Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0919258	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Scientific Laboratory	8744 Shermer Rd, Niles, IL	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manuals, reports, and an interview with the technical supervisor (TS), the laboratory failed to meet the manufacturer's test system criteria for acceptability of control materials before reporting patient test results in the specialty of General Chemistry, affecting 49 patients. Findings: 1. The laboratory's policy and procedure for quality control (QC) failures are as follows: a). Record QC failures in the "CORRECTIVE ACTIONS LOG" under the 'Problem' column; b). In the next column, the 'Resolution' section; document the actions taken to solve the QC problem. c). For QC failures, the controls are to be repeated and, if necessary, calibrators tested. c). Once resolved, testing is resumed and patients' results reported. 2. The Corrective Action log, the BUN (Blood Urea Nitrogen) patient result listing, and QC data sheets revealed the following: 1). The BUN QC's tested on 01/22/2018 at 17:39, failed (results were outside the manufacturer's specifications) and were not repeated. 2). The BUN QC failure from 01/22/2018 is not documented in the Corrective action log. 3). The BUN QC's were next tested on 01/23/2018 at 17:57 and passed. 4). The 49 patients' tested for BUN during the times between 01/22/2018 at 17:39 and 01/23/2018 at 17:56 were reported to their respective providers. 3. On a Recertification survey conducted on 05/30/2018 at 3:00 PM, the TS, general supervisor (GS) and laboratory director (LD) confirmed the above findings.
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 the surveyor's review of the laboratory's records, manuals and an interview with the technical supervisor (TS), the laboratory failed to 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, in the specialty of General Chemistry. Findings: 1. The laboratory's policy and procedure for quality control (QC) failures are as follows: a). Record QC failures in the "CORRECTIVE ACTIONS LOG" under the 'Problem' column; b). In the next column, the 'Resolution' section; document the actions taken to solve the QC problem. c). For QC failures, the controls are to be repeated and, if necessary, calibrators tested. c). Once resolved, testing is resumed and patients' results reported. 2. The Corrective Actions logs and QC data sheets revealed the following: 1). The QC's were not repeated on 5 out of 9 days controls of various analytes failed: 01/16/2018 for BUN (Blood Urea Nitrogen); 01/29/2018 for FSH (Follicle Stimulating Hormone); 03/20 /2018 for HgbA1C (Hemoglobin A1C) 03/31/2018 for AFP (Alpha Fetoprotein); 03 /12/2018 for NH3 (Ammonia); and 03/02/2018 for BUN. 2). No further actions were taken when the repeated QC's continued to fail on 6 out of 9 test days; 01/03/2018 for Cortisol; 01/05/2018 for HgbA1C, CRP (C-reactive Protein -high sensitivity) and Estradiol,; and 01/16/2018 for Cholesterol. 3). No documentation was provided as evidence the laboratory calibrated the Chemistry analyzer when the repeated QC's continue to fail. 3. No documentation was presented to the surveyor as proof the laboratory resolved the random QC failures or established written corrective actions to prevent the reoccurrence of the above control failures. 4. On a Recertification survey conducted on 05/30/2018 at 3:00 PM, the TS, general supervisor (GS) and laboratory director (LD) confirmed the above findings.