

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0859658	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Douglas Hamilton Md	Street Address, City, State 6325 Topanga Cyn Blvd, Ste 301, Woodland Hills, 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 patient test results records, the laboratory's policies and procedures manual, and interviews with the administrator and medical assistant (MA), it was determined that the laboratory failed to follow the established written policies and procedures for quality assessment as part of an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the preanalytic, analytic, and postanalytic systems. The findings include: 1. Based on the survey on October 30, 2024, no documentation was available to support the monthly checking of records as specified in the laboratory's policies and procedures. 2. For one (1) out of five (5) randomly chosen patient test results reviewed for Mohs, the date of service in the log sheet did not match other records. No corrective action report was available at the time of the survey. 3. The administrator and MA affirmed by interview on October 30, 2024, at approximately 11:30 a.m. that the laboratory did not have any monthly records for quality assessment checks. 4. Based on the laboratory's annual test declaration submitted at the time of the survey, the estimated laboratory test volume was 638 tests, for which no monthly quality assessment records were performed to monitor, assess, and, when indicated, correct problems identified in all phases of testing.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p>

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 the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observation during the laboratory tour, and interviews with the administrator and medical assistant on October 30, 2024, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. See D5891.