

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2137521	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Molecular Characterization Laboratory	Street Address, City, State 321 Ware Drive, Frederick, 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	Federal Jurisdictional Survey The laboratory is on compliance with 42 CFR part 493 with standard level deficiencies cited:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologist's (CAP) proficiency testing (PT) records from 2019, interview with the laboratory director and the QA coordinator, the laboratory failed to evaluate and document review of their proficiency testing as evidenced by: 1. In review of the CAP PT records for NEO-A 2019, the laboratory failed to document corrective action and the reason for failures for NEO-04 and NEO-08 which were scored unacceptable. 2. In review of the CAP PT records for NEO-B 2019, the laboratory failed to document corrective action and the reason for failures for NEO-18 which was scored unacceptable. 3. The laboratory did not maintain a procedure for evaluating unacceptable individual specimen scores. 4. In interview with the Laboratory Director on 11-17-2020 @0956 he stated that they don't review unacceptable score. He thought since they received an acceptable score overall that evaluation of unacceptable was not needed. He also stated that they did not follow through for investigation 5. In interview with the Quality Assurance Coordinator on 11-17-2020 @0957 states that they did not have documentation for the unacceptable individual specimen failures.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education</p>

appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 form, personnel records, the laboratory's policy, and interview with the Laboratory Director and Quality Assurance (QA) coordinator, the Technical Supervisor failed to perform competency on 5 of 5 testing personnel for once a year for 2018, 2019, 2020 as evidenced by: 1. In review of the laboratory's policy titled MCC-SOP0005 MoCha Competency and Proficiency Testing program, states, "This document has been approved for use in the Molecular Characterization Laboratory (MoCha) at the Frederick National Laboratory for Cancer Research. " The laboratory policy also states in 8.1.2 "Operator competency is assessed via a 6 point evaluation process incorporating five (5) procedural and one (1) analysis components [42 CFR 493.1451] as described below. Observation and reviews are conducted by laboratory manager or subject matter expert (SME) The CLIA Laboratory Director is responsible for overall assessment conclusion and approval." 2. In review of the laboratory's personnel records, none of the 5 testing personnel recorded on the CMS-209 form had maintained competency records for 2018, 2019, and 2020. None of the personnel were new from the last survey. The laboratory did not provide documentation of personnel competency. 3. In interview with the QA Coordinator and Laboratory Director @1011 stated that they did not have competency assessments. They didn't think testing personnel needed competency since they were not reviewing slides for pathology. It was confirmed per interview @1012 that the Laboratory personnel were performing grossing activities on specimen, i.e. measurements.