

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0687251	<b>(X3) Date Survey Completed</b> 04/12/2018
<b>Name of Provider or Supplier</b> Qualderm Partners	<b>Street Address, City, State</b> 24 White Bridge Pike, Nashville, TN	
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>D5413</b>	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) temperature records for the cryostat and an interview with the laboratory director, the laboratory failed to document the daily operational temperatures from March 2016 to June 2017. Findings include: 1. There were no documented QC cryostat temperatures available for review for the period of March 1, 2016 to June 30, 2017. 2. In an interview, on April 12, 2018, at 11:45 a.m. with the laboratory director confirmed the missing QC temperature cryostat records from March 2016 to June 2017.</p>
<b>D5805</b>	<p>TEST REPORT 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</p>

acceptability.

This STANDARD is not met as evidenced by:

Based on review of four patient final test results, the Centers for Medicare and Medicaid Services (CMS)-116 form and interview with the laboratory director, the laboratory name and address were not correct on the final laboratory reports. The findings include: 1) Review of four patients audited for final test results dated 120616, 050417, 100317, and 021518 revealed either a missing name or address on the final test reports. 2) Review of the CMS -116 form revealed the laboratory name and address is Belle Meade Dermatology at 24 White Bridge Road, Nashville, TN 37205. 3) Interview on April 12, 2018 at 11:30 a.m. with the laboratory director confirmed the name and address incomplete on the laboratory final reports.