Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2099667	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Numedical Sc	2600 N Mayfair Rd Ste 1140, Wauwatosa, WI	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of policies and procedures and competence evaluation records, and interview with the Director of Operations, the laboratory has not developed policies and procedures or documented the assessment of the competence of one of one technical consultant. Findings include: 1. Review of policies and procedures showed no evidence of established procedures to assess the competence of the technical consultant in fulfilling their responsibilities. 2. Review of competence evaluation records from 2021 and 2022 showed no documented evaluation of the performance of the technical consultant. 3. Interview with the Director of Operations (staff A) on April 13, 2022 at 8:25 AM confirmed the laboratory had not developed procedures to evaluate the competence of the technical consultant and had not documented assessment of the competence of the technical consultant since the current consultant assumed the responsibilities of the role in January 2020.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Director of Operations, the laboratory director did not verify that the manufacturer's performance specifications for nine of nine analytes tested on the Tosoh AIA 900 were comparable to those obtained by the laboratory after the laboratory moved the analyzer and prior to patient testing. Findings include: 1. Review of laboratory records showed the laboratory evaluated performance specifications for prostate-specific antigen, estradiol, testosterone, progesterone, dehydroepiandrosterone, free triiodothyronine, free thyroxine, follicle-stimulating hormone, and thyroid stimulating hormone tests on the Tosoh AIA900 analyzer. The laboratory director approved the evaluations on April 6, 2022. 2. Interview with the Director of Operations (staff A) on April 13, 2022 at 10:12 AM confirmed the laboratory moved and reinstalled the Tosoh AIA 900 analyzer in March 2022 and confirmed the laboratory performed patient testing on the analyzer starting on March 21, 2022. Further interview confirmed the director did not approve the performance evaluation studies prior to the use of the analyzer for patient testing.