

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465387	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Chicot Memorial Medical Center	Street Address, City, State 2729 S Hwy 65 & 82, Lake Village, AR	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the manufacturer's instructions for the analyte Lactic Acid (LA), patient medical records, lack of documentation as well as interviews with staff, it was determined the laboratory failed to ensure the optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results. Survey findings Follow: A. A review of manufacturer's instructions for Lactic Acid revealed "Specimens for Lactic Acid analysis must be centrifuged and separated within fifteen minutes and analyzed immediately. If the test cannot be performed immediately, refrigerate the separate plasma for up to 24 hours or freeze specimen up to 30 days." B. A review of Lactic Acid patient results for March (one of four months) of 2021 revealed five of fifty-one patient results were not performed according to manufacturer' instructions. Patient #80113638 Lactic acid collected at 0410 completed at 0626; Patient #80113739 Lactic acid collected at 1125 completed at 1223; Patient #80114398 Lactic acid collected at 1557 completed 1654; Patient #80114278 Lactic acid collected at 1054 completed at 1159 and Patient #80114163 Lactic acid collected at 0012 completed at 0125. C. Upon request the laboratory could not provide documentation that the specimens had been refrigerated or frozen for future analysis. D. In an interview at 1300 on 05/05/2021, testing personnel #4 (as listed on form CMS 209) confirmed the laboratory did not follow manufacturer's instructions when testing Lactic Acid.</p>
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Through observation, review of package insert, and interview it was determined that the laboratory failed to document the date opened and the expiration date of three of three vials of XN Check Hematology controls in current use. A. A review of the package insert of the XN Check Hematology controls revealed "the product expiration date changes to fourteen days after the vial is opened and the product is placed into use. B. During a tour of the laboratory on 5/6/2021 at 10:12 a.m. three vials of XN Check Hematology controls (lot 10960804, 10960805, and 10960806) were observed in the laboratory refrigerator without labels of the date opened or the amended expiration date. C. In an interview on 05/06/201 at 10:12 a.m., laboratory personnel #4 (as listed on form CMS-209) confirmed that the vials of controls were not labeled with the date opened and/or the amended expiration date.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of Respiratory policy and procedure manual, Quality Control (QC) documentation for January and March of 2021 and August 2020, lack of documentation, as well as interviews with staff, it was determined the Blood Gas laboratory failed to have documentation of QC performed for one of thirty days when patients were tested. Survey Findings follow: A. A review of the Blood Gas laboratory policy and procedure manual revealed the quality control protocol: " Two levels of QC are performed every eight hours of patient testing." B. A review of QC records for August 16, 2020 (one of thirty days) revealed the times Blood Gas QC was analyzed: At 06:03 level 1 and level 2 was in acceptable range for analytes PH, PCO2 and PO2: at 15:03 level 3 (only one level of QC was in range) was in acceptable range for analytes PH, PCO2 and PO2. C. A review of ten patient medical records revealed Patient #8010648 (one of ten patient medical records reviewed) was analyzed and resulted at 17:55 when only one level of QC was in acceptable range. D. In an interview at 11:00 on 05/4/2021, the technical consultant confirmed the Blood Gas laboratory resulted patients with only one level of QC in acceptable range.

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Through a review of Coagulation policy and procedure manual, Quality Control (QC) documentation for January and March of 2021, August of 2020, laboratory patient logs, lack of documentation and interviews with staff, it was determined the laboratory failed to perform D-Dimer QC each eight hours of patient testing. Survey findings follow: A. A review of the Coagulation policy and procedure manual revealed "Two levels of quality control are performed every eight hours of testing. Patients results will not be reported until QC is properly verified." B. A review of QC documentation for August 2020 (one of three months reviewed) revealed that on August 12, 2020, D-Dimer QC was analyzed at 9:51 a.m. C. A review of laboratory patients logs revealed the patient #69845 was tested for D-Dimer (tested at 1839) greater than eight hours after QC was performed. D. Upon request, the laboratory could not provide QC documentation for every eight hours of patient testing. E. In an interview on 05/04/2021, testing personnel #3 (as listed on form CMS-209) confirmed the laboratory failed to perform D-dimer QC each eight hours of patient testing.