points, but we do have a procedure they follow. During the exit interview at 3:00 pm on 02/04 /2021, the Lab director confirmed the above finding.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on interview and lack of documentation, the laboratory failed to demonstrate the laboratory methods for monitoring and evaluating a comparison of test results for acceptable differences in test values for the identical models of 3730XL sequencers the facility operates interchangeably. Findings include: During an interview on February 04, 2021 at approximately 2:15 pm, the federal surveyor requested comparison studies for the two 3730 XL DNA Analyzers the facility operates for routine testing. The technical supervisor (TS#1) stated, "We used to do reproducibility but was told to stop by facility maintenance engineering (FME) department" During the exit interview at 3:00 pm the LD confirmed the above finding.