Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0665911	02/20/2020
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Nurse Manager (NM), the laboratory failed to maintain the Attestation Statements (AS) signed by the analyst and laboratory director for Hematology and Mircrobiology tests performed with the College of American Pathologists in the calendar year 2019. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples for events below: a. Microbiology and Hematology - Event 1 the Laboratory Director (LD) failed to sign the attestation statement b. Microbiology and Hematology - Event 2 the LD and Testing Personnel (TP) failed to sign the attestation statement c. Microbiology - Event 3 the LD failed to sign the attestation statement d. Hematology - Event 3 the LD and TP failed to sign the attestation statement 2. The NM confirmed on 2/20/20 at 9:35 am that the laboratory did not maintain all records for PT.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)

	The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports and interview with the Nurse Manager (NM), the laboratory failed to ensure that the laboratory accurately recorded the date and time specimens were received from 3/27/18 to the date of survey. The NM confirmed on 2/20/20 at 12:20 pm that the laboratory did not ensure that specimen date and time was entered accurately.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintance Record (MR) and interview with the Nurse Manager (NM), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Medonic CBC analyzer used for Hematology tests from August 2018 to January 1 2020. The finding includes: 1. The MR revealed maintenance was not performed as below: a. Monthly Maintenance was not performed from November 2018 to December 2019. b. A six month clean was not performed in February 2018. 2. The NM confirmed on 2/20/20 at 10:05 am that maintenance as specified by the manufacturer was not performed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Nurse Manager (NM), the laboratory failed to perform and document two level of controls on each day of patient testing for Hematology testing performed on the Medonic CBC analyzer in August 2018. The findings include: 1. Controls were not run 8/13/19, 8/14/19, 8/23/19 through 8/27/19. 2. Approximately ten patients were run and reported each day QC was not done. 3. The NM confirmed on 2/20/20 at 10:40 am that two levels of QC were not performed every day of patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Nurse Manager (NM), the laboratory failed to check each new lot number and shipment of Throat and Urine Culture media for sterility, ability to support growth and select or inhibit organisms from 3/27/18 to the date of the survey. The findings include: 1. There was no documented evidence Throat Culture (TC) media was checked for its ability to inhibit organisms. 2. There was no documented evidence Urine Culture (UC) media was checked for sterility and its ability to support growth and select or inhibit organisms. 3. Approximately 20 TC and 3 UC tests were run per month. 4. The NM confirmed on 2/20/20 at 11:30 pm the laboratory did not perform the QC above.
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 Quality Control (QC) records and interview with the Nurse Manager (NM), the laboratory failed to take and document Corrective Action (CA) taken when Hematology controls run on the Medonic CBC analyzer were unacceptable or out of range from September to November 2018. The findings include: 1. There was no documented evidence of CA taken when Hematology controls were out of range as follows: a. Normal QC failed from 11/11/19 through 11/14/19. b. Low Control Lot 2190851 was run 13 times on 10/31/19 and three times on 10/25/19 and 10/27/19. c. Normal Control Lot 2190852 was run three times on 10/28/19, 10/29/19 and 10/30/19. d. High Control Lot 2190853 was run three times on 10/14/19 and 10/25/19. 2. Approximately ten patients were run per day. 3. The NM confirmed on 2/20/20 at 10:45 am that corrective action was not taken for out of range controls.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Report (TR) and interview with the Nurse Manager (NM), the laboratory failed to include the test report date for Throat, Urine and Hematology tests from 3/27/18 to the date of survey. The NM confirmed on 2/20 /20 at 11:40 am that the report date was not on the TR.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Nurse Manager (NM), the laboratory failed to establish a procedure for verifying manually entered results from 3/27/18 to the date of survey. The NM confirmed on 2 /20/20 at 11:30 am that the laboratory did not have the procedure mentioned above.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor observation of a lack of a Quality Assurance (QA) plan and interview with the Nurse Manager (NM), the Laboratory Director failed to establish a QA plan from 3/27/18 to the date of the survey. The NM confirmed on 2/20/20 at 12: 00 pm that a QA plan had not been established.