

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0958660	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Valley Dermatology Center Inc	Street Address, City, State 851 E Westpoint Drive Suite B-10, Wasilla, AK	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2021, 2022, and 2023 quality control (QC) records, test procedures, and an interview with the medical assistant, the laboratory failed to take corrective actions when the quality control organism intended to check the Dermatophyte Test Medium (DTM) for its ability to inhibit the growth of certain organisms, did not yield the expected results. Findings include: 1. Six of the six quality control records for new shipments of DTM (9/10/21, 10/28/21, 3/22/22, 4/20/22, 12/20/22, and 3/15/23) revealed the negative control (E. coli) used to check for inhibition had documented growth and DTM color change. No follow-up corrective actions were documented. 2. The procedure manual states the negative control should not have growth or change the color of the DTM. 3. In an interview on 9/20/23 at 14:30 PM the medical assistant confirmed these findings. 4. The laboratory reports performing 50 cultures using DTM annually.</p>