Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161475	06/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mid Jefferson Extended Care Hospital Beaumont	860 South 8th Street, Beaumont, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency tests (PT) records from 2019 to 2021, CMS 155 report, and confirmed in an interview revealed the laboratory failed to retain attestation sheets for 1 of 6 PT events. The findings were: 1. Review of CMS155 report revealed the laboratory participated proficiency test (PT) in the following event: 2020 Event 3 for routine chemistry, including PH blood Gas, PCO2 blood gas, PCO2 blood gas, Glucose (non-waived), K, Na, Hematology, and Hct (non-waived) with a score of 100. 2. Review of proficiency tests records from 2019 to 2021 revealed 1 of 6 PT events had no documentation of attestation sheets. 2020 Event 3 for routine chemistry, including PH blood Gas, PCO2 blood gas, PCO2 blood gas, Glucose (non-waived), K, Na, Hematology, and Hct (non-waived) with a score of 100. 3. An interview with the laboratory director (LD) and testing personnel#1 (TP#1) on 6/1/21 at 1133 am in the conference room confirmed the above findings.
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 review of the manufacturer's instructions, laboratory's performance verification studies, and confirmed in an interview, the laboratory failed to document reference range (normal range) verification studies for 3 of 3 analytes, pH, pCO2, and pO2 on the GEM Premier 3500 instrument. The findings were: 1. Review GEM Premier 3500 operation manual (Copyright @ January 2009 Instrument Laboratory) revealed the following reference ranges for arterial blood: pH 7.35 to 7.45 pCO2 35 to 48 mmHg (4.66 to 6.38 pKa) pO2 83 to 108 mmHg (11.04 to 14.36 pKa) 2. Review of the performance verification studies for the GEM Premier 3500 revealed the laboratory had no documentation of normal range verification studies for the reference ranges above. 3. Review CMS-116 signed by the laboratory director, the laboratory performed 1800 chemistry tests annually starting on 6/10/2019. 4. An interview with the laboratory director (LD) and testing personnel#1 (TP#1) on 6/1/21 at 1220 pm in the conference room confirmed the facility uses the manufacturer's reference range and did not perform a study to verify the normal ranges.
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: Based on review of the laboratory and quality control test records from December 2020 to June 2021 and confirmed in interview, the laboratory failed to monitor over time 2 of 2 chemistry controls for the blood gas analysis (pH, pCO2, and pO2) on the GEM Premier 3500 instrument. Findings were: 1. Review of the laboratory quality control records from December 2020 to June 2021 revealed the laboratory used the following 2 controls for blood gas analysis (pH, pCO2, and pO2) on the GEM Premier 3500 instrument. CVP 1 lot 1840, exp 3/31/22 CVP 2 lot 2840, exp 3/31/22 2. Review of the laboratory records available revealed no documentation of the laboratory monitoring over time the accuracy and precision of the above quality controls. 3. Review of the CMS116 signed by the laboratory director on 6/1/21 revealed the laboratory performed 1800 chemistry tests annually. 4. An interview with the laboratory director on 6/1/21 at 1330 hours in the conference room confirmed the above findings.