Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0869645	04/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Allergy Immunology Diagnostic Lab Center	8701 Watertown Plank Rd, Milwaukee, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review laboratory policies and procedures and interview with testing personnel, staff A, the laboratory did not have a written policy and procedure to monitor, assess and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. Review of laboratory policies and procedures showed no evidence of a written policy or procedure to monitor, assess and correct problems identified in the general laboratory systems for preanalytical, analytical and postanalytical systems. 2. Interview with staff A on April 25, 2022 at 11:30 AM confirmed the laboratory did not have a written policy and procedure to monitor, assess and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and interview with testing personnel, staff A, the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on the Sanyo freezer for thirty-one of two hundred fifty-four days in 2021. Findings include: 1. Review of Sanyo freezer temperature logs revealed no documentation of corrective action on temperature readings outside the acceptable range of -18 to -26 degrees Celsius (C) on the following days in 2021: January 5, 7, 21, 25, 26, 29 February 3, 5, 11, 24 March 2, 4, 10, 17, 22 April 5, 21 May 3, 4, 12, 14, 19, 26 June 28 July 13, 22 August 2, 3, 11, 17 September 14 2. Interview with staff A on April 25, 2022 at 11:35 AM confirmed the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on the Sanyo freezer for thirty-one of two hundred fifty-four days in 2021.