

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0888863	(X3) Date Survey Completed 10/29/2020
Name of Provider or Supplier Matthew K Abele Md Pc	Street Address, City, State 2700 10th Avenue South Suite 501 Bdg 2, Birmingham, AL	
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
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 the review of accuracy verifications for Potassium Hydroxide preparations (KOH) and Scabies, a review of policies and procedures, and a lack of a written procedure, and an interview with the Laboratory Director, the laboratory failed to perform accuracy verifications at least twice annually in 2019. The laboratory further failed to have a written policy and procedure to address the performance of accuracy verifications for the above mentioned tests. The findings include: 1. A review of the 2018 - 2020 accuracy verifications for KOH and Scabies interpretations revealed in 2019 one Scabies accuracy verification was performed, dated 9/27/19. There was no documentation of KOH verifications for 2019. 2. A review of the procedure for KOH revealed it does not include how accuracy is being performed or the frequency in which the accuracy verifications will be done. 3. During an interview conducted on 10/29/2020 at 12:42 PM, the Laboratory Director (LD) confirmed no KOH was performed in 2019 and one Scabies accuracy verification was done. The LD further stated he was unaware this was a requirement.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of the cryostat's Operators' Manual and an interview with the histotech, the laboratory failed to monitor and document room temperature and humidity for the Mohs laboratory. This affected the survey review period, 4/13/2018 - 10/29/2020 (day of the survey). The findings include: 1. A review of cryostat Operators' Manual revealed the following: "Temperature (Recommended Operation) +15 degrees C (Celsius) to +30 degrees C (at a max. Relative humidity of 60%) Note Performance may deteriorate when operated outside of this range." 2. During an interview conducted on 10/29/2020 at 1:05 PM, the histotech confirmed the laboratory had not monitored room temperature and humidity.