

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0641802	(X3) Date Survey Completed 10/21/2021
Name of Provider or Supplier Lake Martin Community Hospital	Street Address, City, State 201 Mariarden Road, Dadeville, AL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Vitamin B12 records, Proficiency Testing records, and an interview with the General Supervisor, the laboratory failed to verify the accuracy of Vitamin B12 at least twice annually. This was noted from July 2020 (when analyte was added to the Dimension EXL 200) to October 2021. The findings include: 1. A review of the Vitamin B12 records revealed a lack of accuracy verification being performed at least twice annually. 2. A review of Proficiency Testing records revealed the laboratory did not add Vitamin B12 when patient testing started in July of 2020. 2. During an interview on 10/20/2021 at 04:15 PM, the General Supervisor confirmed accuracy was not being verified at least twice annually for Vitamin B12.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Chemistry Procedure Manual, Blood Bank Procedure Manual, and an interview with the General Supervisor, the current Laboratory Director 1) failed to document approval of the Policies and Procedures when he assumed the responsibilities as the Laboratory Director, and 2) failed to document approval of new Policies and Procedures before patient testing began. This was noted</p>

from August 2020 to September 29, 2021 for Blood Bank and August 2020 to October 14, 2021 for Chemistry when the procedures were signed by the current Laboratory Director. The findings include: 1. A review of the Chemistry Procedure Manual revealed that the former Laboratory Director signed the Policy and Procedure Manual on 12/19/2019. The current Laboratory Director started in August 2020 and did not sign the Chemistry Procedure Manual until 10/14/2021. 2. A review of the Chemistry menu revealed 3 new analyte procedures, as follows: A) Hemoglobin A1c: started patient testing on 08/18/2020 and procedure was not signed by previous Laboratory Director and was not signed by the current Laboratory Director until 10/14/2021. B) Vitamin B12: started patient testing on 07/01/2020 and procedure was not signed by previous Laboratory Director and was not signed by the current Laboratory Director until 10/14/2021. C) Vitamin D: started patient testing on 06/11/2021 and procedure was not signed by Laboratory Director until 10/14/2021. 3. A review of the Blood Bank Procedure Manual revealed most procedures were updated by the General Supervisor in February 2021 and was not reviewed by the Laboratory Director until 09/29/2021. 4. During an interview on 10/21/2021 at 10:00 AM, the General Supervisor confirmed the above findings.

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 a review of the temperature records, a walk through of the laboratory, and an interview with the General Supervisor, the laboratory's criteria for Refrigerator temperatures failed to be consistent with the manufacturer's instructions. This was noted from February 2021 to October 2021. The findings include: 1. A review of the temperature records revealed the acceptable range for the Chemistry Refrigerator and Special Refrigerator was changed from 2 - 8 degrees Celsius to 0 - 8 degrees Celsius in February 2021. The temperatures recorded from February 2021 to October 2021 for both refrigerators fell below 2 degrees Celsius on multiple days. 2. During a walk through of the laboratory the Special Refrigerator contained the following items with their manufacturer's temperature requirements: a) Siemens Ci-Trol controls: 2 - 8 degrees Celsius b) C. Diff Quik Chek Complete: 2 - 8 degrees Celsius c) Triage D-Dimer Test: 2 - 8 degrees Celsius d) Quantify Plus Controls Bio-Rad: 2 - 8 degrees Celsius. 3. During a walk through of the laboratory the Chemistry Refrigerator contained the following items with their manufacturer's temperature requirements: a) Siemens Dimension reagents cartridges (multiple reagents): 2 - 8 degrees Celsius b) Siemens Calibrators (multiple calibrators): 2 - 8 degrees Celsius. 4. During an interview on 10/21/2021 at 1:45 PM, the General Supervisor confirmed he changed the range of both refrigerators because controls/reagents were running ok.

D5421

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)**

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of the validation study for the Dimension EXL 200 Vitamin B12 and Hemoglobin A1C and an interview with the General Supervisor (GS), the laboratory failed to review and evaluate the verification data prior to patient testing starting. This was noted on two out of three validations reviewed by the surveyor. The findings include: 1. A review of the validation for the Dimension EXL 200 Vitamin B12 revealed the validation was performed on 06/14/2019 and patient testing started on 07/01/2020. The General Supervisor approved by signature on 09/20/2020 and the Laboratory Director approved by signature on 10/14/2021. 2. A review of the validation for the Dimension EXL 200 Hemoglobin A1C revealed the validation was performed on 07/17/2020 and patient testing started on 08/18/2020. The General Supervisor approved by signature on 09/20/2020 and the Laboratory Director approved by signature on 10/14/2021. 3. During an interview on 10/21/2021 at 10:00 AM, the General Supervisor confirmed the laboratory failed to review and evaluate the verification data for Vitamin B12 and Hemoglobin A1C prior to patient testing starting.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the Chemistry Quality Control (QC) records for the Dimension EXL 200 and an interview with the General Supervisor, the laboratory failed to ensure at least two levels of QC were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted one day out of 3 months reviewed (January 2020, October 2020, and May 2021) by the surveyor. The findings include: 1. A review of the QC records for the Dimension EXL 200 analyzer revealed only the High control was run and acceptable for all analytes on 10/27/2020; there was no evidence the Low control was run on this date. 2. During an interview on 10/21/2021 at 12:45 PM, the General Supervisor confirmed chemistry patient testing would have been performed on 10/27/2020, when only one level of QC was run.