

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0576827	(X3) Date Survey Completed 01/10/2020
Name of Provider or Supplier William P Baugh, Md Inc	Street Address, City, State 333 W Bastanchury Rd Ste 110, Fullerton, 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
D5891	<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's patient testing result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to follow written policies and procedures effectively for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. The laboratory has been certificated for histopathology and test performed including the biopsy diagnosis and Mohs surgery procedures tissue slide readings. b. Review of 8 patient testing result reports covering 2018 and 2019 for accuracy of the histopathology testing result reports. c. One of the 8 reports, a Pathology Report identified by Patient ID #109399, Accession #HS19-339, and Date Collected on 07/17/19 with Date Reported on 08/30/19 was noted to have discrepancy and incorrect specimen information of the site of the tissue collected. d. The site on the Pathology Report indicated "Right Superior Eyelid" while the site indicated on the slide label is "RLAUPREYELID" which translated by the laboratory personnel as "Right Lateral Eyelid". e. The laboratory personnel stated (01/10/2020 @ 12:30 PM) that the laboratory currently newly installed electronic medical record (EMR) system, EMA, and was told by the vendor that no correction can be made once incorrect. f. The EMA system prevent the laboratory personnel to make corrective actions when the laboratory detected and noticed any errors in the reports and tried to correct and document the corrective actions. g. The CLIA 493.1282(a)(b) states that corrective action policies and procedures must be available and follow as necessary to maintain the laboratory's operation for testing patient specimen in a manner that ensure the accurate and reliable patient test results and reports. h. Further more the laboratory</p>

must retain the incorrect and corrected result reports according to CLIA regulations or longer time period and follows the laboratory written policies and procedures for the retention of laboratory documents. {493.1105(a)(b)}.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must 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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's patient testing result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur., The findings included: a. The laboratory has been certificated for histopathology and test performed including the biopsy diagnosis and Mohs surgery procedures. b. Review of 8 patient testing result reports covering 2018 and 2019 for accuracy of the testing result reports (see D-5891)