

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0857935	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier Preferred Dermatology	Street Address, City, State 7937 S Painter Ave, Whittier, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature recording charts, and interview with the laboratory staff, it was determined that the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The findings included: a. The laboratory operated a histology laboratory inside the laboratory to process biopsy and Mohs surgery specimens. b. A various listed of equipment used in the laboratory, a record sheet identified as "Equipment Quality Control Form 18: Room and Temperature Log Sheet" c. They are "Room Temperature", "Refrigerator", "Freezer", "Cryostat", "Drying Oven", "Water Bath", and "Paraffin Embedding Processor" d. The acceptable temperature ranges were set as and on 10/2/2018 the temperature records as shown below: Equipment Quality Control Form 18: Room and Temperature Log Sheet Month October Year 2018 Equip Range (oC) Recorded "Rm Temp", 27 - 29 27 "Refrig", -2 - 8 -4 "Freezer", 5 or cooler -4 "Cryostat", 30 - 20 / "Drying Oven", 60 - 70 60 "Water Bath", 40 - 50 / "Paraffin " 61 - 66 63 Rm = Room Temp = temperature Refrig = refrigerator Paraffin = Paraffin Embedding Processor e. The laboratory has established the acceptable/optimal temperature for cryostat to cut the skin tissues between 30 - 20 oC is not scientifically sound and correct, neither for refrigerator between -2 and -8 oC. f. On the 10/2/2018 the refrigerator temperature</p>

	<p>was monitored and recorded at -4 oC for refrigeration, not sound scientifically. g. When interview with the laboratory testing personnel, the testing personnel showed lack of knowledge of the temperature acceptable ranges or the importance of temperature monitoring in the laboratory operations.</p>
<p>D5785</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when any of the following occur: a. The laboratory failed to establish acceptable temperature ranges, and record temperatures correctly and accordingly. b. See D-5413</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, and interview with the laboratory staff and a transcriber, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems specified. The findings included: a. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified. b. Review of three laboratory test result reports, one of the result reports, identified as Specimen number 18 PA 0130, with a date of surgery February 21, 2018, c. The specimen ID was imprinted on the histology slide as 18PA-0130, while the Pathology Report identified the Specimen Number: 18 PA 01310 incorrectly. d. Interview with the laboratory staff, routinely, a transcriber types up the report while listen to the dictation records, then the laboratory director, a board certified pathologist /dermatopathologist reviews it and signs it for approval. e. Interview with the transcriber, the typed reports were read and checked for accuracy by the nurses and then submitted to the laboratory director to review for final approval. f. The laboratory failed to perform the quality assessment of the patient test result reports effectively and failed to identify the problems when it indicated.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to</p>

identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory facility, review of the laboratory records, and interview with the laboratory staff and transcriber, it was determined that the laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5413, D-5785, D-5891