

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2257631	(X3) Date Survey Completed 10/15/2024
Name of Provider or Supplier Elite Dermatology Pllc	Street Address, City, State 2571 Kirby Drive, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's submitted CMS 209 form, personnel files, and staff interview, the technical supervisor failed to ensure that the six defined elements for assessing the competency for one of one testing person were used when performing a competency assessment in 2023. Findings include: 1. A review of the laboratory's policy titled 'Competency and CLIA competency assessment' revealed the following: "The following procedures are requirements for assessment of competency for all personnel performing laboratory testing. 1. Direct observations of routine patient test performance, including preparation, if applicable, specimen handling, processing and testing. 2. Monitoring the recording and reporting test results 3. Review of intermediate test results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance and function checks 5. Assessment of test performance through testing previously testing samples 6. Assessment of problem solving skills." 2. Further review of the laboratory's policy titled 'Competency and CLIA competency assessment' revealed the laboratory failed to include the review of Quality Control (QC) records as part of the 6 defined elements. 3. A review of the laboratory's submitted CMS 209 form revealed one testing person performing high complexity testing. 4. A review of the laboratory's personnel files revealed the competency assessment performed in 2023 for testing</p>

person #1 did not include an assessment of all 6 elements: - Testing person #1 - performed in 10/2023 Failed to include the review of QC records and the assessment of problem solving skills. 5. In an interview on 10/15/24 at 9:30 a.m. in the break room, after review of the records, the manager confirmed the above findings.