Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2029686	01/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advocare Mid-Jersey Pediatrics, Pa	2 Research Way, Monroe Twp, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material in use and interview with the Office Manager (OM), the laboratory failed to label the control material used in Hematology testing with a new expiration date after opening from 9 /10/19 to date of the survey. The findings include: 1) There was no expiration date written on the QC material. 2) The OM confirmed on 1/18/22 at 2:00 pm controls were not labeled correctly. Note: This was previously cited 9/10/19
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) results and interview with the Office Manager (OM), the laboratory use expired QC for Hematology tests run on the Medonic M-series analyzer from 1/13/22 to the date of survey. The findings include: 1. Boule Con-Diff Tri-Level controls Lot 221050 expired 1/13/22. 2.

	Approximately 16 patients were run and reported. 3. The OM confirmed on 1/18/22 at 2:50 pm that the laboratory used expired QC. Note: This was previously cited 9/10/19
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: (a) Based on surveyor review of Calibration (Cal) records, Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Modonic M-series analyzer in the calendar year 2020. The findings include: 1. A review of C records revealed that the laboratory performed Cal once in the calendar year 2020. 2. The OM confirmed on 1/18/21 at 1:30 pm that the laboratory failed to perform and document Cal once every six months. (b) Based on surveyor review of Calibration (Cal) records, Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to meet acceptable Cal limits for Hematology Tests performed on the Modonic M-series analyzer from 5/19/20 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory failed Cal on 5/19/20 as follows: (a) Red Blood Cell Count (RBC) five out of four Cal sample runs. (b) Platelets (PLT) two out of five Cal sample runs. (c) Hemoglobin (HCG) five out of five Cal sample runs. (d)White Blood Cell Count (WBC) five out of five cal sample runs. 2. A review of Cal records revealed that the laboratory failed Cal on 6/3/21 as follows: (a) Mean Corpuscular Volume (MCV) five out of five cal samples runs. 3. The OM confirmed on 1/18/21 at 1:30 pm that the laboratory failed to failed to meet acceptable Cal limits.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Office

	Manager (OM), the Laboratory Director (LD) failed to have appropriate education documentation for all Testing Personnel (TP) performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education or training records for two out of eleven TP listed on the CMS form 209. 2. The OM confirmed on 1/18/22 at 1:40 pm the above records were not on file.