Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2117720	03/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Martell Diagnostic Laboratories	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
D0000	Martell Diagnostic Laboratories was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on March 2, 2024. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1451 Technical supervisor responsibilities 493.1445 Laboratory director responsibilities .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one of two tests at least twice annually in 2022 and failed to verify the accuracy of two of two tests at least twice annually in 2023. Findings are as follows: 1. The laboratory offered proprietary PDL-1 and HER2 testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p.m. on 03/02/24. 2. PDL-1 and HER2 accuracy verification was required three times annually as established in the Proficiency Testing procedure located in the Procedure Manual. 3. Documentation of PDL-1 accuracy verification was not found in laboratory records from 2022. Documentation of PDL-1 and HER2 accuracy verification was not found in laboratory records from 2023. The laboratory was unable to provide the missing accuracy verification records upon request. 4. The laboratory performed HER2 testing on patient specimens in 2022. The laboratory did not not perform HER2 testing on patient specimens in 2023 and did not perform PDL-1 testing on patient specimens in 2022 or 2023. 5. In an interview at 3:20 p.m. on 03 /02/24, the GS confirmed the above finding. *This deficiency was previously cited during the 10/05/20 survey* .

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, laboratory records, and interview with laboratory personnel, the Laboratory Director failed to ensure previously cited deficiencies were corrected. Findings are as follows: The following deficiencies were cited during the 10/05/20 survey and were also out of compliance on 03/02/24. 1. D5217 - the laboratory failed to verify the accuracy of one of two tests in 2022 and two of two tests in 2023. 2. D6128 - the Technical Supervisor failed to assess one of one testing personnel for competency in 2022. .
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to assess competency at least annually for one of one testing personnel (TP) in 2022. Findings are as follows: 1. The laboratory performed proprietary HER2 testing in 2022 as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p.m. on 03/02/24. 2. Testing personnel competency assessments were required annually as established in the Annual Competency Assessment procedure located in the Procedure Manual. 3. HER2 competency assessment documentation for the single TP was not found in 2022 laboratory records. The laboratory was unable to provide the missing records upon request. 4. In an interview at 3:25 p.m. on 03/02/24, the GS confirmed the above finding. *Competency assessment deficiencies were previously cited during the 10/05/20 survey* .