Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652187	06/10/2021
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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION 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 and interview with testing personnel #1 the laboratory failed to meet the condition of analytic systems. (Refer to D5465) **This is a repeat deficiency cited during previous survey conducted October 2, 2018.
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) records, the laboratory's individual QC plan (IQCP), patient records and interview with testing personnel # 1, the laboratory failed to test pregnancy (HCG) control materials in the same manor as patient specimens for

	2019, 2020 and to date June 10, 2021. Findings: 1. Review of QC records showed the laboratory used urine matrix control material when performing serum HCG testing on patient specimens. 2. The Individual Quality Control Plan (IQCP) for Serum Beta hCG signed by laboratory director on October 10, 2018 stated "Serum Control: Roche Immunoassay controls will be used for positive serum control and a known patient with negative HCG will be used a negative control. Positive and negative controls will be performed daily if a patient is run." There was no documentation to show the laboratory performed the positive and negative serum controls as stated in the IQCP. 3. Review of patient records showed, the laboratory tested over 150 patients for serum HCG during 2019, 2020 and to date June 10, 2021. 4. Interview with testing personnel #1 on June 10, 2021 at 10:00 A.M. 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 the 2020 and 2021 proficiency testing (PT) records and interview with the testing personnel TP#1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the hematology/coagulation PT records for the first testing event of 2021 showed the laboratory obtained an "unacceptable" result for lymphocytes, sample XE-03. Review of the Chemistry for the second event of 2020 showed a "not graded" result for folate, sample IA-07. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results or "unacceptable" result. 2. Interview with on June 10, 2021 at 11:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, temperature logs, maintenance records, and interview with testing personnel #1, the technical consultant failed to provide technical and scientific oversight of the laboratory for 2019, 2020 and to date June 10, 2021. Findings: 1. Review of the QC records, temperature logs and maintenance records for 2019, 2020 and to date June 10, 2021 revealed the technical

	consultant failed to provide documentation of technical and scientific oversight of the laboratory. 2. Interview with on testing personnel #1 on June 10th, 2021 confirmed the technical consultant failed to provide documentation of technical and scientific oversight of the laboratory.