

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262347	(X3) Date Survey Completed 06/17/2019
Name of Provider or Supplier Peds Care Pc	Street Address, City, State 1933 Shields Road, Dalton, 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 June 17, 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:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the nurse manager, the laboratory failed to implement and establish safety procedure to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. During the laboratory tour it was observed that there was not a formal installed eyewash station and maintenance log for the eyewash in the laboratory testing area. 2. An interview with the nurse manager on 06/17/2019 at approximately 11:35 a.m. confirmed a formal eyewash station was not installed in the laboratory and there was no weekly maintenance log to go with it.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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</p>

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 quality control (QC) document review and staff interview, the laboratory failed to perform QC in bacteriology as required. Findings include: 1. QC document review revealed the laboratory failed to perform an incubated sterility check for the bacteriology media from September 2017 to June 2019. 3. An interview with the nurse manager in the breakroom on 6/17/19 at approximately 11:30 a.m. confirmed the aforementioned QC was not performed from September 2017 to June 2019.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance and Quality Assurance(QA) records and an interview with the nurse manager, the Technical Consultant (TC) who is also the laboratory director failed to review and sign Monthly Quality Assurance report records from September 2017 to June 2019. Findings include: 1. Review of maintenance and Quality Assurance reports revealed QA logs were not reviewed and signed from September 2017 to June 2019 by the (TC). 2. An interview with the nurse manager on 06/17/2019 at approximately 11:40 am in the review room confirmed that maintenance QA reports were not reviewed and signed by the (TC) from September 2017 to June 2019.