

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0243046	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Gastonia Pediatric Associates Pa	Street Address, City, State 1839 East Garrison Boulevard, Gastonia, NC	
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
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> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's procedures and IQCP(individualized quality control plan), review of quality control records, and interview with TC(technical consultant) on 3/17/21, the laboratory failed to establish the laboratory's IQCP for strep cultures when the laboratory changed to a different reagent media. Findings: Review of the laboratory's procedure and IQCP for strep cultures on 3/17/21 revealed the laboratory uses Health Link JEMBEC Strep Select Agar. The laboratory's IQCP states that as part of the manufacturer's media acceptability requirements the laboratory peels the lower portion of a product bag label(Quality control certificate) for the lot being accepted and affixes to the Quality control log sheet. Review of the laboratory's Quality control log sheets revealed the laboratory changed reagent manufacturer's from the Health Link JEMBEC Strep Select Agar to the Hardy Diagnostic Streplate media on 7/10/19 and changed again to Becton Dickinson BBL Group A select media on 3/5/21. There was no documentation the laboratory established an IQCP when the changes in reagent media occurred. During interview at approximately 4:15pm, the TC confirmed the laboratory had not established an IQCP for strep cultures when the laboratory changed media. He stated the laboratory switched because they were unable to obtain media from the manufacturer.</p>

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 review of the laboratory IQCP(individualized quality control plan) and review of laboratory quality control records 3/17/21, the laboratory failed to perform and document growth and sterility checks as required when the laboratory changed to a different reagent media for strep cultures. Findings: Review of laboratory IQCP records revealed the laboratory failed to establish an IQCP for strep cultures when new media was put into use. See D5445. Review of laboratory quality control records on 3/17/21 revealed the laboratory followed an IQCP for Health Link JEMBEC Strep Select Agar for strep cultures. When the laboratory changed to a different reagent media, there was no documentation to indicate the laboratory had performed growth and sterility checks as required for each lot or shipment of reagent media from 7/10/19 to 3/5/21 for the following lot numbers: 1. Hardy Diagnostics Streplate lot #439860, expiration date: 8/18/19; 2. Hardy Diagnostics Streplate lot #441161, expiration date: 9/18/19; 3. Hardy Diagnostics Streplate lot #443130, expiration date: 10/18/19; 4. Hardy Diagnostics Streplate lot #444529, expiration date: 11/7/19; 5. Hardy Diagnostics Streplate lot # 447922, expiration date: 12/30/19; 6. Hardy Diagnostics Streplate lot #448105, expiration date: 1/7/20; 7. Hardy Diagnostics Streplate lot # 451824, expiration date: 3/1/20; 8. Hardy Diagnostics Streplate lot# 453604, expiration date: 4/8/20; 9. Hardy Diagnostics Streplate lot # 454999; expiration date: 4/28/20; 10. Hardy Diagnostics Streplate lot # 460768, expiration date: 8/4/20; 11. Hardy Diagnostics Selective Strep lot # 131429, expiration date: 11/5/20; 12. Hardy Diagnostics Selective Strep lot # 468365, expiration date: 11/29/20; 13. Hardy Diagnostics Streplate lot # 474920, expiration date: 3/4/21; 14. BD BBL Group A Select lot # 1035650, expiration date: 6/18/21.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of 2018, 2019, 2020, and 2021 temperature and humidity logs and interview with TC(technical consultant) 3/17/21, the laboratory failed to ensure corrective action was taken and documented for room temperature and incubator temperature readings outside the acceptable limits. Findings: Review of 2018, 2019, 2020 and 2021 temperature logs on 3/17/21 revealed: 1. Room temperature was outside the acceptable limits of 61-77 degrees F (Fahrenheit) on the following days with no corrective action documented: a. 2 of 31 days in July 2018 -7/7/, 7/8; b. 2 of

29 days in December 2018 -12/6, 12/10; c. 1 of 30 days in January 2019 -1/11; d. 1 of 29 days in April 2020 - 4/27; e. 2 of 30 days in January 2021 -1/17, 1/31; f. 3 of 28 days in February 2021 -2/6, 2/15, 2/17; 2. Incubator temperature was outside the acceptable limits of 34-37 degrees C(Celsius) on the following days with no corrective action documented: g. 1 of 30 days in December 2019 -12/4; h. 1 of 30 days in January 2020 -1/5. During interview at approximately 4:15p.m, the TC confirmed there was no corrective action documented when the temperatures were out of range.