

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1074130	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Planned Parenthood Of Greater Ohio	Street Address, City, State 444 West Exchange Street, Akron, OH	
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
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the Rhesus (Rh) factor testing procedures performed in the subspecialty of Immunohematology. This deficient practice had the potential to affect two out of two patient Rh tests performed upon the change of Laboratory Director from 11/01/2024 through 11/05/2024. Findings Include: 1. Review of the laboratory's Form CMS-116 submitted by the laboratory for a Laboratory Director change revealed the form was signed and dated by the new /current Laboratory Director on 11/01/2024. 2. Review of the laboratory's electronic policy and procedure titled, "8.13 POCT Rh Typing", provided on the date of the inspection, found an approval date by the new/current Laboratory Director on 11/06 /2024. 3. The Inspector requested the laboratory's policies and procedures, approved by the new/current Laboratory Director, to include all aspects of Rh testing from the TC. The TC confirmed the new/current Laboratory Director did not approve the Rh policy and procedure until 11/6/2024 and was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/18/2024 at 11: 30 AM.</p>