Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0960812	06/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Repro Med Assoc Of Lehigh Valley	1401 North Cedar Crest Blvd, Allentown, PA	

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
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 review of the refrigerator temperature logs, interview technical supervisor (TS) and testing personnel (TP) #2, the laboratory failed to document all corrective actions taken when acceptable internal refrigerator temperature ranges (3 to 7 degrees Celsius) were exceeded in 2020. Findings include: 1. On the day of survey, 06/10/2021, review of the refrigerator temperature logs revealed, the acceptable internal temperature ranges of 3 to 7 degrees Celsius (C) were out of range on the following days in 2020: - 02/03/2020 temperature was 2.5 degrees C. - 04/28/2020 temperature was 7.5 degrees C. - 08/20/2020 temperature was 7.1 degrees C. - 08/21/2020 temperature was 7.4 degrees C. - 11/20/2020 temperature was 7.5 degrees C. - 12/08/2020 temperature was 7.5 degrees C. 2. The TS and TP#2 confirmed on 6/10/2021 around 12:30 pm, that the laboratory did not document the corrective actions taken.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, interview with the technical supervisor (TS) and testing personnel (TP) #2, the laboratory director (LD) failed to ensure all duties were properly performed in 2019 and 2020. Findings include: 1. On the day of survey, 06/10/2021, review of the TS annual competency assessment records revealed, the TS was not assessed annual for their delegated duties as a TS by the LD in 2019 and 2020. 2. An individual not listed on the laboratory personnel report (CMS 209 form) had performed and signed off on the TS competency assessments performed in 2019 and 2020. 3. The TS and TP#2 confirmed the findings above on 6/10/2021 around 11:30 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) and quality assurance (QA) policy, interview with the technical supervisor (TS) and testing personnel (TP) #2, the laboratory director failed to ensure QA programs were maintained to assure the quality of laboratory services provided from June 2019 to May 2021. Findings Include: 1. The QC and QA policy under, I. Quality assurance goals, point K. states, "Monthly staff meetings to discuss issues, problem, changes etc." 2. On the date of survey, 06/10/2021, the laboratory could not provide QA minutes documented on a monthly bases from June 2019 to May 2021. 3. The TS and TP#2 confirmed the findings above on 6/10/2021 around 1:50 pm.