

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2147777	(X3) Date Survey Completed 08/28/2019
Name of Provider or Supplier Advanced Genetics Lab	Street Address, City, State 810 Main St, Monroe, CT	
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 record review and staff interview, the laboratory failed to verify the accuracy bi-annually for multiple non-regulated genes in the specialty of chemistry and hematology. Findings include: 1. Record review of laboratory's test verification /accuracy records on 8/28/19 revealed the laboratory failed to verify the accuracy at least twice annually in 2018 for the following genes: CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, DPYD, F2, F5, SLCO1B1, TPMT and VKORC1. 2. Record review of the laboratory's "Proficiency Testing" (PT) policy on 8/28/19 revealed "For those tests not covered by an Agency PT program, Advanced Genetics Lab will participate in internal or external PT at least every six months." 3. Staff interview with the laboratory director on 8/28/19 at 9:45 AM confirmed the above findings. 4. The laboratory performs 1400 chemistry and 400 hematology gene tests annually.</p>