Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0952240	12/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) instructions and proficiency test (PT) records and confirmed by interview, the laboratory failed to obtain at least 100% for D(Rho) typing for 1 of 3 testing events in 2017 as evidence by: 1. Review of API proficiency testing records for 2017 for D(Rho) typing, revealed 1 of 3 testing events when the laboratory received an 80% (100% satisfactory). 2nd event 2017 = 80% Rh-06, lab result Rh negative (expected result Rh positive) 2. In an interview with the primary testing person on 12/14/18 at 1000 hours in the office, she confirmed that the laboratory received the above scores.
D2160	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any

	unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute proficiency testing records from 2017 and 2018 and confirmed in interview, the laboratory failed to document remedial action for all unacceptable analyte testing event scores. Findings include: 1. Review of the API performance evaluation records revealed "laboratories are responsible for documenting and performing corrective actions for failures and must perform a self-evaluation using statistics presented in the participant summary for samples that have not been graded." 2. Review of the API 2017 2nd event revealed unsatisfactory analyte performance: D(Rho) typing 80%. Cross refer to D2153. 3. Review of the laboratory records available revealed no documentation of corrective action for the above unsatisfactory grade for D(Rho) testing. No documentation was available for review of the remedial action for the unsatisfactory D(Rho) testing event in 2017. 4. Review of the D(Rho) test logs revealed the laboratory performed D(Rho) patient testing from April 2017 to December 2017. Refer to patient alias list. 5. An interview with the primary testing person on 12/14/18 at 1005 hours in the office confirmed the above findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, American proficiency Institute (API) proficiency testing performance evaluations, and confirmed in interview, the laboratory director failed to ensure the laboratory followed an approved corrective action plan when proficiency testing was found unacceptable or unsatisfactory (refer to D2153, D2160).