

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2172775	(X3) Date Survey Completed 08/13/2021
Name of Provider or Supplier Elite Dermatology	Street Address, City, State 20326 Tomball Parkway, Suite #400, Houston, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, laboratory proficiency testing (PT) records from 2020 to 2021, and confirmed in an interview revealed the laboratory failed to have documentation of 1 of 2 twice annual accuracy assessments for Mohs slide interpretations in 2020. Findings: 1. Review of the laboratory's Proficiency Policy "MOHS MICROGRAPHIC SURGERY SKIN SPECIMENS" revealed "Semi-annually, the tech or Risk Manager will send two cases containing the original slides,..." 2. Review of the PT records from 2020-2021 revealed 1 of 2 accuracy assessment in 2020. No documentation was found of the first annual accuracy assessment. 3. An interview with the practice manager on 8/13/21 at 11:45 am in the breakroom confirmed the laboratory missed 1 accuracy assessment in 2020.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, proficiency test (PT) records from 2020 to 2021, and confirmed in an interview revealed the laboratory failed to evaluate 3 of 3 accuracy assessments in 2020 and 2021. The findings were: 1. Review of the laboratory's Proficiency Policy "MOHS MICROGRAPHIC SURGERY SKIN SPECIMENS" revealed "Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician." 2. Review of laboratory accuracy assessment PT records revealed the laboratory performed accuracy assessments on December, 2020, June, 2021, and August, 2021. 3. Review of the accuracy assessment PT records revealed the laboratory had no documentation of evaluation 3 of 3 accuracy assessment PT in 2020 and 2021. 4. An interview with the practice manager on 8/13/21 at 11:45 am in the breakroom confirmed the laboratory had no documentation of accuracy assessment evaluation.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted CMS 209 form, the laboratory's policy, testing personnel (TP) initial training records in 2020, and confirmed in an interview revealed the laboratory failed to have documentation of initial training for 1 of 2 testing personnel (TP) for Mohs testing. The findings were: 1. Review of the laboratory's submitted CMS 209 form revealed the the laboratory identified 2 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. 2. Review of the laboratory's policy "TRAINING AND INFORMATION" revealed "Initial training will be done by a qualified Histology /Mohs Technician." 3. Review of testing personnel's initial training records revealed no documentation for 1 of 2 testing personnel (TP) initial training in 2020. TP#2 Hired date: 3/20/2020 4. An interview with the practice manager on 8/13/21 at 11:45 am in the breakroom confirmed the above findings.