Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0665911	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advocare Mid-Jersey Pediatrics	610 Cranbury Road, East Brunswick, NJ	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Office Manager (OM), the laboratory failed to evaluate results when the laboratory received an unacceptable score Hematology events performed with the American Proficiency Institute (API) for 2nd event 2024. The findings include: 1. The following samples were graded as unacceptable for the 2nd Hematology event of 2024. a) Sample HSY-07 for Monocytes/Mixed b) Sample HSY-08 for Monocytes/Mixed 2. No evaluation was documented for the unacceptable PT score.. 3. The OM confirmed by phone on 11/7/24 at 12:05 PM that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual and interview with the Office Manager (OM)), the Laboratory Director (LD) failed to establish a complete Quality Control (QC) plan from 10/11/23 to 11/7/24. The findings include: 1) The QC procedure did not define the frequency on when to review and generated levy

	Jennings charts. 2) The QC procedure did not specify who will review QC. 3) The QC procedure to not specify what to do with QC is out of range. 4) The OM confirmed on 11/7/24 at 11:00 am that the LD failed to establish a complete QC program.
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 the Temperature Logs (TL) and interview with the Office Manager (OM), the laboratory did not document corrective action taken when the Incubator Temperature (IT) was out of range from 2/22/24 through 8/23/2024. The findings include: 1. A review of the TL revealed that IT was outside the established range: a. 2/22/24, 3/17/24, 3/18/24, 5/13/24, 7/12/24, and 8/23/24 2. There was no documented evidence of corrective action taken. 3. The OM confirmed on 11/7/24 at 11:00 am the laboratory did not document corrective action.