Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2076326	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Howell Healthcare	Street Address, City, State 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, an interview with the laboratory director and a laboratory testing person and on 10/09/2018 (survey date) and review of manufacturer's instructions (package inserts), the laboratory failed to follow manufacturer's guidelines/operator's manual for quality control materials for all waived testing performed. The findings included. a. The laboratory staff stated per interview on 10/09/2018 that the Quality control (QC) policy for waived testing(s) was to performed QC once every thirty (30) days. Sekisui Diagnostic Influenza A & B manufacturer's guidelines under "External Quality Control Testing" states: Quality Control requirements should be established in accordance with local, state and federal regulators or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative controls be run with each new lot, shipment received and with each new operator. Alere BinaxNow RSV card manufacturer's guidelines under "Quality Control (QC)" states: Test these swabs once with each new shipment received. Medline Strep A Test strip manufacturer's guidelines under "External Quality Control" states: It is recommended that a positive and negative external control be run once per kit. Rapid Mononucleosis test manufacturer's guidelines under "Quality control" states: That positive and negative controls be run once for each untrained operator, once for each new shipment of kits - provided that each different lot received in the shipment is tested - and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, State, and Federal

	regulations or accreditation requirements. b. The laboratory director and a testing person affirmed on 10/09/2018, 12:00 that quality controls were not being performed in accordance with manufacture's guidelines.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0096D), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Hematology constituting unsuccessful PT performances. (See D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review eight (8) randomly selected patient reports from 03/01/2017 to 09/08/2018, quality control (QC) records and CMS PT records (CMS CASPER 0096D), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, WBC Differential, resulting in an "initial" (first) unsuccessful performance. The findings include: a. The laboratory failed to maintain successful performance with the American Proficiency Institute (API) PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analyte, WBC Differential performed on the Coulter AC-TDiff II analyzer, as follows: White Blood Cell Diff 2016 Q2 (20%) 2017 Q3 (60%) 2018 Q2 (40%) Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve

	satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an non-initial (subsequent) unsuccessful performance for the analyte, WBC Differential. c. The laboratory director affirmed on 10/09/2018, 12:00 (survey date) that the PT resulted in an non-initial (subsequent) unsuccessful performance for the analyte, WBC Differential. d. The laboratory testing declaration form, signed by the laboratory Director on 10/09/2018 that the laboratory performs approximately 500 automated CBCD tests annually.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on the lack of review of the laboratory's confidential morbidity reports (CMR), and interview with laboratory director, the laboratory failed to retain a copy of the original report for at least two years (January 2017 to October 09, 2018). Findings included: a. No confidential morbidity reports could be retrieved on 10/09/2018 (survey date) for patients with reactive results reported using the Quidel QuickVue (moderate complexity) for Chlamydia testing. b) The laboratory director affirmed 10 /09/2008, 12:00 that the patient confidential morbidity reports were not retained in the laboratory for at least two years. c. The laboratory estimated the volume of bacteriology (Chlamydia) testing as seventy-one (71) from January 2017 to 10/09 /2018 .
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 interview with the laboratory director on October 09, 2018 (survey date) and test data provided on October 10, 2018 for seventy-one (71) patients Chlamydia (moderate complexity) testing from January, 2017 to October 09, 2018, the laboratory failed to verify the testing accuracy of the Quidel QuickVue test performed at least twice annually for the years 2017 and 2018. The findings included: a. The laboratory was unable to provide documentation or previous records for verification of the Quidel QuickVue Chlamydia testing accuracy at least twice annually from 2017 to September, 2018. b. The laboratory director on October 09, 2018, 2018, 12:00 affirmed that the laboratory failed to verify the accuracy of the test twice annually. c. The laboratory Director on October 10, 2018, stated (per e-mail) that the laboratory performed approximately seventy-one (71) patients Chlamydia (moderate complexity) testing from January, 2017 to October 09, 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records for Chlamydia (moderate complexity) testing using the Quidel QuickVue kit and an interview with the laboratory director 10/09/2018 (survey date), it was determined that the laboratory failed to perform control procedures as defined per manufacturer's guidelines, or CLIA regulation 493.1256 (d) (2) "For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in" (d)(3) "At least once each day patient specimens are assayed or examined perform the following for:" (whichever is more stringent). The laboratory also had not instituted an alternate "Individual Quality Control Plan" (IQCP) including Risk Assessment, Quality Control and Quality Assessment. The findings included: a. The laboratory performs Chlamydia (moderate complexity) testing using the Quidel QuickVue kit. The manufacturer's guidelines under QC Testing Procedure states: "The QuickVue Positive and Negative solutions should be tested with each new lot or shipment of test materials once for 25-test kit and as otherwise required by your laboratory's standard quality control procedure", or the default CLIA regulation 493.1256 (d) (2), (d)(3), whichever is more stringent. b. The laboratory director affirmed on 10/09/2018, 12:00 (survey date) that QC was not performed in accordance with manufacturer's guidelines, or CLIA regulation 493.1256 (d) (2), (d) (3) and that no alternative IQCP program was instituted for the Chlamydia (moderate complexity) for testing performed and reported. c. The laboratory Director stated on October 10, 2018 (per e-mail), that the laboratory performed approximately seventy-one (71) patients Chlamydia (moderate complexity) testing from January, 2017 to October 09, 2018.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review and lack of documentation of annual personnel competency records and interview with the laboratory director (technical consultant), it was determined that the technical consultant failed to evaluate and document competencies for one testing personnel responsible for moderate complexity testing. The findings included: a. No evidence could be retrieved for annual competencies for all testing personnel of moderate complexity testing in the year 2017 performing moderate complexity testing for automated Complete blood counts with differential (CBCD) performed on the Coulter AC-TDiff II analyzer. b. The laboratory director affirmed 10/09/2018, 12:00 (survey date) that testing personnel competency records could not be retrieved for the

	annual performance of the testing personnel for the year 2017. c. The laboratory testing declaration form, signed by the laboratory Director on 10/09/2018 that the laboratory performs approximately 500 automated CBCD tests annually.