Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999134	07/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp-Ks Houston Center	1200 Mckinney Suite 473, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 the laboratory's validation records for the Remel Mono-lex Infectious Mononucleosis test, the laboratory's On-site Validation Report Template, and staff interview, it was revealed the laboratory failed to ensure the validation studies were complete prior to patient testing. Findings include: 1. A review of the validation records for the Remel Mono-lex Infectious Mononucleosis test performed in in April

	2018 revealed the laboratory failed to have documentation of performing a precision study. 2. A review of the laboratory's On-site Validation Report Template states the following "scope of studies is required for methods categorized as qualitative, FDA cleared: -Agreement -Clinical and/or relative sensitivity -Clinical and/or relative specificity -Negative and positive predictive values (NPV and PPV) -Verification of the cutoff (when applicable) -Carry-over (when applicable) -Reference intervals verification/establishment (may be derived from NPV and PPV)" 3. An interview with the Quality Assurance Manager in the conference room on 7/10/19 at 11:00 am revealed the laboratory had not performed a precision study for this method. This confirmed the above findings.