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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0203526 | (X3) Date Survey Completed 05/19/2022 |
| Name of Provider or Supplier Planned Parenthood Sepa | Street Address, City, State 8 South Wayne Street, West Chester, 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 |
|---------------------------|--|
| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the review of Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Laboratory Manager (LM), the Laboratory failed to provide 6 of 6 MLE PT attestation statement documents for Potassium Hydroxide (KOH) and wet mounts microscopic examinations for 2020, 2021 and 2022. Findings include: 1. On the day of survey, 05/19/2022 at 10:45am, the LM could not provide the following 6 of 6 attestation statements for KOH and wet mounts: 2020 = Event 2 and Event 3 2021 = Event 1, Event 2 and Event 3 2022 = Event 1 2. The LM confirmed the findings above on 5/19/2022 at 12:30 pm.</p> |
| D6016 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency test (PT) records and interview with the Laboratory Manager (LM) on the date of the survey 05 /20/2022, the Laboratory Director (LD) failed to ensure that all proficiency testing</p> |

attestations were signed by appropriate staff for Rhesus factor (Rh) in 2021. Findings include: 1. On the day of survey 5/19/2022 at 10:46am, the Laboratory Director failed to sign the AAB Event 1 and Event 2 2021 proficiency attestations. 2. Interview with Laboratory Manager on 5/19/2022 at 12:35pm, confirmed this finding above.

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 competency assessment records and interview with Laboratory Manager (LM), the Technical Consultant (TC) failed to provide separate competency records for 3 of 3 testing personnel (TP) who performed potassium hydroxide (KOH) and wet mounts microscopic examinations for 2020 and 2021. Findings include: 1. On the day of survey 5/19/2022 at 10:25am, the Technical Consultant (TC) failed to provide separate competency records for KOH and Wet mount procedures for 2 of 3 TP (CMS 209 personnel # 6 and # 8) for 2020 and 2021. 2. The laboratory could not provide competency records for 1 of 3 TP (CMS 209 personnel # 7) who performed KOH and wet mounts in 2021. 3. Interview with Laboratory Manager on 5/19/2022 at 12:20pm, confirmed the findings above.