

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>06D2034881</p>	<p>(X3) Date Survey Completed</p> <p>03/27/2026</p>
<p>Name of Provider or Supplier</p> <p>Alta Vista Dermatology</p>	<p>Street Address, City, State</p> <p>206 W County Line Rd, Ste 240, Highlands Ranch, CO</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>Based on an on-site certification survey conducted on March 27, 2026, deficiencies were cited for Alta Vista Dermatology located in Highlands Ranch, Colorado.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedures and an interview with the laboratory director during the survey, the laboratory failed to write a complete Mart-1 immunohistochemical stain procedure manual. The laboratory performs</p>

approximately 30 Mart-1 stains annually. Findings include: 1. A review of the laboratory procedures revealed that the Mart-1 procedure was lacking requirements for patient preparation, microscopic examination, control procedures, corrective actions to take, the laboratory system for entering results in the patient record, and description of the course of action to take if a test system becomes inoperable. 2. An interview with the laboratory director on March 27, 2026 at 12 PM confirmed that the laboratory procedure for Mart 1 lacked requirements for patient preparation, microscopic examination, control procedures, corrective actions to take, the laboratory system for entering results in the patient record, and description of the course of action to take if a test system becomes inoperable.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory maintenance records and an interview with the laboratory director during the survey, the laboratory failed to perform the initial and periodic maintenance for the laboratory cryostat. Findings include: 1. A review of the laboratory maintenance records on March 27, 2026 at 10 AM revealed that the laboratory did not perform maintenance for the laboratory cryostat in 2024 or 2025. 2. An interview with the laboratory director on March 27, 2026 at approximately 10:30 AM confirmed that the laboratory did not perform maintenance for the cryostat since acquiring the instrument in 2024.

D5475

CONTROL PROCEDURES
CFR(s): 493.1256(e)(3)(g)

(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory quality control documents and an interview with the laboratory director during the survey, the laboratory failed to document the quality control for the Mart-1 stain. Findings include: 1. A review of the laboratory documents on March 27, 2026 at 10 AM revealed that the laboratory failed to record quality control of the Mart-1 stain each time the stain is used. 2. An interview with the laboratory director on March 27, 2026 at approximately 12:00 PM confirmed the laboratory failed to record quality control of the Mart-1 stain each time the stain is used.