

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0977930	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Planned Parenthood Of Illinois - Austin	Street Address, City, State 5937 W Chicago Ave, Chicago, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on the Laboratory Personnel Report (CMS 209), the laboratory's records and an interview with the office manager; the laboratory failed to evaluate all proficiency testing activities for 11 out of 11 testing personnel (TP). Findings: 1. The CMS 209, personnel records, provider performed microscopy proficiency testing (PPM-PT), and the procedures manual were reviewed. 2. The competencies and PPM-PT records revealed the laboratory director (LD) or technical consultant (TC1) failed to review PT completion records for 11 out of 11 TP 3. The manual failed to define the method /procedure the LD or TC1 would use to show all PT participants' results or completions are reviewed. 4. On a Recertification survey conducted on 04/24/19 at 1: 15 PM, the office manager confirmed the above findings and stated that they were unaware of the requirement.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</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)(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</p>

review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on the Laboratory Personnel Report (CMS 209), the laboratory's records and an interview with the office manager; the laboratory director (LD) failed to specify in writing the authorization of each individual engaged in the performance of the analytic phase of testing, prior to reporting patient test results for 11 out of 11 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and the procedures manual were reviewed. 2. The personnel files of TP performing Potassium Hydroxide (KOH) testing and Wet mount Preparations (Wet Preps) revealed the following: a). The LD failed to have written authorizations for 11 out of 11 TP performing patient testing and reporting results. b). The LD failed to specify in writing, for 11 out of 11 TP, whether supervision is required for test performance or results reporting, and whether a consultant or director review is required. c). The responsibility of authorizing laboratory personnel for testing was not included in the LD's job description. 3. The requirement for authorizing laboratory personnel to test patients was not included in its procedures manual. 4. On a Recertification survey conducted on 04/24/19 at 1:15 PM, the office manager confirmed the above findings and stated that they were unaware of the requirement.

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 the Laboratory Personnel Report (CMS 209), the laboratory's records, the lack of documentation and an interview with the office manager; the technical consultant (TC1) failed to evaluate the competency of all testing personnel (TP), for 12 out of 12 TP. Findings: 1. The CMS 209, personnel records, and the procedures manual were reviewed. 2. The personnel files of TP performing Potassium Hydroxide (KOH) testing and Wet mount Preparations (Wet Preps) revealed the following: a). The TC1 failed to perform the competencies for 12 out of 12 TP for the years of 2018 thru 2019. b). The competency assessments were conducted by other TP. c). The TPs conducting the competencies did not have written authorization to perform this responsibility by the LD. d). The TC1 failed to provide documentation to show the TP assessing competency and trainings, have met CLIA requirements for TCs. 3. The laboratory's training and competency policy failed to include the TC as responsible for evaluating TP. The policy delegates this responsibility to laboratory personnel, a designee, or the laboratory director. 4. On a Recertification survey conducted on 04/24 /19 at 1:15 PM, the office manager confirmed the above findings.