Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2182040	05/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Namida Lab, Inc	1905 E Mission Blvd, Suite 6, Fayetteville, AR	

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: Through a review of the quality control documentation for January through April 2022, corrective actions documented for failed quality control, and interviews with laboratory staff, it was determined the laboratory failed to correct problems identified in the analytic systems. Survey findings include: A. A review of quality control documentation for January through April 2002 revealed the High control failed to meet the acceptability requirements on 1/27/2022, 2/1/2022, 2/7/2022, 2/14/2022, 3/14 /2022, and 4/5/2022. On each day of High control failure a handwritten note was documented on the data that stated, "see attached. High control failed. Patient results not affected. Standard curve was within limits." There was no other documented corrective actions to bring the High control within acceptable range. B. In an interview, at 12:45 on 5/25, laboratory employee #2 (as listed on the form CMS-209) stated that the investigation into the failures determined the quality control material in use was in such a concentrated form that the dilluted mixture was not uniform. She confirmed that, the laboratory had identified the cause of failed quality control, but had not developed a corrective action.