

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0668676	(X3) Date Survey Completed 03/12/2020
Name of Provider or Supplier Planned Parenthood Vandalia Health Center	Street Address, City, State 671 Vandalia Street, Saint Paul, MN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain 14 of 15 new employee training records for at least 2 years. Findings are as follows: 1. The laboratory performed Rh testing as confirmed by the laboratory representative (LR) during a tour of the laboratory at 1:15 p.m. on 03/12/20. 2. Rh training records for 15 of 15 employees hired since 2018 were not found during record review on date of survey. The laboratory was unable to provide the documents upon request. 3. In an interview at 3:45 p.m. on 03/12/20, the LR indicated the laboratory was having difficulty locating the documents. The laboratory was given seven days to produce the training documents. 4. In an email received on 03/18/20, the Regional Senior Director of Clinical Quality Assurance & Compliance provided the training document for 1 of 15 new employees and indicated they were unable to locate the original training documentation for the remaining staff.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical</p>

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 document review and interview with laboratory personnel, the Laboratory Director (LD) failed to ensure 14 of 17 testing personnel were assessed at least annually in 2019 through testing previously analyzed specimens, blind samples, or proficiency testing samples. Findings are as follows: 1. The laboratory was cited for non-performance of blind sample evaluations during the previous survey conducted on 05/15/18. 2. Blind sample evaluations were not found on date of current survey for 14 of 17 testing personnel in 2019 competency assessment records. See D6051. 3. In an interview at 4:10 p.m. on 03/12/20, the laboratory representative confirmed the above finding.

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 document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure 1 of 15 testing personnel in 2018 was evaluated for test procedure competency. Findings are as follows: 1. The laboratory performed Rh testing as confirmed by the laboratory representative (LR) during a tour of the laboratory at 1:15 p.m. on 03/12/20. 2. Competency evaluations were required annually as established in the electronic Laboratory Policy and Procedures Manual. 3. An annual Rh competency evaluation was not found for Testing Personnel 2 during review of laboratory records. The laboratory was unable to provide the document upon request. 4. In an interview at 4:10 p.m. on 03/12/20, the LR confirmed the above finding.

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 document review and interview with laboratory personnel, the technical consultant failed to ensure 14 of 17 testing personnel (TP) were assessed at least annually through testing previously analyzed specimens, blind samples, or proficiency testing samples during 2019 competency assessments. Findings are as follows: 1. The laboratory performed Rh testing as confirmed by the laboratory representative (LR) during a tour of the laboratory at 1:15 p.m. on 03/12/20. 2. Blind sample assessment documenting was not included on the 2019 Annual Laboratory Evaluation form for 17

of 17 TP. 3. Laboratory records indicated 3 of 17 TP participated in 2019 Rh proficiency testing; TP13, TP16, and TP19 4. The laboratory was unable to provide documented 2019 blind sample evaluations for the remaining TP upon request. 5. In an interview at 4:10 p.m. on 03/12/20, the LR confirmed the above finding. *This is a repeat citation from the previous survey on 05/15/18. See D6030*