

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0928131	(X3) Date Survey Completed 11/04/2024
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and staff interview, the laboratory failed to establish a written policy or procedure defining the quality activities used to monitor, assess, and correct problems in the laboratory's testing systems for 2023 and 2024. The findings include: 1. A review of the laboratory procedure manual revealed no policy or procedure defining the laboratory's quality assessment activities used to monitor, assess, and correct problems in the laboratory's testing systems on the survey date (11/04/2024). 2. An interview with the office manager and laboratory consultant on 11/04/2024 at 1:30 p.m. confirmed that the laboratory did not have written quality assessment policies for monitoring and evaluating the pre-analytical, analytical, and post-analytical phases of the testing process.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory procedure manual, environmental monitoring records, and staff interview, the laboratory failed to follow its temperature and humidity monitoring procedure for 23 of 24 months in 2022, 2023, and 2024. The findings include: 1. A review of the laboratory's "Temperature and Humidity Monitoring" policy revealed the following: - The laboratory is "to monitor room, incubator, refrigerator, and freezer temperature to assure reagent stability and room humidity of testing environment for quality instrument operation." - "In the event of a temperature or humidity that is found outside of acceptable range, steps must be taken to evaluate the contents of the storage container." - "Quality control logs containing temperature checks and eye wash station flush will be reviewed monthly." 2. A review of the laboratory's 2022, 2023, and 2024 "Monthly Temperature Checks" logs revealed the following: - The laboratory's acceptable room temperature range is 20 - 23 degrees Celsius(C). - The laboratory recorded the following room temperatures outside their established acceptable ranges: 23.2C on 11/03/2022, 23.4C on 11/11/2022, 18.5C on 11/14/2022, 19.7C on 12/16/2022, 23.9C on 02/06/2023, 23.4C on 02/23/2023, 23.5C on 03/02/2023, 23.4C on 03/31/2023, 23.4C on 08/09/2023, 19.7C on 11/13/2023, 19.7C on 11/27/2023, 19.9C on 12/19/2023, 19.7C on 12/21/2023, 19.9C on 12/22/2023, 19.1C on 01/29/2024, 23.2C on 04/08/2024, 23.4C on 04/11/2024, 23.2C on 04/30/2024, 23.4C on 06/03/2024, 23.4C on 06/05/2024, 23.4C on 06/19/2024, 23.4C on 07/17/2024, and 23.4C on 07/31/2024. - The laboratory did not document any corrective actions for the dates where the room temperature was outside the acceptable range or monthly reviews of the temperature logs from November 2022 to October 2024. 3. An interview with the office manager and laboratory consultant on 11/04/2024 at 1:30 p.m. confirmed the laboratory did not review the "Monthly Temperature Checks" logs or document corrective actions when the room temperature was outside its acceptable range.