Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2076326	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Howell Healthcare	11126 Chandler Blvd, North Hollywood, CA	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the testing personnel (TP) it was determined; that the laboratory failed to update protocols in place when changes occurred in the laboratory and the effective date and signature of approval by the laboratory director (LD) of such changes. The findings included: 1. On the day of the survey 07/14/2021 approximately 12:30 p.m. the procedure manual in place had not being updated to reflect current testing performed in the laboratory. 2. The TP affirmed on July 14, 2021 at approximately 1:00 p.m. that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 5,000 samples annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on observation of the laboratory's reagent materials and testing kits and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to label reagents to indicate the opening, preparation, and expiration dates when such reagents are used. The findings included: 1. Based on the surveyor's observation during the laboratory tour on July 14, 2021 at approximately 11:00 a.m., the TP indicated that no opening, preparation, or expiration date labels were documented for all the reagents used in the laboratory. 2. The laboratory's TP affirmed in an interview conducted July 14, 2021 at approximately 11:30 a.m. that the reagents currently used to test patients samples were not labeled with opening, preparation, and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 5,000 samples annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, and interview with the testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, July 14, 2021 at approximately 11:30 a.m., the surveyor found the following reagents being used beyond its expiration date: Reagent Lot # Expiration Date One Step Cardiac Panel WCOIA June 2021 BD Vacutainer UA 93444900 5/31/2021 AMIES Transpor Swab 1916574 1/31/2021 2. The TP affirmed on 7/14/2021 at approximately 11:45 a.m. using the reagents listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 5,000 tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's records for policies and procedures, labelling and expiration date of reagents in use, and interview with laboratory staff on July 14, 2021; it was determined that the laboratory director failed to ensure that several aspects of the preanalytical and analytical phases of laboratory testing were monitored. See D5407, D5415, and D5417.