

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2128776	(X3) Date Survey Completed 01/17/2020
Name of Provider or Supplier Integrated Dermatology	Street Address, City, State 26691 Plaza Ste 230, Mission Viejo, 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 an audit of 6 patient reports (in the date range of 1/1/2018-11/30/2019) and the associated tissue slides, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include a. On 1/17/2020, an audit was conducted with a review of 6 randomly selected histology and MOHS patients. b. One patient report/slide set demonstrated an inconsistency with the slide label date and the associated report date- the slide indicated 12/17/19 and the report indicated 12/23/19. The laboratory failed to document a discrepancy on this patient and to generate a correction action report. c. Laboratory personnel (LP) confirmed (1/17/2020 at 11:45 a.m.) that the above description was inconsistent and that no corrective action workup was completed.</p>
D6094	<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 identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on an audit of 6 patient reports (in the date range of 1/1/2018-11/30/2019) and</p>

the associated tissue slides, the laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: a. The laboratory failed to effectively follow its QA program to assess and monitor the accuracy of its test reports (see D-5891).