

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2029686	(X3) Date Survey Completed 05/21/2024
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM), Procedure Manual (PM), Work Records (WR) and interview with the Testing Personnel (TP) the laboratory failed to follow the OM for "9.2 System Information Messages" from 1/18/24 to the date of survey. The findings include: 1. The OM stated "Indicator TU, possible orifice blockage: Run prime cycle amid then re-analyze. Action: Run a "prime cycle", before re-analyzing the sample"" 2. Two out of five WR had an indicator code TU for White Blood Cell Count (WBC). 3. There was no evidence that the aforementioned procedure was followed 4. The TP confirmed on 5/21/24 at 10:45 am that the laboratory did not follow the OM.</p>