

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2010923	(X3) Date Survey Completed 09/03/2026
Name of Provider or Supplier Southern Oncology Specialists	Street Address, City, State 9930 Kincey Avenue Suite 165, Huntersville, NC	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of 2026 temperature logs, observation, and interview with the TC (technical consultant) 9/3/26, the laboratory failed to establish an acceptable freezer temperature range that was consistent with manufacturers' requirements for storage of supplies. Findings: 1. Review of 2026 temperature logs revealed an acceptable freezer temperature range of -10 to -30 degrees Celsius. 2. During a tour of the laboratory at approximately 1:45 p.m., the surveyor observed items stored in the laboratory's freezer with various storage temperature ranges included. Examples: a. Beckman Coulter Access Folate Calibrators - instructions require storage at -20 degrees Celsius or colder. b. Validate G3 Test Set - instructions require storage at -10 to -25 degrees Celsius. c. Bio-Rad Liquichek Immunoassay Premium Control - instructions require storage at -20 to -70 degrees Celsius. d. Technopath Multichem S Plus Control - instructions require storage at -20 to -80 degrees Celsius. 3. During interview at approximately 3:20 p.m., the TC confirmed the freezer temperature acceptable range needed to be adjusted to ensure all supplies were stored appropriately based on manufacturers' requirements.
D5785	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on observation, review of 2026 temperature logs, and interview with the TC 9/3/26, the laboratory failed to ensure freezer temperatures met manufacturer's requirements for proper storage of supplies 95 of 167 days from 1/2/26 to 8/31/26..

Findings: 1. During a tour of the laboratory at approximately 1:45 p.m., the surveyor observed items stored in the laboratory's freezer with various storage temperature ranges included. Examples: a. Beckman Coulter Access Folate Calibrators - instructions require storage at -20 degrees Celsius or colder. b. Validate G3 Test Set - instructions require storage at -10 to -25 degrees Celsius. c. Bio-Rad Liquichek Immunoassay Premium Control - instructions require storage at -20 to -70 degrees Celsius. d. Technopath Multichem S Plus Control - instructions require storage at -20 to -80 degrees Celsius. 2. Review of 2026 temperature logs revealed recorded temperatures that were below the -10 to -25 degrees Celsius specified by the manufacturer for storage of the Validate G3 Test Set. The laboratory recorded temperatures below -25 degrees Celsius during the following months: a. January - 14 of 20 days b. February - 11 of 19 days c. March - 12 of 22 days d. April - 12 of 21 days e. May - 7 of 20 days f. June - 17 of 22 days g. July - 14 of 22 days h. August - 8 of 21 days 3. During interview at approximately 3:20 p.m., the TC confirmed the freezer temperature acceptable range needed to be adjusted to ensure all supplies were stored appropriately based on manufacturers' requirements.