

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D1004150	<b>(X3) Date Survey Completed</b> 05/04/2026
<b>Name of Provider or Supplier</b> Grace Primary Care A Division Of Summit Medical	<b>Street Address, City, State</b> 950 Baker Hwy, Ste 4, Huntsville, 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>D0000</b>	During a recertification survey completed on May 4, 2026, the laboratory was found out of compliance with the following condition: 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 observations of the laboratory, a review of the laboratory procedure manual, and staff interviews, the laboratory failed to ensure its competency assessment policy was in compliance with Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations when it did not include the six required elements defined in Subpart M. The findings include: 1. Observation of the laboratory on 05.04.2026 at 8:20 a.m. revealed the Abbott Cell Dyn (serial number 8394) hematology analyzer used for complete blood count with automated differential (CBC w/ diff) patient testing. 2. A review of the laboratory policy titled "Training and Competency of Lab Testing Personnel" revealed that the procedure did not include the six required elements (A. Direct observation of patient testing, B. Monitoring the recording and reporting of test results, C. Record review, D. Direct observation of instrument and maintenance function checks, E. Blind testing, F. Evaluation of problem solving), as defined in Subpart M of the CLIA regulations. 3. An interview with the Laboratory Lead and Site Manager on 05.04.2026 at 12:20 p.m. confirmed the survey findings.</p>
<b>D5417</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Citation One: Based on laboratory observation and staff interviews, the laboratory failed to ensure that it did not use Becton, Dickinson and Company (BD) Dipotassium Ethylenediaminetetraacetic Acid (K2EDTA) Vacutainer tubes for blood collection for patient testing after their expiration date on the survey date, 05.04.2026. The findings include: 1. Observation of the laboratory on 05.04.2026 at 08:20 a.m. revealed an Abbott Cell Dyn (serial number 8394) hematology analyzer used for complete blood count with automated differential (CBC w/ diff) patient testing. Also observed were 3 BD K2EDTA Vacutainer blood collector tubes (used for collecting CBC w/ diff samples), lot number 4257276, expiration date 01.31.2026. 2. An interview with the Laboratory Lead on 05.04.2026 at 8:30 a.m. confirmed the above survey findings. A subsequent interview on 05.04.2026 at 12:20 p.m. with the Site Manager confirmed that 1,524 patient samples were run for CBC w/ diff from 02.01.2026 through 05.03.2026. Citation Two: Based on laboratory observation and staff interviews, the laboratory failed to ensure that it did not use Becton, Dickinson and Company (BD) Serum Separator Tubes (SST) Vacutainer tubes for blood collection for reference laboratory patient testing past their expiration date on the survey date, 05.04.2026 The findings include: 1. Observation of the laboratory on 05.04.2026 at 8:20 a.m. revealed the following: 28 expired BD SST collection tubes used for reference laboratory patient testing, which included: -5 tubes, lot number: 4059220, expiration date of 02.28.2025 -4 tubes, lot number: 4100336, expiration date of 03.31.2025 -2 tubes, lot number: 4136935, expiration date of 04.30.2025 -9 tubes, lot number: 4302039, expiration date of 09.3.2025 -3 tubes, lot number: 4345039, expiration date of 11.30.2025 -1 tube, lot number: 5042682, expiration date of 01.31.2026 -4 tubes, lot number: 5071289, expiration date of 02.28.2026 2. An interview on 05.04.2026 at 8:30 a.m. with the Laboratory Lead confirmed the above survey findings.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), review of personnel records, lack of documentation, and staff interview, the laboratory director failed to ensure that the person performing technical consultant duties in 2024 through the survey date (05.04.2026) had the appropriate education to qualify as technical consultants (TC) (Refer to D6033 and D6035). The findings include: 1. A review of the Form CMS-209 revealed thirteen testing personnel (TP) who performed moderately complex complete blood count with automated differential (CBC w/ diff) patient testing and one TC. 2. A review of the laboratory's personnel records revealed the following: Competency Assessments were initialized by TP1 in the "reviewer" box and signed by

TP1 in the "reviewer signature" section for the following twelve TPs. TP2: Annual Competency on 09.10.2024 and 06.17.2025 TP3: Annual Competency on 09.10.2024 and 06.17.2025 TP4: Annual Competency on 09.10.2024 and 06.17.2025 TP5: Annual Competency on 09.10.2024 and 06.17.2025 TP6: Annual Competency on 09.10.2024 and 06.17.2025 TP7: Annual Competency on 09.10.2024 and 06.17.2025 TP8: Annual Competency on 09.10.2024 and 06.17.2025 TP9: Six Month Competency on 10.22.2024 and Annual Competency on 05.01.2025 TP10: Initial Competency on 02.24.2025, Six Month Competency on 07.30.2025, and Annual Competency on 01.13.2026 TP11: Initial Competency on 03.08.2024, Six Month Competency on 08.08.2024, and Annual Competency on 06.17.2025 TP12: Initial Competency on 03.06.2024, Six Month Competency on 08.08.2024, and Annual Competency on 06.17.2025. TP13: Initial Competency on 01.06.2025, Six Month Competency on 06.17.2025, and Annual Competency on 12.09.2025. 3. There was no evidence in the personnel records that TP1 met the minimum regulatory requirements to qualify as a technical consultant at CFR 493.1411. 4. An interview with the Laboratory Lead and Site Manager on 05.04.2026 at 12:20 p.m. confirmed the above survey findings. Word Key: CLIA = Clinical Laboratory Improvement Amendments

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on a review of testing personnel competency assessments and personnel education verification records, the person who performed testing personnel competency assessments did not meet the minimum requirements to perform technical consultant duties. (Refer to D6035)

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the

designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of testing personnel competency assessments, personnel education verification, and an interview with the Laboratory Lead, TP1, who performed technical consultant duties, did not have the required education to perform those duties on the survey date (05.04.2026). The findings include: 1. A review of the laboratory's personnel records revealed the following: Competency Assessments were initialized by TP1 in the "reviewer" box and signed by TP1 in the "reviewer signature" section for the following twelve TPs. TP2: Annual Competency on 09.10.2024 and 06.17.2025 TP3: Annual Competency on 09.10.2024 and 06.17.2025 TP4: Annual Competency on 09.10.2024 and 06.17.2025 TP5: Annual Competency on 09.10.2024 and 06.17.2025 TP6: Annual Competency on 09.10.2024 and 06.17.2025 TP7: Annual Competency on 09.10.2024 and 06.17.2025 TP8: Annual Competency on 09.10.2024 and 06.17.2025 TP9: Six Month Competency on 10.22.2024 and Annual Competency on 05.01.2025 TP10: Initial Competency on 02.24.2025, Six Month Competency on 07.30.2025, and Annual Competency on 01.13.2026 TP11: Initial Competency on 03.08.2024, Six Month Competency on 08.08.2024, and Annual Competency on 06.17.2025 TP12: Initial Competency on 03.06.2024, Six Month Competency on 08.08.2024, and Annual Competency on 06.17.2025. TP13: Initial Competency on 01.06.2025, Six Month Competency on 06.17.2025, and Annual Competency on 12.09.2025. 2. A review of the documentation of the highest level of education revealed that TP1 did not have the required education as defined in the regulations to perform the TC duties. 3. An interview with the Laboratory Lead and Site Manager on 05.04.2026 at 12:20 p.m. confirmed the above survey findings. Word Key: TP = Testing Personnel