Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652187	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kneibert Clinic Laboratory	686 Lester Street, Poplar Bluff, MO	

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
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: Review of calibration records for the chemistry analzers Cobas e 411 and the Cobas c 501 and interview testing personnel #1 showed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the calibration records for September 2017 and to date October 2, 2018 for the analytes: CO2, alkaline

	phophatase, sodium, potassium, chloride, Hgb A1C, total bilirubin, direct bilirubin, c-peptide, insulin, vitamin D, vitamin B12, ALT, AST, glucose, creatinine, triglycerides, albumin, BUN, HDL, total protein, amylase, cholesterol, T4, T3, TSH, digoxin, testosterone, PSA, serum pregnancy, calcium and folate analytes showed the laboratory failed to perform a calibration every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. 2. Interview with testing personnel #1 on October 2, 2018 at 2:00 PM confirmed the laboratory failed to perform a calibration every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC), procedures and interview with testing personnel #1 the laboratory failed to test serum pregnancy control materials in the same manner as patient specimens. Findings: 1. Serum pregnancy patient testing is performed using patients serum. QC for serum pregnancy is performed using a urine matrix. 2. Interview with testing personnel #1 on October 2, 2018 at 2:00 PM confirmed the laboratory failed to test control material for serum pregnancy in the same manner as patient specimens.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results for 2017 and 2018 and interview with testing personnel #1, the laboratory director failed to ensure PT testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of 2017 first event PT results for CH-01 Triglycerides was not graded and no evaluation was documented. 2. Review of 2017 first event PT results for LDL cholesterol showed all five PT results were not graded and no evaluation was documented. 3. Review of 2017 second event PT results for LDL cholesterol showed all five PT results were not graded and no evaluation was documented. 4. Review of 2018 second event PT results for myoglobin showed 60% result and no evaluation or corrective action was documented. 5. Interview with testing personnel #1 on October 2, 2018 at 2:00 PM

	confirmed the laboratory director did not ensure all PT results were evaluated and if required a corrective action completed.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results for 2017 and 2018 and interview with testing personnel #1 the laboratory director failed to ensure that an approved corrective action plan is followed when any PT testing results are found to be unacceptable. Findings: 1. Review of PT results for 2018 second event Myoglobin shows results for CM-06 and CM-10 were unacceptable and did not include a corrective action plan. 2. Interview with testing personnel #1 on October 2, 2018 at 2: 00 PM confirmed the laboratory director failed to ensure that an approved corrective action plan for second event Myoglobin in 2018.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of procedures and interview with testing personnel #1 on October 2, 2018 at 2:00 PM confirmed the laboratory director did not approve a procedure for serum pregnancy.