

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0116189	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Advocare Basking Ridge Pediatrics	Street Address, City, State 150 North Finley Ave, Basking Ridge, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all records from Throat Culture PT events performed with the American Proficiency Institute in the calendar year 2019. The findings include: 1. The attestation was not retained from the 1-2019 event. 2. The work records were not retained in the 2019 PT events. 3. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 10:30 am that PT records were not retained.</p>
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP) the laboratory failed to ensure that the quality systems for the analytical phases of Bacteriology testing were monitored from 11/29/17 to the date of survey. The findings include: 1. The laboratory failed to ensure that an acceptable Room Temperature and Incubator range was defined. Cross Refer to D5471. 2. The laboratory failed to ensure that quality control on Bacitracin discs was done. Cross</p>

	<p>Refer to D5471. 3. The laboratory failed to ensure that quality control on media was performed. Cross Refer to D5477. 4. The laboratory failed to take corrective action when Strep Select Agar plates did not pass QC. Cross Refer to 5873.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a. Based on surveyor review of the Temperature Logs (TL) and interview with the Testing Personnel (TP), the laboratory failed to define an acceptable temperature range for the Incubator where Throat Culture (TC) tests were kept from 11/29/17 to the date of survey. The finding includes: 1. A review of the Incubator Log (IL) revealed an acceptable temperature range to be between 37 and 48 degrees Celsius (C) but the procedure manual stated TC must be incubated between 35-37 C. 2. The IL was out of range 61 days out of 66 days from September thru November 2019. 3. Approximately seven TC were performed each day. 4. The TP #1 listed on CMS 209 confirmed on 12/19/19 at 9:30 am that the laboratory did not define an appropriate Incubator temperature. b. Based on surveyor review of the TL and interview with the TP, the laboratory failed to define a temperature range for the Room Temperature (RT) where Bacitracin discs were kept from 11/29/17 to the date of survey. The TP #1 confirmed on 11/29/19 at 9:40 am that the laboratory did not define RT.</p>
<p>D5471</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 2/3/19 to the date of the survey. The TP #1 listed on the CMS form 209 confirmed on 12/19/19 at 11:00 am that QC was not performed. Note: This deficiency was previously cited on 11/29/17. The Plan of Corrections stated "In the future our lab will adhere better to make sure each batch are checked."</p>
<p>D5477</p>	<p>CONTROL PROCEDURES</p>

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 Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Throat Culture media for appearance, sterility, ability to support growth and select or inhibit organisms from 2/25/19 to the date of the survey. The findings include: 1. There was no documented evidence appearance, sterility, ability to support growth and select or inhibit organisms was checked on any lot number of media. 2. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 10:50 am the laboratory did not perform the above QC. Note: This deficiency was cited on survey performed on 11/29/17. The Plan of Correction stated: In the future each batch will be tested for appearance, sterility, ability to support growth and select or inhibit growth.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when QC for Throat Culture (TC) plates failed in February 2019. The findings include: 1. A review of the QC records revealed the Negative QC was positive for growth on Select Strep Agar (SSA) lots 1829605 and 1830900. 2. SSA expired 2/12/19 and 2/25/19 respectively. 3. Approximately 75 patients were run with the SSA lots listed above. 4. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 11:50 am that corrective action on failed of QC was not performed.

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 Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR included all required information from February 2019 to the date of the survey. The finding includes: 1. A review of five FR revealed that two out of five did not have the Test Report Date. 2. The TP #1 listed on the CMS form 209 confirmed on 12/19/19 at 11:50 pm that the FR did not include all required information.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on an surveyors review of the laboratory's records, procedures and interview with the Testing Personnel, the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 11/29/17 to the date of the survey. 1. The LD failed to ensure corrective action was taken when Quality Control (QC) was unacceptable. Cross Refer to 5783. 2. The LD failed to ensure that all PT results received were reviewed by the appropriate staff. Cross Refer to 6018. 3. The LD failed to ensure that the established QC program was maintained. Cross Refer to D6020 4. The LD failed to establish a Quality Assurance plan. Cross Refer to D6021 5. The LD failed to establish a Competency Assessment procedure with the applicable elements. Cross Refer to D6030. 6. The LD failed to have an approved procedure manual available for Throat Culture testing. Cross Refer to D6031

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Throat Culture testing performed with American

	<p>Proficiency Institute in the calendar year 2019. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 10:40 am that the PT results were not reviewed. Note: This deficiency was previously cited on 11/29/17. The Plan of Corrections stated "In the future all proficiency testing reports received will be reviewed by the appropriate staff."</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the established QC program was maintained for laboratory services provided from 2/25/19 to the date of the survey. The TP #1 listed on CMS form 209 confirmed 12/19/19 at 10:50 am the LD did not ensure the QC plan was maintained.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 12:00 pm that a QA plan had not been established.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have education and training documented for two out of two TP from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 10:00 am that all education and 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 failed to establish a Competency Assessment (CA) procedure with the required elements from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 10:30 am that a CA procedure was not established. Note: This deficiency was previously cited on 11/29 /17. The Plan of Corrections stated "In the future the Laboratory Director will ensure policies and procedures are established to monitor" competency.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

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 Director failed to have an approved procedure manual available for Throat Culture testing from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 12/19/19 at 11:30 am an approved PM was not available.