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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0670261 | (X3) Date Survey Completed 05/16/2019 |
| Name of Provider or Supplier Pediatric Team , The | Street Address, City, State 909 W Maple, Clawson, MI | |
| 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 |
|---------------------------|---|
| 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 document review and interview, the laboratory failed to meet Bacteriology requirements as specified in 493.1230 through 493.1256. Findings include: 1. The laboratory failed to include the quality control (QC) plan for the microbiology throat culture testing. Refer to D5445. 2. The laboratory failed to perform quality control for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci". Refer to D5471. 3. The laboratory failed to check each lot and shipment of Group A Selective Streptococcus A (ssA) media for sterility, support growth, inhibit growth, and physical characteristics. Refer to D5477.</p> |
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> |

This STANDARD is not met as evidenced by:
 . Based on procedure review, lack of documentation, and interview with testing personnel #2 (TP2), the laboratory failed to include the quality control (QC) plan for the microbiology throat culture testing for two (May 2017 to May 2019) of two years when implementing the Individualized Quality Control Plan (IQCP). Findings include: 1. Review of the IQCP plan for the "Throat Culture: Group A Selective Strep Agar with 5% sheep Blood (ssA)" revealed the IQCP did not contain a QC plan. 2. Review of the "Bacitracin Susceptibility" log revealed there was no documentation to show the QC was performed with each new lot number or shipment for two of two years. 3. An interview with TP2 on 5/16/19 at 10:04 am revealed the IQCP did not contain a QC plan for the commercially prepared media.

D5471

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(1)(g)

(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.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with testing personnel #2 (TP2), the laboratory failed to perform quality control for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" for 17 (December 2017 to May 2019) of 24 months reviewed. Findings include: 1. A review of the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" package insert stated, "at the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions. The use of Streptococcus pyogenes ATCC 12384 is recommended to demonstrate zone formation. One or more beta-hemolytic streptococcal species belonging to groups B, C, D, and/or G may be employed to demonstrate lack of zone formation." 2. A review of the "Bacitracin QC Testing" procedure revealed quality control is "to be performed weekly" using "S. faecalis ATCC 29212 and S. pyogenes ATCC 19615." 3. A review of the "Bacitracin Susceptibility" log revealed weekly quality control testing was not performed for 17 of 24 months. 4. An interview with TP2 on 5/16/19 at 10:30 am revealed quality control testing for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" had not been completed since 12/7/17.

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 document review and interview with testing personnel #2 (TP2), the laboratory failed to check each lot number and/or shipment of Group A Selective Streptococcus A (ssA) media for sterility, support growth, inhibit growth, and physical characteristics for 17 (December 2017 to May 2019) of 24 months reviewed. Findings include: 1. A review of the "BBL Group A Selective Strep Agar Quality Control Procedures" package insert revealed the manufacturer requires a "Performance Test Procedure" of quality control using the following organisms: a. one organism supported by the media (Streptococcus pyogenes) b. one organism inhibited by the media (Staphylococcus aureus, Neisseria subflava, or Pseudomonas aeruginosa). 2. A review of the "Quality Assurance Program" procedure states, "All new lot numbers of reagents, test kits and media are verified for quality before use." 3. A review of the "Isolation and Presumptive Identification of Group A Streptococci from Throat Cultures and Other Specimens" procedure states, "In order to comply with CLIA '88 regulations (Section 493.1227), positive and negative reactivity with control organisms must be checked each week of use for bacitracin. This also applies to new shipments of media and bacitracin." 4. A review of the "Isolation and Presumptive Identification of Group A Streptococci from Throat Cultures and Other Specimens" procedure under product deterioration states, "Do not use plates if they show evidence of microbial contamination, hemolysis, drying, cracking or other signs of deterioration." 5. A review of the "Culture Media Quality and Sterility Check" log revealed sterility, support growth, inhibit growth, and physical characteristics had not been completed since 11/22/17. 6. When requested on 5/16/19 at 10:30 am, TP2 was unable to provide the surveyor the documentation for sterility, support growth, inhibit growth, and physical characteristics for 17 (December 2017 to May 2019) of 24 months of testing. 7. During the interview on 5/16/19 at 10:30 am, TP2 confirmed the laboratory failed to check each lot number and/or shipment for sterility, support growth, inhibit growth, and physical characteristics.

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 record review and interview with testing personnel #2 (TP2), the laboratory failed to ensure for 2 (1st event 2019 and 3rd event 2018) of 6 proficiency testing (PT) events the final reports were reviewed by the appropriate testing personnel. Findings include: 1. Record review for 2 of 6 proficiency testing events revealed a lack of documentation of the Laboratory Director (LD) and testing personnel's (TP) review of the final PT reports. 2. A interview on 5/16/19 at 9:44 am with TP2 confirmed the LD and TP did not document review of the final graded proficiency testing reports.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on procedure review, record review, and interview with testing personnel #2 (TP2), the laboratory failed to follow and maintain the quality assurance program for 3 (December 2017, June and December 2018) of 3 semi-annual events. Findings include: 1. Review of the "Quality Assurance Program" procedure states, the Individualized Quality Control Plan (IQCP) will be monitored semi-annually to "determine if any additions or changes should be considered to ensure quality of testing in all phases". 2. Review of the "IQCP Semi-Annual Review" log revealed a lack of documentation for 3 of 3 semi-annual events in 2017 and 2018. 3. An interview with TP2 on 5/16/19 at 11:18 am revealed the semi-annual IQCP review had not been completed since 6/30/17.