

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1104243	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 37605 Pembroke Avenue, Livonia, MI	
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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to retain its histopathology slides for at least 10 years for slides examined between July 2013 and December 2013. Findings include: 1. A review of the laboratory's previous survey documentation showed the laboratory had been performing histopathology testing during the 6/11/13 and the 4/9/15 surveys. 2. The surveyor requested histopathology slides from 2013 on 7/25/23 at 2:12 pm and were not made available. 3. An interview on 7/25/23 at 3:08 pm with the Mohs Technician confirmed the laboratory had not retained histopathology slides from examinations performed in 2013.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.</p>

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Mohs Technician, the laboratory failed to include the reportable range for test results for mycology Potassium Hydroxide (KOH) preparation testing for 2 (July 2021 to July 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Potassium Hydroxide (KOH)" procedure revealed a lack of reportable range for test results. 2. A review of mycology KOH preparation patient test results revealed the following results outside of positive or negative for fungal elements: a. Patient NH2 had a KOH preparation test performed on 1/17/22 with the result of "+/-." b. Patient RZ5 had a KOH preparation test performed on 5/16/23 with the result of "demodex." 3. An interview on 7/25/23 at 3:00 pm with the Mohs Technician confirmed the laboratory had not established a reportable range for its mycology KOH preparation testing.