

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2039532	(X3) Date Survey Completed 07/14/2022
Name of Provider or Supplier Main Line Dermatology	Street Address, City, State 1246 Wrights Lane, West Chester, PA	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure positive identification from the time of collection through the completion of testing for 1 of 4 patient specimens. Findings include: 1. During the inspection, 1 of 4 patient specimens containing 18 slides was observed to be labeled with an incorrect patient name on 3 of the 18 slides at 11:30 am on 7/14/2022. 2. During an interview at 12:30pm on 07/14/2022, the laboratory director confirmed this finding.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the Laboratory Director failed to verify the accuracy of MOH's testing in 2021. Findings Include: 1. On 7/14/2022 at 10:50 am, the laboratory failed to provide documentation of a second MOHs testing event for the verification of accuracy during 2021. 2. During an interview at 12:30pm on 07/14/2022 the laboratory director confirmed this finding.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure a written procedure was available for twice annual accuracy verification of analytes not found in Subpart I. Findings include: 1. On 7/14/2022 at 10:40 am the surveyor requested a written procedure regarding proficiency testing requirements for non-regulated analytes. The laboratory failed to provide a written procedure prior to the end of the survey on 7/14/2022 at 12:30 PM. 2. The Laboratory Director confirmed the findings above in an interview at 12:30pm on 07/14/2022.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on record review and interview, it was determined that room temperature was recorded out of acceptable range for 12 of 46 days with no corrective action present. from 01/03/2022 to date of survey 07/14/2022. Findings: 1. A review of the room temperature log at the time of inspection revealed an acceptable range of 68-82 degree Fahrenheit. 2. A review of the room temperature log at the time of inspection around 10:55 am revealed out of range of temperature on 12 of 46 days from 01/01/2022 to 07/14/2022. No documented corrective action was provided for temperatures recorded out of range. 3. Interview with LD confirmed the out of range temperature at 12:30pm on 07/14/2022.