Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0991209	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Medscan Laboratory, Inc	**Street Address, City, State** 1502 13th Ave W Suite 201, Williston, ND	

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
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 record review, staff interview, and policy review, the laboratory failed to monitor the analytic system for four of five specialties/sub-specialties (general immunology, routine chemistry, endocrinology, and hematology) for the year 2020. Findings include: 1. Reviewed at 3:25 p.m. on 09/29/21, the 2020 quality assessment records lacked evidence of analytic system monitoring for the specialties/sub-specialties of general immunology, routine chemistry, endocrinology, and hematology. 2. During interview at 4:25 p.m. on 09/29/21, a technical supervisor (#1) confirmed the laboratory had not performed analytic monitoring for the specialties/sub-specialties of general immunology, routine chemistry, endocrinology, and hematology in 2020. 3. Reviewed on 09/29/21, the policy "Blood Quality Assurance," updated 01/08/20, stated, ". . . Analytical Lot to Lot Comparisons - Perform quarterly. Random test analyte selection. Run 20 samples on the old lot and the same 20 samples on the new lot. Compare the results; should be within 20% of each other. Reviewed quarterly by the laboratory supervisor. . . ."