Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0681749	01/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Kansas Pathology Services, Llc	1212 E 27th Street Unit B, Hays, 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
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy, lack of preanalytical assessment documents and interview, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment. Findings: 1. Review of the policy Quality Assessment (Monthly) showed the requirement of monitoring specimen quality and developing corrective action (CA) to address errors or potential problems. 2. No specimen rejection log was available for review at the time of survey. 2. When Testing Personnel (TP) #1 was asked how the specimen rejections were reviewed to determine if CA was needed, she stated that specimen rejection was noted only on the requisition, but no review or CA process was in place. 3. Interview of TP #1 on January 28, 2020 at 10:00 a.m. confirmed, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Review of policies and interview with staff revealed, the laboratory failed to follow it's policy for annual review of policies and procedures. Findings: 1. Review of policy- Annual Review of Policies or Procedures, dated 1/20/2012 revealed: a. Item #1 "Establish protocol to follow by the Laboratory Director to review Policies and Procedures on an annual basis for CLIA approved laboratories." b. No documentation of Laboratory Director (LD) review since effective date. 2. Review of policy -Control Reports for End of Month Review, dated 12/01/2014, showed no documentation of review by LD since effective date. 3. Review of KPS LabDAQ Test Panels, dated 1/1 /2015 showed Protime/INR in test list. a. TP#1 stated Protime/INR testing was discontinued in 2018. b. No documentation of Laboratory Director (LD) review since effective date. 4. When request was made for any documentation of LD review of policies and or procedures post effective date, none was made available at the time of survey. 5. Interview with LD January 28, 2020 at 12:05 p.m. confirmed, the laboratory failed to follow it's policy for annual review of policies and procedures.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documents and interview, the laboratory failed to establish and follow a routine accuracy check for four of five thermometers. Findings: 1. Request was made for accuracy check records for the five thermometers used in the laboratory. Documentation for one thermometer was provided. No documentation of a function check for four of five thermometers was made available at the time of survey. 2. Interview with TP#1 on January 28, 2020 at 1:30 p.m. confirmed, the laboratory failed to establish and follow a routine accuracy check for four of five thermometers.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview, the laboratory failed to include

	the name and address of the laboratory location were the test was performed on the patient report. Findings: 1. Review of selected patient test reports for reference laboratory testing showed a lack of the name and address of the referred laboratory location where the test was performed. 2. Interview with TP #1 on January 28, 2020 at 1:00 p.m. confirmed the laboratory failed to include name and address of the laboratory location were the test was performed on the patient report.