

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D2079061	<b>(X3) Date Survey Completed</b>  09/27/2018
<b>Name of Provider or Supplier</b>  Advanced Dermatology Of Sc	<b>Street Address, City, State</b>  1650 Skylyn Drive, Spartanburg, SC	
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>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: During an onsite validation survey on 09/27/2018, based on laboratory quality control records, lack of documentation, and testing personnel interview, the laboratory failed to perform quality control checks for each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response before, or concurrent with, initial use for two of two years reviewed from 2016 to 2018. Findings include: 1. Review of laboratory quality control records revealed that end user quality control for each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response was not being performed on the dermatophyte test medium (DTM). 2. Records of daily quality control testing or an acceptable Individualized Quality Control Plan (IQCP) for the DTM test was unavailable for review for twenty two out of two years reviewed from 2016 to 2018 (September 2016 through September 2018). 3. Testing personnel confirmed during an onsite interview on 09/27/2018 at 2:30 that the laboratory had failed to perform daily quality control testing or establish an acceptable IQCP for DTM testing</p>