

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0859137	(X3) Date Survey Completed 09/25/2023
Name of Provider or Supplier Galen Medical Group Laboratory Pc	Street Address, City, State 4976 Alpha Lane, 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
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> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's procedures and environmental logs, and interview with the laboratory manager, determined the laboratory failed to follow their own written procedure for performing and documenting corrective actions for unacceptable refrigerator temperature for 42 out of 384 days from April 2022 through the survey date of September 25, 2023. Findings included: 1. Direct observation of the laboratory on 09.25.2023 at 11:10 am revealed a microbiology refrigerator (S#50394) in use for storing the following Microbiology testing media and quality control (QC): a. BBL TSA agar b. BBL Maconkey agar c. LIM Broth d. Selective Strep agar e. Mueller Hinton agar f. Kwik Stik P.aeruginosa g. Kwik Stik S. gallolyticus h. Kwik Stik E. coli i. Kwik Stik K. oxytoca j. Kwik Stik S. agalactiae 2. Review of the laboratory's "Temperature Monitoring" procedure stated, "Temperatures are monitored and recorded for all containers used for storage of samples and/or supplies used for testing. Temperatures are recorded daily on the Temperature Log. In the event of a temperature failure, steps must be taken to evaluate the contents of the storage container. 1. Define refrigerator/freezer problem and time of discovery. 2. Define immediate steps taken to rectify problem (such as moving contents to a working refrigerator/freezer) and document time of transfer. 3. Report problem to maintenance department for repair as soon as possible. 4. After repair and temperature has stabilized to the correct temperature, transfer contents back. 5. All the stored items must be checked. If stored items are reagents, put reagents on instruments and run quality control to verify that the reagent integrity has</p>

not been compromised. If stored items were calibrators or controls, run all QC and calibrators to verify integrity of these items. 6. Document all the above on the temperature log." 3. Review of the manufacturer's storage requirements listed on the BBL TSA agar, BBL Maconkey agar, LIM Broth, Selective Strep agar, Mueller Hinton agar, Kwik Stik P.aeruginosa, Kwik Stik S. galloluticus, Kwik Stik E. coli, Kwik Stik K. oxytoca, and Kwik Stik S. agalactiae stated temperature requirements of "2-8 C. " 4. Review of the laboratory's environmental logs revealed the Microbiology refrigerator temperature was out of acceptable range and no corrective action documented for the following dates: 2023-08-01, 2023-08-02, 2023-08-03, 2023-08-07, 2023-08-08, 2023-09-01, 2023-09-05, 2023-09-06, 2023-09-07, 2023-09-08, 2023-09-11, 2023-09-12, 2023-09-13, 2023-09-14, 2023-09-15, 2023-09-18, 2023-09-19, 2023-09-20, 2023-09-21, 2023-09-22 5. Review of the laboratory's environmental logs revealed the Microbiology refrigerator temperature was not recorded and no corrective action documented for the following dates: 2023-06-01, 2023-06-02, 2023-06-05, 2023-06-06, 2023-06-07, 2023-06-08, 2023-06-09, 2023-06-12, 2023-06-13, 2023-06-14, 2023-06-15, 2023-06-16, 2023-06-19, 2023-06-20, 2023-06-21, 2023-06-22, 2023-06-23, 2023-06-26, 2023-06-27, 2023-06-28, 2023-06-29, 2023-06-30 4. Interview with the laboratory manager on September 25, 2023 at 1:00 p.m. confirmed the laboratory failed to follow their own written procedure for performing and documenting corrective actions for unacceptable refrigerator temperature for 42 out of 384 days from April 2022 through the survey date of September 25, 2023. Word Key: C = degrees Celsius

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 the laboratory's procedures and environmental logs, and interview with the laboratory manager, determined the laboratory failed to document temperature and humidity for 2 of 384 days from April 2022 through the survey date of September 25, 2023. The findings include: 1. Observation of the laboratory at 11:00 am on 09.25.2023 revealed the following: a. Blood Bank refrigerator (S#48241) b. Specimen refrigerator #1(S#48693) c. Specimen freezer #1 (S#48298) d. Specimen refrigerator #2 (S#39739) e. Specimen freezer #2 (S#28297) f. Specimen refrigerator #3 (48239) g. Specimen freezer #3 (48905) h. Hematology refrigerator (S#50375) i. Microbiology refrigerator (S#50364) j. Microbiology freezer (S#50394) k. Large incubator (S#44860) l. small incubator (S#50359) m. Room temp /humidity hygrometer (S#50369) n. Atellica refrigerator (S#44929) 2. Review of the laboratory's "Temperature Monitoring" procedure stated, "Purpose: To monitoring room, incubator, refrigerator, and freezer temperature to assure reagent stability and testing environment. Temperatures are monitored and recorded for all containers used for storage of samples and/or supplies used for testing. Temperatures are recorded daily on the Temperature Log 3. Review of the laboratory's environmental records from April 2022 through September 25, 2023 revealed no temperatures and/or

humidity were documented for 06.01.2023 and 06.02.2023. 4. Interview with the laboratory manager on September 25.2023 at 1:00 pm confirmed the laboratory failed to document temperature and humidity for 2 of 384 days from April 2022 through the survey date of September 25, 2023 Word Key: C = degrees Celsius