

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0868280	<b>(X3) Date Survey Completed</b>  04/10/2019
<b>Name of Provider or Supplier</b>  Medical Specialists Inc	<b>Street Address, City, State</b>  305 Jones Avenue, Waynesboro, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 10, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
<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 review of the Laboratory Freezer Temperature charts for the years 2017, 2018, 2019, and Package Inserts for the Bio-Rad controls, the laboratory was not storing the Bio-Rad controls within the manufacturers required range equal to or less than -20 degrees centigrade. Findings: 1. Review of the Package Inserts for the Bio-Rad controls state that the storage temperature should be equal to or less than -20 degree centigrade. Review of the Laboratory Freezer Temperature charts for 2017, 2018, and 2019 showed that from June to December, 2017, the freezer temperature was documented as being greater than -20 degree centigrade 139 days. In 12 months of 2018, the freezer temperature was documented as being greater than -20 degree centigrade 252 times. The first three months of 2019, the freezer was documented as being greater than -20 degrees centigrade 5 times. 2. Staff interview with the office</p>

manager and the laboratory supervisor, on Wednesday, April 10, 2019 at approximately 4:45 pm in the conference room, confirmed that the temperature was out of range the aforementioned days for 2017, 2018, and 2019.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel(TP) documents and an interview with the office manager and the lab supervisor , the technical consultant (TC) failed to perform semiannual competency on all testing personnel. Findings: 1. Based of review of TP competency documents the TC failed to perform semiannual competency on three of the 19 testing personnel. 2. Interview with the office manager, and the lab supervisor on April 10, 2019 at approximately 4:20pm in the conference room confirmed that the TC failed to perform semiannual competency on three of the 19 testing personnel.