

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0262347	<b>(X3) Date Survey Completed</b>  12/16/2021
<b>Name of Provider or Supplier</b>  Peds Care Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 16, 2021. 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:
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with Testing Personnel(TP), the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The laboratory's procedure manual did not include a written policy and procedure to include: collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance for staff to follow when sending specimens to reference laboratories (Hamilton, Diathrix, and Medtox). 2. During an interview, on December 16, 2021, at 2:00 PM, TP #6 and #9(CMS 209), in a back office, near the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory.</p>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. During an interview with Testing Personnel #6 and #9(CMS 209), on December 16, 2021, at approximately 2:05 PM, in a back office , near the breakroom, confirmed the SOP did not contain the duties and responsibilities policy and procedure for all personnel engaged in the performance of clinical laboratory testing.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's testing personnel competency assessment checklist as well as interview with the the supervisors, the laboratory failed to ensure the competency assessment policy and procedure for testing performed in the speciality of Microbiology to have met the 6 required criteria. The Findings include: 1. Laboratory document review revealed the laboratory was performing competency, but their competency assessment checklist did not include the 6 required criteria for the specialty of Microbiology. 2. During an interview with Testing Personnel #6 and #9(CMS 209) on December 16, 2021 at approximately 2:10 PM, confirmed that the laboratory was performing competency on the testing personnel, but it did not follow the 6 required criteria for the specialty of Microbiology.