Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2172775	04/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Elite Dermatology	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	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's twice annual test proficiency verification records for 2021, 2022 and 2023, review of laboratory's policies and procedures and staff interview, the laboratory failed to document evaluation of 5 of 5 twice annual test accuracy verification (proficiency testing) events. Findings included: 1. Review of laboratory's twice annual test accuracy verification records for 2021, 2022 and 2023 revealed the following 5 of 5 verification events did not have documentation of evaluation of the test accuracy verification results by either the laboratory director or designee: 2021 June Event Case numbers included: LC21-016 and LC21-021 2021 August Event Case numbers included: LC21-203, LC21-247, LC21-234 and LC21-236 2022 January Event Case numbers included: LC22-001, LC22-004, and LC22-

	021 2022 July Event Case numbers included: LC22-300, LC22-315, LC22-316 and LC22-334 2023 February Event Case numbers included: LC22-273, LC22-538, LC22-549 and LC22-329 2. Review of laboratory's policies and procedures revealed the laboratory's Quality Assurance Proficiency Testing policy (placed into effect in 2020) did not include protocols for evaluation of results of the twice annual test accuracy verification process. 3. In an interview on 04/11/2023 at 0930 hours in the break room, the facility's COO (as defined on submitted Survey and/or Complaint Investigation Entrance Conference document), after review of the data, confirmed the findings.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's H&E (hematoxylin and eosin) stain quality control (QC) records for 2021 and 2022, review of laboratory's Chemical Logs for the same interval, review of laboratory's policies and procedures and staff interview, the laboratory failed to document lot numbers and expiration dates of stain reagents at time of use for H&E stain, one of one stain procedures performed in the laboratory. Findings included: 1. Review of the laboratory's H&E stain QC records for 2021 and 2022 revealed there was no documentation of reagent's lot numbers or expiration dates for any of the stain reagents at time of use during that interval. 2. Review of laboratory's Chemical Logs for 2021 and 2022 revealed the laboratory documented the lot and expiration date of each H&E reagent at receipt but did not document when each one was placed in use. 3. Review of laboratory's policy "Quality Control Policies and Documentation" (placed into effect in 2020) revealed" "2. Reagent lot numbers and expiration dates will be recorded." There was no protocol in place addressing documentation of reagent lot numbers and expiration dates at time of use. 4. In an interview on 04/11/2023 at 1030 hours in the break room, the facility's COO (as defined on submitted Survey and/or Complaint Investigation Entrance Conference document), after review of the data, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory's temperature records for 2021 and 2022, review of laboratory's policies and procedures and staff interview, the laboratory failed to document corrective actions for out of acceptable range room temperature for 4 of 65 days the temperature was recorded. Findings included: 1. Review of laboratory's temperature records for 2021 and 2022 revealed the laboratory defined acceptable room temperature as "68-76 F (F - degrees Fahrenheit)". 2. Further review of the temperature records revealed the following 4 of 65 reviewed days the temperature was

	out of laboratory defined acceptable range that did not have corrective action documented: Date: Temperature: 07/24/2021 67.5F 02/26/2023 65.7F 08/27/2023 67.3 F 12/17/2023 67.7F 3. Review of laboratory's policies and procedures revealed there was no policy/procedure addressing room temperature monitoring and/or corrective actions for when temperature was out of laboratory defined acceptable range. 4. In an interview on 04/11/2023 at 1045 hours in the break room, the facility's COO (as defined on submitted Survey and/or Complaint Investigation Entrance Conference document), after review of the data, confirmed the findings.