

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2157658	(X3) Date Survey Completed 08/04/2020
Name of Provider or Supplier Ruffolo Hooper & Associates Md Pa	Street Address, City, State 13220 Usf Laurel Drive, Tampa, FL	
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	An announced CLIA recertification survey was conducted at Ruffolo, Hooper, & Associates MD PA on 08/04/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director and review of the laboratory's procedure manual and College of American Pathologists (CAP) proficiency testing records, the laboratory failed to verify the accuracy of analytes that did not receive a grade for one (2nd Event 2019) out of two (2nd Event 2019 and 1st Event 2020) events for human epidermal growth factor receptor 2 (HER2) and three (1st and 2nd Event 2019 and 1st event 2020) events out of three events for estrogen receptor and progesterone receptor (ER/PGR). Findings included: Record review of the laboratory procedure manual revealed "If PT result is linked to a non-graded exception code will follow actions required by CAP. Will perform self-evaluation and document on the "CAP PT Testing Exception Remedial Action" form." Record review of CAP proficiency testing records revealed the 2nd Event 2019 for HER2 and the 1st and 2nd Event 2019 and 1st event 2020 for ER/PGR proficiency testing results were not evaluated or scored by CAP and had not been graded by the laboratory. The following were the ungraded results and the corresponding codes: Event Her2 - B 2019 -HER2 Immunochemistry - Method - Core 4 (pathway) - specimen number - HER2 - 03 - code 27 (Lack of Participant or referee consensus) Event PM2-A 2019-ER/PGR Immunochemistry - Method - PGR Core 3 - % Staining - specimen number - PM2-03</p>

- code 27 Method - PGR Core 9 - % Staining - specimen number - PM2-03 - code 27 Method - PGR Core 7 - % Staining - specimen number - PM2-04 - code 27 Method - PGR Core 10 - % Staining - specimen number - PM2-04 - code 27 Event PM2 - B 2019 - ER/PGR Immunochimistry Method - PGR Core 6 - % Staining - specimen number - PM2 - 07 - code 27 Method - PGR Core 9 - % Staining - specimen number - PM2 -07 - code 27 Method - PGR Core 7 - % Staining - specimen number - PM2-08 - code 27 Interview on 08/04/20 at 11:00 a.m. with the Laboratory Director revealed she did not know she had to self grade results not graded by CAP proficiency testing.