Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0690559	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advocare Washington Avenue Pediatrics	95 North Washington Avenue, Bergenfield, 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
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 surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Selective Strep Agar (SSA) used for Throat Culture testing from 9/27/16 to the date of the survey. The findings include: 1. The laboratory did not check SSA for: a. Ability to support growth b. Ability to select or inhibit specific organisms 2. This was cited on the previous survey performed 9/27/16 and the Plan of Correction stated by 11/25/16 QC would be performed. 3. The TP #2 listed on CMS form 209 confirmed on 8/28/18 at 10:30 am that the laboratory did not perform the above mentioned QC checks.
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 Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for Throat Cultures from 9/27/16 to the date of survey. The TP #2 listed on CMS form 209 confirmed on 8/28/18 at 11:35 am that the TRD was not on the FR.
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 Testing Personnel (TP), the laboratory failed to have a procedure to verify manually entered results into electronic medical records from 9 /27/16 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 8/28/18 at 11:15 am that the laboratory did not have the procedure mentioned above.