

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0105786	<b>(X3) Date Survey Completed</b>  02/05/2019
<b>Name of Provider or Supplier</b>  Center For Dermatology	<b>Street Address, City, State</b>  128 Columbia Turnpike, 2nd Floor, Florham Park, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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:</p> <p>a. Based on surveyor review of the Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) tests twice annually in the calendar years 2017 and 2018. The TP #2 listed on CMS form 209 confirmed on 2/5/19 at 10:00 am that the laboratory did not verify the accuracy of KOH tests twice annually. b. Based on surveyor review of the BA records and interview with the TP, the laboratory failed to verify the accuracy of Dermatophyte tests twice annually in the calendar years 2017. The TP #2 listed on CMS form 209 confirmed on 2/5/19 at 10:10 am that the laboratory did not verify the accuracy of Dermatophyte tests twice annually.</p>
<b>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each batch of ACU-derm Dermatophyte Test Media (DTM) for its ability to inhibit growth from 3/7/17 to the date of the survey. The TP # 2 listed on the CMS form 209 on 2/5/19 at 11:10 am that the laboratory did not perform the above QC.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for Dermatophyte and Potassium Hydroxide (KOH) tests from 3/7/17 to the date of survey. The TP # 2 listed on CMS form 209 confirmed on 2/5/19 at 10:35 am that the TRD was not on the FR.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to verify manually entered Dermatophyte and Potassium Hydroxide (KOH) test results into the Patient's Medical Record for accuracy from 3/7/17 to the date of the survey. The TP #2 listed on CMS 209 confirmed on 2/5/19 at 11:15 am that the laboratory did not have the procedure mentioned above.</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that all BA reports received were reviewed by the appropriate staff to evaluate laboratory's performance and to identify any problem that required corrective action for Dermatophyte tests in the calendar year 2018. The TP #2 listed on CMS form 209 confirmed on 2/5/19 at 10:30 am that BA reports were reviewed.