

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0668676	(X3) Date Survey Completed 05/15/2018
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to perform testing on Immunoematology proficiency testing samples in the same manner patient specimens are tested. Findings are as follows: 1. The laboratory performed Rh testing under the Specialty of Immunoematology as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 05/15/18 at 1:15 p.m.. 2. Proficiency testing (PT) attestation statements indicated two testing personnel (TP) were involved proficiency sample testing in 3 of 6 events reviewed. See below Event Testing personnel Date 2016-2 TP10 and former TP CJ 08/09/16 2016-3 TP2 and TP8 12/17/16 2017-1 TP5 and TP6 4/11/17 3. Proficiency samples were to be tested in the same manner as patent specimens as established in Appendix H - Proficiency Testing Instruction located in the Laboratory Policy and Procedure Manual. 4. In an interview on 05/15/18 at 2:20 p.m., the LD confirmed the above finding. The LD explained one TP had performed the testing for each event while another TP observed. The LD stated patient samples would not be tested in this manner.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p>

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 all testing personnel were assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples at least annually. Findings are as follows: 1. The laboratory performed Rh testing under the Specialty of Immunohematology as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 05/15/18 at 1:15 p.m. 2. Requirements to assess testing personnel competency via blind testing using previously analyzed specimens, blind samples or proficiency testing samples were not found in the Laboratory Policy and Procedure Manual. Documentation of blind testing was not included on the annual assessment form. 3. Laboratory records indicated 7 of 11 testing personnel (TP) were not assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples in 2016. In 2017, 9 of 13 TP were not assessed in this manner. See below. TP performed proficiency testing as indicated by "x" TP 2016 2017 1 2 x 3 4 x 5 x 6 x 7 8 x x 9 N/A 10 x 11 N/A x 12 13 *N/A - not applicable, newly hired in 2016 4. In an interview on 05/15/18 at 2:05 p.m., the LD confirmed the above finding.