

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0203526	(X3) Date Survey Completed 12/09/2019
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
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 laboratory procedure manuals and interview with the center manager, the laboratory failed to establish a procedure to assess the competency of 1 of 1 technical consultant (TC) from 2017 and 2019. Findings Include: 1. On the day of survey, 12/09/2019, the laboratory failed to provide a written policy to assess the competency of 1 of 1 TC from 11/08/2017 to 12/09/2019. 2. The center manager confirmed the finding above on 12/09/2019 around 09:55 am.</p>
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 the laboratory's in-house evaluation process for KOH and wet mount examination records and interview with center manager, the laboratory failed perform at least twice annually the accuracy of KOH and wet mount examinations from 2018 to the date of survey. Findings Include: 1. On the day of survey, 12/09/2019, review of the laboratory's in-house evaluation process for KOH and wet mount examination records revealed, the laboratory did not perform KOH and wet mount evaluations at least twice annually for accuracy in 2018 and 2019. 2. The laboratory</p>

only provided evaluation records performed for KOH and wet mount examinations, once in 2018 and once in 2019. 3. The center manager confirmed the findings above on 12/09/2019 around 10:25 am. ****KOH= Potassium Hydroxide

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manuals and interview with the center manager, the laboratory failed to establish written policy to assess the quality of its laboratory systems from 11/08/2019 to the day of survey. Findings Include: 1. On the day of survey, 12/09/2019, review of laboratory manuals revealed, the laboratory did not have a written policy to assess the quality of its laboratory pre-analytical, analytical and post-analytical systems for Rh D typing, KOH and wet preps examination from 11/08/2019 to 12/09/2019. 2. The center manager confirmed the finding above on 12/09/2019 around 11:15 am. ****KOH= Potassium Hydroxide

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on the review of patient test reports and interview with the center manager, the laboratory failed to include on test reports (3 of 3 reviewed) the interpretation of Rh D typing, KOH and Wet prep examination results from 11/08/2017 to the day of survey. Finding Include: 1. On the day of survey, 12/09/2019, a review of some test reports (3 of 3) revealed the test reports did not include the interpretation for Rh D typing, KOH and Wet prep examinations results from 11/08/2017 to 12/09/2019. 2. The center manger confirmed the finding above on 12/09/2019 around 11:00 am. ****KOH= Potassium Hydroxide

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 laboratory testing personnel competency records and interview with the center manager, the technical consultant (Laboratory Director) failed to evaluate the competency of 1 of 1 Testing personnel (TP) performing KOH and Wet Prep examinations in 2018 and 2019. Findings Include: 1. On the day of survey, 12/09/2019, the laboratory could not provide competency assessment documentation for 1 of 1 TP who performed KOH and Wet Prep testing in 2018 and 2019. 2. The center manager confirmed the finding above on 12/09/2019 around 10:45 am. ****KOH= Potassium Hydroxide

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) records, the American Association Proficiency Institute (API) 2018 and 2019 proficiency testing (PT) attestation sheets and interview with the center manager, the technical consultant (TC) failed to assess the competency of 1 of 3 TP through internal blind testing samples or external PT for immunohematology Rh D typing in 2018. Findings Include: 1. On the day of survey, 12/09/2019, review of TP records and API PT attestation sheets revealed, the laboratory did not assess the test performance of 1 of 3 TP (#3) for immunohematology Rh D typing samples or internal blind testing samples in 2018. 2. The center manager confirmed the finding above on 12/09/2019 around 10:42 am.