

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2029686	(X3) Date Survey Completed 09/10/2019
Name of Provider or Supplier Advocare Mid-Jersey Pediatrics, Pa	Street Address, City, State 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material in use and interview with the Testing Personnel (TP), the laboratory failed to label the control material used in Hematology testing with an open and new expiration date after opening from 9/26/17 to date of the survey. The findings include: 1) There was no open and expiration date written on the QC material. 2) The TP #9 listed on CMS form 209 confirmed on 9/10/19 at 10:10 am controls were not labeled.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Boule Con-Diff Tri Level Control Kit Manufacture's Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory used expired QC material for the Hematology testing performed on the Medonic analyzer from 9/26/17 to the</p>

date of survey. The findings include: 1. The MPI stated open vial stability was for 14 days. 2. The laboratory did not know control material expired 14 days after opening. 3. TP stated that "control material on average lasted 21 days". 4. The TP stated that the laboratory "runs on average approximately 5-6 patients per day". 5. Approximately 170 patients were run and reported with expired QC . 4. The TP #9 confirmed on 9/10/19 at 11:00 am that the laboratory used expired QC material.

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 lack of Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have training documented for one out of nine TP from July 2019 to the date of the survey. The findings include: 1. There was no documentation of training for throat and urine culture testing. 2. There was no documentation of training for hematology tests performed on the Medoic analyzer. 3. The TP #9 confirmed on 9/10/19 at 10:00 am that training records were not available.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements for Throat Culture, Urine Culture and Hematology tests performed on the Medonic analyzer from 9/26/17 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 9/10/19 at 9:30 am that a CA procedure was not established.