

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2137521	(X3) Date Survey Completed 05/02/2018
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and interview, the laboratory failed to establish and implement a procedure for verifying the accuracy of the tumor percentage testing being performed. Findings include: 1. The laboratory reports estimated tumor content in its histology processing record. 2. Review of the laboratory standard operating procedure revealed that no procedure was in place to verify accuracy of the tumor content testing twice per year 3. During interview at 2:40 pm on 5/2/2018 the general supervisor and laboratory director confirmed that there was no procedure for verifying the accuracy of the testing twice per year.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the laboratory test report did not include the name and address of the location where the testing was performed. Findings include:

1. During interview at 3:30 pm on 5/2/2018 the general supervisor stated that the record of patient testing was maintained on the Histology Processing Record form.
2. By e-mail on 5/4/2018 the general supervisor provided a copy of the Sequencing Clinical Report template. Review of the template revealed that the form did not contain a place to record the result of the percent tumor content determination or the location where that testing was performed.