

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1104243	(X3) Date Survey Completed 09/24/2019
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
D3033	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Manager, the laboratory failed to retain Leica Cryostat operating temperatures for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A record review of laboratory maintenance logs revealed a lack of Leica Cryostat operating temperatures between September 2017 to September 2019. 2. A record review of the Leica Cryostat operating manual revealed the required temperature range is 0 to -30 degrees Celsius. 3. An interview on 9/23/19 at 10:25 am with the Quality Assurance Manager confirmed the Leica Cryostat temperature logs were not retained by the laboratory.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Manager, the laboratory failed to follow policies to assess testing personnel competencies for 1 (testing personnel #1) of 1 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of employee competency files revealed a lack of</p>

documented competency for testing personnel #1. 2. An interview on 9/23/19 at 11:24 am with the Quality Assurance Manger confirmed competency was not available for testing personnel #1.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Quality Assurance Manager, the laboratory failed to verify the accuracy of histopathology testing for 1 (2018) of 2 years reviewed. Findings included: 1. A record review of twice a year verification of accuracy records for MOHS histopathology testing revealed a lack of records for 2018. 2. An interview on 9/23/19 at 11:49 am with the Quality Assurance Manager confirmed twice a year verification of accuracy records were not available for 2018.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Quality Assurance Manager, the laboratory failed to include the name and address of the laboratory location where testing was performed for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A review of patient MOHS maps revealed a lack of name and address of the testing location. 2. An interview on 9/23/19 at 10:41 am with the Quality Assurance Manager confirmed the MOHS maps used by the laboratory did not have the name or address of the laboratory.