

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0230376	<b>(X3) Date Survey Completed</b>  06/29/2023
<b>Name of Provider or Supplier</b>  Pediatric Center, Pc	<b>Street Address, City, State</b>  901 Enterprise Pkwy - Suite 200, Hampton, VA	
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>	An announced CLIA recertification survey was conducted at Pediatric Center, PC on June 29, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
<b>D6013</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a review of initial hematology instrument performance verification documentation, manufacturer's user guide instructions, lack of documentation, patient test logs, and an interview, the laboratory director (LD) failed to evaluate/verify the accuracy, precision, and normal values (reference ranges) for Complete Blood Count (CBC) testing prior to reporting one hundred sixty-eight (168) pediatric patient CBC panels from July 21, 2021 to the date of the survey on June 29, 2023. Findings include: 1. Review of the laboratory's instrument validation records revealed that a Sysmex field service technical representative installed a new hematology Poch-100i analyzer on 7/21/21. The inspector noted there was no LD signature recording an evaluation for the validation data of accuracy/precision/cross over studies performed by the field service representative. Additionally, the inspector noted there was no documentation of CBC pediatric patient normal value studies for the new hematology analyzer (Serial Number G6574). The inspector requested to review documentation</p>

that the LD established the PocH-100i analyzer pediatric patient normal value ranges and verified the accuracy/precision/cross over data prior to patient testing. No documentation of LD review was available. 2. Review of the Sysmex Users Guide for the new instrument revealed installation instructions for accuracy/precision/cross over studies and statement: "The patient normal values (Reference Range) must be validated by the laboratory". 3. Review of the patient test logs revealed that the lab had assayed/reported 168 CBC panels on the PocH-100i during the timeframe of 7/21/21 - 6/29/23. 4. An exit interview with the lead laboratory testing personnel on 6/29/23 at approximately 2:00 PM confirmed the above findings.