Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2167461	02/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cabot Emergency Hospital	212 Willie Ray Drive, Cabot, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Through observations made during a tour of the laboratory, as well as interview with staff, it was determined the laboratory had BD Vacutainer Lithium Heparin blood collection tubes available for use when they had exceeded their expiration date. Survey Findings Follow: A. During a tour of the laboratory on 02/28/2020 at 0945, the Surveyor observed twenty of twenty BD Vacutainer Lithium Heparin blood collection tubes (lot # 8215679 expiration date 12/31/2019) located on lower shelf in the laboratory available for use. B. In an interview on 02/28/2020 at 0945, laboratory personnel #2 (as listed on form CMS-209) confirmed the expiration date and the BD Vacutainer Lithium Heparin blood collection tubes were available for use.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Through a review of the Individualized Quality Control Plan (IQCP), lack of documentation and interviews with staff, it was determined the laboratory failed to specify which external control material will be utilized in the IQCP. Survey Findings Follow. A. A review of IQCP (three of three IQCP) for the Alere MeterPro Cardiac Panel, Alere MeterPro D-Dimer and Abott I-Stat System revealed the laboratory failed to specify which external controls will be utilized in the Quality Control component of the IQCP. B. In an interview at 1430 on 02/28/2020, laboratory personnel #2 (as listed on form CMS 209) confirmed the laboratory failed specify which external controls will be used in the Quality Control component of the IQCP.
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: . Through a review of the laboratory Quality Control (QC) and Corrective Action policies, QC data for 2019 and 2020, patient medical records, lack of documentation, and interviews with staff, it was determined the laboratory failed to document two levels of QC on days when patients were tested. Survey Findings Follow. A. A review of the laboratory QC policies revealed " Three levels of quality control material will be tested each day of patient testing. At least two levels must be within acceptable ranges before patient testing is performed. Patients results may not be reported unless control values meet the laboratory's criteria." B. The laboratory started patient testing for Arterial Blood Gases on October 20, 2019. A review of QC data for Arterial Blood Gases for October 2019-February 2020 (five of five months) revealed on October 24 and October 27, 2019 (two of 11 days) the laboratory resulted patients without documentation of quality control. C. A review of patients medical records for October 2019 revealed on 10/24/2019 patient #114-1 had Aterial Blood Gases reported at 21: 11 pm without documentation of QC results. On 10/24/19 patient #182-1 had Arterial Blood gases reported at 10:24 a.m. without the documentation of QC results. D. Upon request, the laboratory was unable to provide records of acceptable QC testing performed on October 24 and October 27, 2019. E. In an interview on 2/27/20 at 1:00 p.m., laboratory personnel #2 (as listed on Form CMS 209) confirmed that patients were tested and resulted without the documentation of acceptable QC results on October 24 and October 27, 2019.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Through review of quality control policy and procedure, quality control results, patient records, lack of documentation, and interview it was determined that on one out of three months reviewed the laboratory did not follow its policy of taking corrective action before releasing patient test results when quality control (QC) results were outside of acceptable range. Findings follow: A) Review of the laboratory's policy for quality control revealed; " Three levels of quality control material will be tested each day of patient testing, at least two levels must be within acceptable ranges before patient testing is performed". B) Review of the quality control results for October 2019 revealed that on October 30, 2019 at 00:32:46 hours level two QC, lot # 2190822 with acceptable range for white blood cell count (WBC) of (7.9 to 9.1) was reported as 9.8 with a flag of "H" and at 00:34:07 hours level one QC, lot # 2190901 with acceptable range for white blood cell count (WBC) of (3.0 to 3.6) was reported as 7.5. with a flag of "H". C) Review of the quality control results for October 2019 revealed that on October 30, 2019 at 00:32:46 hours level two QC, lot # 2190822 with acceptable range for red blood cell count (RBC) of (4.02 to 4.38) was reported as 4.40 with a flag of "H" and at 00:34:07 hours level one QC, lot # 2190901 with acceptable range for red blood cell count (RBC) of (2.08 to 2.32) was reported as 2.73 with a flag of "H". D) Review of patient CBC results for October 2019 revealed that CBC testing was performed and reported on ten patients, identified as numbers three through twelve on a separate patient identification list, on October 30, 2019 between the hours of 02:30 and 20.08. E) Upon request, the laboratory was unable to provide records of acceptable QC testing performed on October 30, 2019. F) In an interview on 2/27/20 at approximately 01:45 PM, the laboratory staff member, identified as number two on the CMS 209 form confirmed that QC results for WBC and RBC failed to meet the laboraatory's criteria for acceptability on October 30, 2019 and results were reported on ten patients, identified above, on that date.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of quality control policy and procedure, quality control results, patient records, lack of documentation, and interview it was determined that the laboratory did not take required corrective action in one of three months reviewed by failing to evaluate patient results back to the last successful quality control after quality control was unacceptable on 10/30/19 affecting eight patients. A) Review of the laboratory's policy for quality control revealed; " Three levels of quality control material will be tested each day of patient testing, at least two levels must be within acceptable ranges before patient testing is performed". B) Review of the quality control results for October 2019 revealed that on October 30, 2019 at 00:32:46 hours level two QC, lot # 2190822 with acceptable range for wbite blood cell count (WBC) of (7.9 to 9.1) was reported as 9.8 with a flag of "H" and at 00:34:07 hours level one QC, lot # 2190901 with acceptable range for wbite blood cell count (WBC) of (3.0 to 3.6) was reported as 7.5. with a flag of "H". C) Review of the quality control results

	for October 2019 revealed that on October 30, 2019 at 00:32:46 hours level two QC, lot # 2190822 with acceptable range for red blood cell count (RBC) of (4.02 to 4.38) was reported as 4.40 with a flag of "H" and at 00:34:07 hours level one QC, lot # 2190901 with acceptable range for red blood cell count (RBC) of (2.08 to 2.32) was reported as 2.73 with a flag of "H". D) Review of the quality control results for October 2019 revealed that the last successful quality control for WBC and RBC testing prior to 10/30/19 was performed on 10/29/19 at 12:30 AM. E) Review of patient results revealed that eight patients, identified as numbers thirteen through twenty on a separate patient identification list, had WBC and RBC tests performed and reported between 06:03 hours and 21:55 hours on 10/29/19. F) Upon request, the laboratory was unable to provide documentation that WBC and RBC resullts on the patients identified above were evaluated. G) In an interview of 2/27/20 at approximately 1:45 PM the laboratory staff member identified as number 2 on the CMS 209 form confirmed that the WBC and RBC results performed and reported on 10/29/19 on the patients identified above had not been evaluated.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through review of personnel records, patient results, lack of documentation and interview it was determined that the laboratory director failed to give written authorization to perform moderately complex complete blood count (CBC) testing for one of thirty-two testing personnel present on the CMS 209 form. Findings follow: A) Review of personnel records revealed that written authorization to perform moderately complex CBC testing was lacking for the testing personnel identified as number twenty-three on the CMS 209 form. B) Upon request, the laboratory was unable to provide written authorization to perform CBC testing for the testing personnel identified as number twenty-three on the CMS 209 form. C) Review of 10 patient CBC results chosen at random performed in February 2020 revealed that two of the ten patients, identified as numbers one and two on a separate patient identification list, were performed by the testing personnel, identified as number twenty-three on the CMS 209 form, on February 3, 2020. D) In an interview on 2/27 /20 at approximately 10:00 AM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the testing personnel identified above lacked authorization to perform CBC testing and had performed CBC testing during the month of February 2020.