Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D0928131	**(X3) Date Survey Completed** 07/13/2026
Name of Provider or Supplier Galen North Pediatrics	**Street Address, City, State** 1039 Executive Dr Ste #101, Hixson, TN	

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	During a recertification survey completed on July 13, 2026, the laboratory was found out of compliance with the following conditions: 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the manufacturer's control package insert, review of laboratory policy, and staff interviews, the laboratory failed to label three of three control vials used for performing quality control on the Beckman Coulter DxH520 hematology analyzer with an open date and a revised expiration date on the survey date (07.13.2026). The findings include: 1. An observation of the laboratory on 07.13.2026 at 9:15 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: BC111133) used for complete blood count with automated differential (CBC w/diff) patient testing. Observation also revealed three levels of DxH500 Series hematology controls (lot numbers: abnormal low-352618611, normal-362618612, abnormal high-372618613) that lacked open dates and revised expiration dates. 2. A review of the manufacturer's control package insert revealed that "16* Open Vial Days, *Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided they are handled properly." 3. A review of the laboratory's "Reagent Storage/Preparation" procedure revealed, "Materials should be dated when received and again when opened

	or reconstituted and if the expiration date changes after opening, the new expiration date should be written on the label." 4. An interview with the Office Manager on 07.13.2026 at 09:18 a.m. confirmed the survey findings above. Word key: IFU = Instructions for Use
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: Based on laboratory observation and staff interview, the laboratory failed to ensure that it did not use blood collection tubes for reference laboratory patient testing past their expiration date on the date of the survey, 07.13.2026. The findings include: 1. Laboratory observation on 07.13.2026 at 9:15 a.m. revealed a drawer with blood collection supplies, which included 58 Becton Dickinson (BD) Lithium Heparin Microtainer blood collection tubes (46 of lot number: 418046N, expiration date: 12.31.2025, and 12 of lot number: 331018N, expiration date: 04.30.2025) for reference laboratory testing. 2. An interview with the Office Manager at 09:25 a.m. confirmed the above survey findings.
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(s) who performed testing personnel competency assessments did not meet the minimum requirements to perform technical consultant duties. (Refer to D6035 and D6053)
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 staff interviews, the personnel (TP1 and TP2) who performed technical consultant duties did not have the required education to perform those duties on the survey date (07.13.2026). The findings include: 1. A review of the laboratory's personnel records revealed the following: Competency Assessments signed by TP1 in the "reviewer signature & date" section: -TP2: Annual Competencies 03.06.2025 and 05.07.2026 -TP3: Initial Competency 03.06.2025 and Annual Competency 05.07.2026 -TP4: Initial Competency 03.06.2025 and Annual Competency 05.07.2026 -TP5: Initial Competency 05.07.2026 -TP6: Initial Competency 05.07.2026 -TP7: Initial Competency 05.07.2026 Competency Assessments signed by TP2 in the "reviewer signature & date" section: -TP1: Annual Competencies 03.06.2025 and 05.07.2026 2. A review of the documentation of the highest level of education revealed that TP1 and TP2 did not have the required education as defined in the regulations to perform the technical consultant duties. 3. An interview with the Office Manager and Technical Consultant on 07.13.2026 at 12:00 p.m. confirmed the above survey findings. Word Key: TP = Testing Personnel
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel (TP) records, and staff interview, the technical consultant failed to evaluate competency at least twice within the first year of patient testing for two of seven testing personnel in 2025. The findings include: 1. Observation of the laboratory on 07.13.2026 at 9:11 a.m. revealed a Beckman Coulter DxH 520 hematology analyzer (serial number BC111133) used for complete blood count with automated differential (CBC w/ diff) patient testing. 2. A review of Form CMS-209 revealed seven testing personnel who performed moderately complex patient testing for CBC w/ diff. 3. A review of testing personnel records revealed no documentation of competency twice annually during the first year of patient testing for TP3 (initial competency on 03.06.2025) and TP4 (initial competency on 03.06.2025). 4. An interview with the Office Manager and Technical Consultant on 07.13.2026 at 12:00 p. m. confirmed the survey findings above.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION 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 testing personnel (TP) records, and staff interviews, two of five new TP since the date of the last survey (11.04.2024), did not qualify to perform moderately complex complete blood count with automated differential (CBC w/ diff) patient testing due to a lack of documentation of the highest level of education. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the Centers for Medicare and

	Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel (TP) records, and staff interview, two of five new TP since the date of the last survey (11.04.2024), did not qualify to perform moderately complex complete blood count with automated differential (CBC w/ diff) patient testing due to a lack of documentation of the highest level of education on the survey date, 07.13.2026. The findings include: 1. Observation of the laboratory on 07.13.2026 at 9:11 a.m. revealed a Beckman Coulter DxH 520 hematology analyzer (serial number BC111133) used for moderately complex CBC w/ diff patient testing. 2. A review of the Form CMS-209 revealed seven TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) listed as performing moderately complex CBC w/ diff patient testing. TP3, TP4, TP5, TP6, and TP7 were new testing personnel since the last survey (11.04.2024). 3. A review of TP records revealed no documentation of the highest level of education for TP6 and TP7. 4. An interview with the Office Manager and Technical Consultant on 07.13.2026 at 12:00 p.m. confirmed the above survey.