

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2143728	(X3) Date Survey Completed 10/22/2019
Name of Provider or Supplier Planned Parenthood Of Illinois - Peoria	Street Address, City, State 2709 N Knoxville Ave, Peoria, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to perform bi-annual evaluations for vaginal wet mount testing with and without potassium hydroxide (KOH) in 2019. Findings Include: 1. Review of proficiency testing records revealed the laboratory failed to enroll in vaginal wet mounts with and without KOH reagent in 2019 with the American Proficiency Institute. 2. Interview with the laboratory representative on 10-22-2019 at 10:30 am confirmed the laboratory dropped enrollment with the American Proficiency Institute for vaginal wet mounts with and without KOH. 3. Review of PT documentation found no bi-annual verification documentation for vaginal wet mounts with and without KOH for 2019. 4. Interview with the laboratory representative at 2:00 pm confirmed the laboratory initiated a new "CAL" proficiency testing program for vaginal wet mounts with and without KOH. 5. Review of documentation for the "CAL" program found no documentation for the laboratory except a completion certificate that is specific to an individual. Personnel take the assessment until a passing score is achieved but no documentation is retained other than a completion certificate. What is assessed and how the laboratory performed is not retained and documented. 6. The "CAL" program is not tied to each CLIA number but to an individual therefore there was way to ensure bi-annual verification of vaginal wet mounts with and without KOH were completed for the Peoria, Illinois laboratory location. 7. Interview with the laboratory representative on 10-22-2019 at 1:15 pm confirmed 1,626 vaginal wet mounts had been performed in 2018 through 2019. 8. Interview with the laboratory representative on 10-22-2019 at 2:00 pm confirmed the surveyor's findings.</p>

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with a laboratory representative; the laboratory director (LD) failed to ensure a remedial action plan for vaginal wet mount preparation proficiency testing (PT) failure in event 3 of 2018 was completed. Findings Include: 1. Review of American Proficiency Institute (API) PT records for vaginal wet mount testing revealed the laboratory scored a 0% for vaginal wet mount preparations for event 3 in 2018. 2. Review of PT documentation found the laboratory director failed to ensure a corrective action plan was followed as outlined in the laboratory's "Corrective Action Procedure For Failed API Hematology/Coagulation 3rd Quarter Event" document. 3. Interview with the laboratory representative on 10-22-2019 at 2:00 pm confirmed the LD failed to ensure a remedial action was completed for the 3rd event of 2018 vaginal wet mount preparation failure.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with a laboratory representative; the laboratory director (LD) failed to ensure the bi-annual competency assessment policy was maintained to monitor the competency for 5 of 6 testing personnel (TP) performing vaginal wet mounts with and without potassium hydroxide (KOH). Findings Include: 1. Review of the laboratory policy, "Bi-Annual Microscopy Competency Assessment Requirement for Clinicians" revealed that personnel performing vaginal wet mounts with and without KOH will have bi-annual competency assessments. 2. Review of competency assessment records found no bi-annual competency assessment records were completed in 2018 and 2019 for 5 of 6 TP identified on the CMS-209 at the Peoria, Illinois laboratory location. TP Identifier Competency Dates TP#2 4-2018 (lab location not identified), 4-2019 (at alternate location, Flossmoor) TP#3 4-2018 (lab location not identified), 4-2019 (at alternate location, Pekin) TP#4 12-2018 (lab location not identified) TP#5 4-2018 (lab location

not identified), 4-2019 (at alternate location, Rogers Park) TP#6 1-2019 (lab location not identified) 3. Interview with the laboratory representative on 10-22-2019 at 2:00 pm, confirmed bi-annual competency assessments were not completed for 5 of 6 TP at the Peoria, Illinois laboratory location were the individuals perform vaginal wet mount testing.