

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2117720	(X3) Date Survey Completed 10/05/2020
Name of Provider or Supplier Martell Diagnostic Laboratories	Street Address, City, State 4 Strathmore Road, Natick, MA	
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 document review and interview with laboratory personnel, the laboratory failed to verify the accuracy at least twice annually of 2 of 2 tests performed in 2019. Findings are as follows: 1. The laboratory performed proprietary testing for PDL-1 and HER2 beginning in 03/27/19 and 05/21/19, respectively, as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 10/05/20. 2. Documentation of twice annual accuracy verification of the above tests was not found in laboratory records from 2019. The laboratory was unable to provide verification documents for calendar year 2019 upon request. 3. In an interview at 10:35 a.m. on 10/05/20, the GS confirmed the above finding. .</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 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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical</p>

Supervisor (TS) failed to ensure 1 of 1 new testing personnel received documented training for 2 of 2 tests performed by the laboratory. Findings are as follows: 1. The laboratory performed proprietary testing for PDL-1 and HER2 beginning in 03/27/19 and 05/21/19, respectively, as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 10/05/20 2. The GS performed the PDL-1 test on 03/27/19 and the HER2 test on 05/21/19 as indicated in laboratory records. 3. Documentation of the GS's initial training was not found during review of laboratory personnel records. The laboratory was unable to provide the missing document upon request. 4. In an interview at 10:25 a.m. on 10/05/20, the GS confirmed the above finding. .

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 1 of 1 new testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. The laboratory performed proprietary testing for PDL-1 and HER2 beginning in 03/27/19 and 05/21/19, respectively, as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 10/05/20. 2. The GS performed the PDL-1 test on 03/27/19 and the HER2 test on 05/21/19 as indicated in laboratory records. 3. Documentation of the GS's initial training for the above tests was not found during review of laboratory personnel records. See D6120 4. Documentation of the GS's semiannual competency assessment for the above tests was not found during review of laboratory personnel records. The laboratory was unable to provide the missing semiannual competency assessments upon request. 5. In an interview at 10:25 a.m. on 10/05/20, the GS confirmed the above finding