

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0720020	(X3) Date Survey Completed 03/26/2026
Name of Provider or Supplier Blue Ridge Cancer Care	Street Address, City, State 1995 West Ridge Rd, Wytheville, VA	
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
D0000	An announced CLIA validation survey was conducted at Blue Ridge Cancer Care on March 26, 2026, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, lack of technical consultant (TC) competency assessment records and interview with testing personnel (TP) #1 and 3, the laboratory failed to establish a competency assessment procedure to assess the competency for 3 of 4 TCs delegated supervisory responsibilities by the laboratory director. Findings: 1. Review of laboratory delegation procedure revealed the LD delegated the following roles to individuals qualified as a TC, "Establishes a quality control program, appropriate for the testing performed, establishes the acceptable levels of analytical; performance , and ensures these levels are maintained throughout the testing process". 2. Review of the laboratory competency procedure revealed the competency assessment procedure did not included the assessment of TC for their delegated TC responsibilities. 3. Interview with TP#1 and #3 on March 26, 2026 at 1: 15 pm, confirmed the laboratory competency procedure did not include the assessment of TC for their delegated TC responsibilities nor were TC competency assessments performed for the 3 TCs.</p>
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 observation, the lack of temperature monitoring records, and interview with testing personnel (TP) #1 and #3, the laboratory failed to monitor the temperature of the 4 of 4 rooms where Becton Dickinson (BD) Vacutainer tubes were stored. Findings: 1. Tour of building revealed the following areas where BD Vacutainer tubes were kept with the manufacturer stated temperature requirement of 4-25 degrees Celsius: a. First Floor - treatment area and one draw station. 2. Second Floor - two draw stations. 2. The following sampling of BD Vacutainer tubes were observed available for use: I. Draw station - a. 01 case of Blue Top Sodium Citrate tubes - Lot #5260122. b. 0 cases of Green lithium heparin (LH) tubes - Lot#5048333 c. 04 cases of Yellow top SST (Serum Separator Tube) - Lot #5286776 d. 04 cases of Purple top EDTA (Ethylenediaminetetraacetic acid) tubes - Lot#5101395 e. 05 cases of Black /red top SST - Lot#5325119 f. 14 tubes of Pink Top Microtainer tubes - Lot#5174584 II. Treatment room, on a rolling cart - a. 05 tubes of Purple top EDTA (Ethylenediaminetetraacetic acid) - Lot#5101395 b. 02 tubes of Yellow top SST (Serum Separator Tube) - Lot #5286776 3. The laboratory was unable to provide temperature monitoring records for the above room where the above BD vacutainer tubes were stored for 2 years (March 2024 - March 2026). 4. By interview on March 26, 2026, at 12:30 pm, TP#1 and #3 confirmed temperatures were not monitored or documented in the treatment area and in the draw stations.