

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2188374	(X3) Date Survey Completed 06/06/2022
Name of Provider or Supplier Uderm, Pllc	Street Address, City, State 5243 Little Debbie Pkwy, Ste 111, Ooltewah, TN	
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 observation of the laboratory, review of patient test reports, request for laboratory records, and interview with the laboratory director, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) assay twice a year in 2022. The findings include: 1. Observation of the laboratory on 06.06.2022 at approximately 9:30 a.m. revealed Clorazol Black E KOH prep and a microscope in use for patient testing for KOH skin scrapings for mycology and parasitology. 2. Review of random patient test reports revealed KOH was reported on the following patients/dates: Patient #3567 reported on 03.14.2022 Patient #4192 reported on 05.05.2022 3. Request made to the laboratory director on 06.06.2022 at 9:30 a.m. for records verifying the accuracy of the KOH test revealed no records were available. 4. Interview with the laboratory director on June 6, 2022 at approximately 12:00 p.m. confirmed the laboratory failed to verify the accuracy of KOH test twice a year in and 2022. =====</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 ===== Based on observation of the provider testing area, review of the laboratory procedure manual and interview with the Laboratory Director, the laboratory failed to provide a procedure for the potassium hydroxide examination (KOH). The findings include: 1. Observation of the provider testing area on June 6, 2022 at approximately 9:30 a.m. revealed a bottle of KOH on the counter, in use for patient testing. 2. Review of the laboratory procedure manual revealed no procedure for the KOH test. 3. Interview on June 6, 2022 at approximately 12:00 p.m. with the Laboratory Director confirmed the KOH reagent is in use for patient testing with no KOH procedure.
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D6030

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
 ===== Based on one of two testing personnel listed on the Laboratory Personnel Report (CLIA), (form CMS-209), who perform potassium hydroxide (KOH) testing, lack of policy for monitoring testing personnel performing KOH testing, lack of competency documentation for one of two testing personnel performing KOH testing and interview with the laboratory director, the laboratory director failed to ensure a policy was in place to monitor testing personnel performing KOH testing since October 2021. The findings include: 1. Testing personnel #2 listed on the CMS-209 form who performed KOH testing. 2. Lack of policy for monitoring testing personnel who performed KOH testing. 3. Lack of competency documentation for one of two testing personnel performing KOH testing since testing personnel hire date October 2021. 4. Interview at approximately 12:00 p.m. June 6, 2022 with the Laboratory Director confirmed there was no policy or competency documentation for monitoring one of two testing personnel listed on CMS-209 form who performed KOH testing since October 2021.
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