Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0044790	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Crawford Memorial Hospital	1000 N Allen St, Robinson, IL	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with general supervisor (GS) #1; the laboratory failed to verify the accuracy of ungraded compatibility testing for proficiency testing (PT) event 3 of 2018. Findings Include: 1. Review of American Proficiency Institute (API) PT results for the 3nd event of 2018 found 2 of 5 PT samples for compatibility were ungraded. Sample Performance SER-11 Not Graded SER-14 Not Graded 2. Review of the laboratory's policy, "Proficiency Testing", stated the following: "7. Upon receipt of evaluation results from API, the Lab Manager will review the outcome for each analyte, including assessment of non-graded tests, or scoring irregularities" 3. Review of the API document, "Proficiency Testing Performance Evaluation", found the laboratory designee reviewed and signed the document on 1-30-2019 and stated the following: Corrective action taken (if indicated): "None Required." 4. Interview at 5:20 pm, on 3-6-2019, with GS#1 confirmed no remedial action was taken for the ungraded compatibility PT samples in the 3rd event of 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with general supervisor (GS) #1; the laboratory failed to conduct calibration verifications as required for hemoglobin A1c testing on the Bio-Rad D-10 chemistry analyzer in 2018. Findings include: 1. Review of the laboratory procedure, "Bio-Rad D-10 HA1C analyzer", failed to include a calibration verification procedure for hemoglobin A1c testing on the Bio-Rad D-10 analyzer. 2. Review of hemoglobin A1c calibration records found the Bio-Rad D-10 analyzer only performs a 2-point calibration hemoglobin A1c. 3. Interview on 03-06-2019, at 5:20 pm, GS#1 confirmed no 6 month calibration verifications had been performed for hemoglobin A1c testing on the Bio-Rad D-10 analyzer in 2018. B. Based on review of direct observation, laboratory records and interview with general supervisor (GS) #1; the laboratory failed to conduct calibration verifications as required for blood gas testing on the Siemens Rapidpoint 500 chemistry analyzer in 2018. Findings include: 1. Direct observation of the laboratory on 3-5-2019 at 11:05am identified two Siemens Rapidpoint 500 analyzers for blood gas analysis. 2. Review of the laboratory procedure, "Siemen's Rapidpoint 500 Blood Gas Machines", failed to include a calibration verification procedure for blood gas testing on the Siemens Rapidpoint 500 analyzers. 3. Review of 2017 and 2018 calibration verification records found the laboratory failed to perform 6 month calibration verifications for both analyzers and ensure the calibration verifications were acceptable for 8 of 8 calibration verifications in 2017 through 2018. 2018 Calibration Verification Records a. 8-18-2018 - Hand transcribed pH data and partial pCO2 data on calibration verification material (CVM) form, analyzer unknown. b. 2-3-2018 - Hand transcribed data for analyzer, serial number 35158 on the CVM form. 2017 Calibration Verification Records a. 1-25-2017 - Instrument print outs from calibration verification samples for analyzer 35156 but no analysis/CVM form. b. 2-3-2017 - Instrument print outs from calibration verification samples for analyzer 35158 but no analysis/CVM form. 4. Interview on 03-06-2019, at 5:20 pm, GS#1 confirmed 6 month calibration verifications were not completed for blood gas testing on the Siemens Rapidpoint 500 analyzers in 2017 through 2018.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with general supervisor (GS) #1; the laboratory failed to have a system in place that twice yearly evaluates the relationship between the Vitros 5600 and Fisher Sure-Vue Serum HCG test kit for human chorianic gonadotropin (hCG) testing. Findings Include: 1. Direct observation on 03-05-2019, at 11:05 AM, identified the Vitros 5600 and the Fisher Sure-Vue Serum HCG tests kits both used for hCG testing. 2. Review of American Proficiency Institute (API) proficiency testing (PT) documentation for core chemistry event 1 of 2018 indicated the laboratory had discontinued qualitative serum hCG testing for the Fisher Sure-Vue Serum HCG test kit. 3. On survey date 03-06-2019, at 5:20 PM, GS#1 confirmed the laboratory failed to evaluate the relationship between the two test systems for hCG in 2018 since the laboratory had discontinued PT for the Fisher Sure-Vue Serum HCG testing.