

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0668196	(X3) Date Survey Completed 11/16/2020
Name of Provider or Supplier Planned Parenthood Of Se Pennsylvania	Street Address, City, State 1144 Locust Street, Philadelphia, PA	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the Testing Personnel #8 (TP#8), the Laboratory Director (LD) failed to ensure a General Laboratory System Quality Assessment (QA) program was established and maintained to ensure the quality of laboratory services provided from 2018 to the day of survey. Findings Include: 1. On the day of survey 11/16/2020, TP#8 could not provide a QA procedure or complete documentation of periodic evaluation of the laboratory that assess its preanalytical, analytical, and postanalytical processes from 2018 to 11/16/2020. 2. TP#8 confirmed the finding above on 11/16/2020 at 11:00 a.m.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing</p>

(PT) records and interview with the technical consultant #1 (TC#1), the TC failed to evaluate the test performance of 7 of 8 testing personnel (TP) through internal blind testing samples or external PT samples for Rhesus (Rh) D factor assay examinations in 2019 and 2020. Findings Include: 1. On the day of survey, 11/16/2020, review of AAB PT records revealed, 1 of 8 TP (TP#1) performed the external PT samples for Rh D factor assay examinations for 3 of 3 events in 2019 and 3 of 3 events in 2020. 2. The TC#1 could not provide documentation of internal blind testing evaluations performed for 7 of 8 TP (TP#2, 3, 4, 5, 6, 7, and 8) for Rh D assay examinations in 2019 and 2020. 3. The TC#1 confirmed the findings above on 11/16/2020 at 11:30 a. m.