Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1023220	(X3) Date Survey Completed 02/06/2018
Name of Provider or Supplier Tristate Diagnostic Laboratory	**Street Address, City, State** 2754 Veach Road, Owensboro, KY	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records from the American Proficiency Institute and interview with staff on 02/06/2018, the Laboratory Director failed to sign attestation statements for two testing events in 2017. Findings include: The Laboratory Director failed to sign the attestation statements for the 2017 Microbiology second event and the 2017 Immunology/Immunohematology third event. The Laboratory Director acknowledged in an interview at 11:30 AM on 02/06/2018, the laboratory failed to have a system in place to ensure attestation statements were signed for all testing events attesting proficiency samples were tested the same as patient samples.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the American Proficiency Institute (API) and staff interview on 02/06/2018, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for the certified analyte Infectious Mononucleosis in the specialty of Immunology. Findings include: Review

	of API results failed to reveal testing scores for the Infectious Mononucleosis analyte for three events in 2016 and three events in 2017. The Laboratory Director acknowledged in an interview at 11:30 AM on 02/06/2017, the laboratory failed to have a system in place to ensure all testing analytes performed in the laboratory were enrolled in an HHS-approved proficiency testing program.