

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2078624	(X3) Date Survey Completed 04/14/2023
Name of Provider or Supplier Clearlyderm, Llc	Street Address, City, State 22191 Powerline Rd Suite 29c, Boca Raton, FL	
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	A recertification survey conducted on 04/14/2023 found the CLEARLYDERM, LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for 17 out of 62 testing dates from 01/05/2022 to 04/12/2023. Findings included: The laboratory uses the "Clearly Derm LLC Boca Control Slide Daily Log" to record the acceptability of the H&E stain. Review of the QC form showed that under the column "Results" it was missing the signature of the Mohs surgeon documenting the review and acceptability of the QC slide for the following dates: 06/29/2022, 12/07/2023, 12/14/2022, 12/21/2022, 12/28/2022, 01/04/2023, 01/18/2023, 01/25/2023, 02/01/2023, 02/08/2023, 02/15/2023, 02/22/2023, 03/01/2023, 03/08/2023, 03/15/2023, 03/22/2023, 03/29/2023, 04/05/2023, 04/12/2023. During an interview on 04/14/2023 at 11:30 AM the Office Consultant confirmed that the laboratory failed to document the acceptability of the Daily QC slide for H& E Stain for the days listed above.</p>