

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0936744	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier McDonough Childrens Specialist Pc	Street Address, City, State 350 Huntington Place Court, McDonough, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 26, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory failed to attain an overall testing event score of at least 80% for 4 of 5 testing events. Findings include: 1. Review of the 2018 and 2019 American Society of Internal Medicine (MLE) PT documents reveals the laboratory received unsatisfactory results for urine colony count culture 4 of 5 testing events: 2018 Event #2 (50%) and #3 (0%) and 2019 event #1 (50%) and #2 (0%) without documentation of corrective actions. 2. Interview with staff #3 (CMS 209) on 9/26/19 at 11:54 AM in the breakroom confirmed the unsatisfactory performance.</p>
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) document review and staff interview, the laboratory failed to document corrective actions for any unsatisfactory testing event. Findings include: 1. Review of the 2018 and 2019 American Society of Internal Medicine (MLE) PT documents reveals the laboratory received unsatisfactory results for urine colony count culture 4 of 5 testing events: 2018 Event #2 (50%) and #3 (0%) and 2019 event #1 (50%) and #2 (0%) without documentation of corrective actions. 2. Interview with staff #3 (CMS 209) on 9/26/19 at 11:54 AM in the breakroom confirmed the lack of corrective action documentation.

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 quality control records for bacteriology and staff interview, the laboratory failed to perform the required sterility check and positive/negative growth checks on each batch of media used to perform urine cultures. Findings include: 1. Review of quality control (QC) records reveals the laboratory is not performing sterility check on CLED culture media. 2. Review of quality control (QC) records reveals the laboratory is not performing positive and negative growth controls on CLED culture media. 3. Interview with staff #3 (CMS 209) on 9/26/19 at 11:56 am in the breakroom reveals the lab is not aware of the requirement to perform sterility check and growth support QC and confirms they are not performing the required QC.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) document review and staff interview, the laboratory director (LD) failed to ensure corrective actions are documented for any unsatisfactory or unacceptable testing event. Findings include: 1. Review of the 2018 and 2019 American Society of Internal Medicine (MLE) PT documents reveals the laboratory received unsatisfactory results for urine colony count culture 4 of 5 testing events: 2018 Event #2 (50%) and #3 (0%) and 2019 event #1 (50%) and #2 (0%)

without documentation of corrective actions. 2. Interview with staff #3 (CMS 209) on 9/26/19 at 11:54 AM in the breakroom confirmed the lack of corrective action documentation.