Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0928131	09/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Galen North Pediatrics	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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: ========== Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services Form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory technical consultant and lead testing person, determined that PT samples were not tested by all testing personnel listed on the CMS-209 in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's API Proficiency Testing Attestation records revealed only two of six testing personnel's signatures as testing PT samples (2020 Event 1, 2 and 3; 2021 Event 1 and 3; 2022 Event 1 and 2). 2. Review of the CMS-209 revealed six personnel who perform patient testing. 3. Interview with the technical consultant and lead testing person on September 22, 2022 at 11:30 am in the laboratory breakroom confirmed that PT samples were not tested by all testing personnel listed on the CMS-209 for 7 events in 2020, 2021, and 2022. ==========
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: ========== Based on direct observation, review of laboratory environmental logs, review of laboratory's Beckman Coulter DxH 520 Operator's Manual, and interview with the technical consultant and lead testing person, determined the laboratory failed to document laboratory room temperature and humidity for 32 of 32 months (01/2020 through 08/2022). The findings include: 1. During a tour of the laboratory on 09.22.2022 at 9:15 A.M., the surveyor observed a Beckman Coulter DxH 520 CBC analyzer on the laboratory counter. 2. Review of laboratory environmental logs revealed laboratory failed to document laboratory room temperature and room humidity for 32 of 32 months (01/2020 through 08/2022). 3. Review of the laboratory's Beckman Coulter DxH520 Operator's Manual, stated, "The instrument configured with DxH 520 consumables meets performance specifications when operated at a temperature of +18 to 32 degrees Celsius (64.4 to 89.6 degrees F). The instrument meets performance claims when operated at a maximum of 80% relative humidity (non-condensing) at 32 degrees Celsius (89.6 degrees F)." 4. Interview with laboratory technical consultant and lead testing person at 11:45 am on 09.22.2022 in the laboratory brekroom confirmed the above findings. ==========