Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1041555	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Labcorp Kansas, Inc - Founder's Circle	**Street Address, City, State** 1947 N Founders Circle #A1h01, Wichita, KS	
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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of Quality Assurance (QA) procedure, the lack of available (QA) documents, and interview with staff revealed that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings: 1. The QA procedure required a mechanism to monitor specimen quality to determine when correction action was needed. 2. No documents were made availible for specimen rejection monitoring at the time of survey. 3. Interview with Technical Consultant (TC) #2 February 25, 2020 at 10:30 a.m. confirmed, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems.
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 performance verification documentation for the AIA 360 Tosoh analyzer and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the AIA 360 Tosoh analyzer, S/N 27868704, installed August 7, 2018, for the analyte Parathyroid hormone (PTH) testing showed no verification of normal values. 2. Interview with TC #2 on February 25,2020 at 12: 20 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A review of the Quality Assessment documentation and interview revealed the laboratory failed to document corrective action for calibration and quality control (QC) failures including trends and shifts for the Tosoh AIA 360. Findings: In the Tosoh AIA 360 log book: 1. QC results section had no review documentation from 6 /21/19 to 1/1/2020. 2. Calibration results section had no review documentation from 1 /10/2019 to date of survey. 3. TC #2 stated that the old Tosoh system had become unreliable and a new instrument was purchased based on its performance. 4. Request to review documentation of the instrument issue and its replacement request was not made availible at the time of survey. 5. Interview with TC #2 on February 25, 2020 at 12:25 p.m. confirmed, the laboratory failed to document corrective action for calibration and quality control (QC) failures including trends and shifts for the Tosoh AIA 360.