

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1073239	(X3) Date Survey Completed 07/10/2019
Name of Provider or Supplier Planned Parenthood Of Illinois- Aurora	Street Address, City, State 3051 E New York St, Aurora, IL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's testing menu, survey forms, laboratory policies, procedures manuals, personnel records and interview with the technical consultant; the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings include: 1. Review of the laboratory's testing menu revealed that the laboratory performed Provider Performed Microscopic Procedures and Rh typing. 2. The laboratory listed a total of 2 technical consultants (TCs) on survey FORM CMS 209 (Laboratory Personnel Report). 3. There was no policy that described the process for assessing the competency of technical consultants. 4. Review of personnel record revealed that there was no documentation to show competency was assessed for 2 of 2 technical consultants. 5. At 10:45 AM on July 10, 2019, TC #2 confirmed the surveyor's findings.</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of presurvey documentation, survey forms, laboratory records, procedures manuals and interview with the site manager; the laboratory failed to</p>

maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). Findings include: 1. Presurvey documentation included the Individual Laboratory Profile of Proficiency Testing Scores. There were no Proficiency Testing scores for the subspecialty of bacteriology documented on the Individual Laboratory Profile for the 1st and 2nd Quarters of 2019. 2. At 10:00 AM on July 10, 2019, review of submitted survey forms revealed that the laboratory did not list any test volumes for the subspecialty of bacteriology on the application for CLIA Certification submitted to the surveyor. 3. At 10:15 AM on July 10, 2019, the site manager stated that the laboratory ceased testing Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) in December of 2018. 3. Review of laboratory records revealed that there were no GC/CT test records available for review after December 2018. 4. Review of the laboratory's procedures manuals revealed that there was no documentation to show that the laboratory documented the date it discontinued GC /CT procedures. 5. At 11:00 AM on July 10, 2019 the site manager confirmed the surveyor's findings.

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 policies and procedures manuals, survey forms, personnel records and interview with the technical consultant; the technical consultant failed to be responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. Findings include: 1. The laboratory's policy states, "Mid-level clinicians will have competency assessed twice a year by the Laboratory Director or designee and documented on the Provider Performed Microscopy (PPM) Competency Form." 2. The laboratory listed a total of 10 persons on FORM CMS 209 (Laboratory Personnel Report) who are authorized to perform PPM procedures. Two old personnel and 8 new personnel. There are also a total of 2 Technical Consultants listed on FORM CMS 209. 3. Review of personnel records revealed that neither the laboratory Director nor the Technical Consultants were responsible for documenting the competency of personnel performing PPM procedures, for 10 of 10 testing personnel in 2018 and 2019. 4. At 10:45 AM on July 10, 2019 technical consultant # 2 confirmed the surveyor's findings.