Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0642478	(X3) Date Survey Completed 02/24/2021
Name of Provider or Supplier Ashley Clinical Diagnostic Lab Inc	**Street Address, City, State** 5542 N Figueroa St, Los Angeles, 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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the America Association of Bioanalysts (AAB) proficiency testing records, eight (8) randomly selected patients from 10/23/2018 to 2/18/2021, and interview with the laboratory director (LD); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for General Immunology. The findings included: 1. The AAB reported the following for General Immunology: Event Analyte Score Reported Q3-2018 ANA 40% Q3-2019 RA/RF 60% Q3-2020 RA/RF 60% 2. Based on the laboratory's annual testing declaration for 2020 the laboratory analyzed and reported approximately 60,550 General Immunology tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The LD affirmed 02/24/2021 at approximately12:15 p.m. that the laboratory received the above unsatisfactory proficiency testing score.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80

	percent of acceptable responses for multiple Chemistry Analytes of proficiency testing (PT) for the first event in 2019 (Q1-2019). The finding included: 1. Based on review of PT records for Q1-2019, AAB reported unsatisfactory scores for the following analytes: Analyte Score % Albumin 0 Bicarbonate 60 Calcium 20 Cholesterol Total 0 Glucose 60 Protein Total 0 Urea Nitrogen 40 Uric Acid 0 Magnesium 20 2. Based on the laboratory testing declaration submitted at the time of the survey on 02/24/2021 the laboratory analyzed and reported approximately 3,650 tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The LD and TP affirmed 02/24/2020 at approximately 12:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) testing records, eight (8) random patients sampling, and interview with the laboratory director (LD); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology for the third event of 2018 (Q3-2018). The findings included: 1. The AAB proficiency program gave an unsatisfactory score of 60% for Blood Cell Identification and 60% as well for Coagulation PT Fibrinogen INR for Q3-2018. 2. Based on the laboratory's annual testing declaration submitted on the day of the survey February 24, 2021, the laboratory analyzed and reported approximately 500 Hematology tests, during the time the laboratory had unsatisfactory proficiency testing results. 3. The LD confirmed on 2/24/2021 at approximately 12:00 pm. that the laboratory received the above proficiency Hematology proficiency testing results described in 1.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's COVID-19 Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory director (LD) and testing personnel (TP) on February 24, 2021 for its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a uni-directional flow with separate areas for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performs PCR testing for the presumptive detection of SARS-CoV-2 using the ABI7500 and Automatic Quant Studio 9600. 2. During the laboratory tour on 02/24/2021 at approximately 11:10 a.m. the examiner observed that storage and preparation of reagents and PCR reaction using the QuantStudioand ABI7500 were all performed in the same area without unidirectional flow. 3. The LD

	and TP confirmed by interview on February 24, 2021 at approximately 11:45 a.m. that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in unidirectional flow areas. 5. Based on laboratory records, the laboratory performed and reported approximately 60,000 SARS-CoV-2 Real time PCR molecular diagnostic tests annually.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on surveyors direct observations of the laboratory's SARS-CoV-2 testing processes and interview with the laboratory director and testing personnel on February 24, 2021; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005.