Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0914105	06/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
American Healthcare Services	700 North Broad St, Elizabeth, NJ	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Package Insert (MPI), the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instruction for Rhesus Factor (RH) testing from 4/6/18 to the date of survey. The finding includes: 1. The MPI states "Tests that show no agglutination within 2 minutes are considered negative". 2. The PM states "If no agglutination is seen in 2 minutes the tests are considered positive."(RH pos) 3. The laboratory perfoms approximately 1850 RH tests/year 4. The TP #5 listed on CMS form 209 confirmed on 6/17/21 at 11:00 am that the laboratory did not follow the MPI.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the

	Testing Personnel (TP), the laboratory failed to correct problems identified in the Rhesus Factor (RH) procedure from 4/6/18 to the date of survey. The findings include: 1. The RH procedure written in the PM stated "If no agglutination is seen in 2 minutes the tests are considered positive. (RH pos) but the Manufacturer's Insert (MPI) stated "Tests that show no agglutination within 2 minutes are considered negative".. 2. The laboratory performs approximately 1850 RH tests per year. 3.The TP confirmed on 6/17/21 at 11:00 am the PM had the incorrect procedure for RH 4. The TP #5 as listed on CMS form 209 confirmed that the laboratory did not correct problems in the analytic system.