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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D0977443 | (X3) Date Survey Completed 02/06/2019 |
| Name of Provider or Supplier Planned Parenthood Of Illinois - Rogers Park | Street Address, City, State 5725 N Broadway, 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 |
|---------------------------|---|
| D2159 | <p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review the the laboratory's records, proficiency testing (PT) reports, and an interview with the laboratory manager, the laboratory failed to return proficiency testing (PT) results within the time frame specified by the PT program for testing in the specialty of Immunohematology, during the year of 2018. Findings: 1. The PT program reported an unsatisfactory performance score of '0' for Rhesus [D (Rho)] testing during Event #3 of 2018 due to the late submission of the PT sample results from the laboratory. 2. The laboratory's PT documents revealed the following: a). The deadline to test and report the D (Rho) results to the PT program was 12/14 /2018 11:59 PM; b). The PT signature sheet attests that the PT samples were tested on 01/04/2019; and c). The D (Rho) test cards used to test the PT samples were dated 01 /04/2019. No documentation was provided to reveal why the PT samples were tested past the deadline and what corrective actions the laboratory needed to establish to prevent the reoccurrence of this incident. 3. On an Initial survey conducted on 02/06 /2019 at 1:45 PM, the laboratory manager confirmed the above findings.</p> |
| 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> |

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's manuals, records, and an interview with the laboratory manager; the laboratory failed to evaluate and train employees performing Potassium Oxide (KOH) and Wet mount testing with competency procedures that meet the criteria for assessing laboratory employees, affecting 8 out of 8 testing personnel (TP). Findings: 1. The CMS 209 lists 8 licensed practitioners (TP) performing KOH and Wet mount testing in the laboratory. 2. The laboratory's competency procedure does not include the following required criteria for assessing TP: 1). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 2). Direct observation of performance of instrument maintenance and function checks (i.e. microscope maintenance, etc.); and 3). Assessment of problem solving skills (must have documented evidence of test /problems given to the TP along with their answers/scores). 3. The personnel files revealed that the competency procedure described in Findings #2 was used to train and evaluate 8 out of 8 TP authorized to perform patient testing. 4. On an Initial survey conducted on 02/06/2019 at 1:45 PM, the laboratory manager confirmed the above findings.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory manager; the laboratory failed to verify the accuracy of its Rhesus [D(Rho)] testing when assigned a proficiency testing (PT) score of "0" due to late submission, affecting 72 patient tests. Findings: 1. The laboratory's PT documents revealed that the laboratory scored '0' for D (Rho) testing for Event #3 of 2018 due to the late submission of its PT results to the PT provider. 2. The laboratory's manual does not include the following: a). A mechanism or step-by-step procedure to investigate PT results when given a "0" score by the PT program due to missing the return deadline b). No documentation was provided to show that the laboratory chose another method to verify the accuracy of its D (Rho) testing during the PT failure period. 3. The laboratory performed 72 patient tests during the period of Event #3 of 2018 to 02/06/2019. 4. On an Initial survey conducted on 02/06/2019 at 1:45 PM, the laboratory manager confirmed the above findings.