

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409577	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Planned Parenthood Of Montana	Street Address, City, State 1500 Cannon Street, Helena, MT	
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
D0000	Based on an on-site recertification survey conducted on 6/5/18-6/12/18, condition level deficiencies were cited for Planned Parenthood of Montana in Missoula, MT.
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform positive and negative controls every day of patient testing for 14 days between 3/1/17 and 12/31/17. The findings include: 1. A review on 6/5/18 at 3:30 p.m. of the Planned Parenthood Laboratory Manual included to review the analyte quality control (QC) form for "evidence of documentation of QC testing for each analyte performed on Form with regular review and evaluation of all QC results." 2. A review on 6/5/18 at 3:50 p.m. of the RH EldonCard Laboratory Log and list of days with charges for Rh testing included 12 days of patient results without quality control documented. a. 7/12/17, 7/16/17, 7/26/17, 8/1/17, 8/2/17, 8/8/17, 8/9/17, 8/15/17, 8/22/17, 8/23/17, 8/29/17, and 8/30/17. 3. On 6/5/18 at 4:30 p.m., staff member A stated the control results were not located in the archived files. 4. A review on 6/12/18 at 2:15 p.m. of the RH EldonCard Laboratory Log included results for patients on 10/11/17 and 12/27/17 without documented quality control results. 5. On 6/12/18 at 2:15 p.m., staff member B stated controls may be performed on a previous day when the clinic is not busy.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p>

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 record review and interview, the laboratory failed to indicate the address of the laboratory where the test was performed on four of four test reports reviewed. The findings include: 1. A review on 6/5/18 at 3:20 p.m. of two test reports lacked the address of the laboratory where the test was performed. 2. On 6/5/18 at 3:20 p.m., staff member A stated the reports did not have the address. 3. A review on 6/5/18 at 3:30 p.m. of the Planned Parenthood Laboratory Manual included the test report "will include name and address of the lab actually performing the tests." 4. A review on 6/12/18 at 2:30 p.m. of two additional test reports lacked the address of the laboratory where the test was performed. 5. On 6/12/18 at 2:30 p.m., staff member A stated the request is submitted to the company to add the address.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to have a qualified technical consultant resulting in the laboratory's lack of technical oversight from 6/21/17 to 6/5/18. See D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have a qualified technical consultant from 6/21/17 to 6/5/18. The findings include: 1. A review on 6/5/18 at 2:35 p.m. of the CMS-209 form filled out by the facility failed to list a technical consultant. 2. On 6/5/18 at 2:45 p.m., staff member A stated the laboratory director does not qualify as the technical consultant but another provider may qualify as technical consultant. 3. A review on 6/5/18 at 3:30 p.m. of the Planned Parenthood Laboratory Manual included under the laboratory director responsibilities that the "lab director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described by CLIA." 4. On 6/5/18 at 5:00 p.m., staff member A stated the other provider was working on updating the resume for qualifying as technical consultant. 5. On 6/12/18 at 2:35 p.m., staff member A stated the provider had not completed the resume and had not provided information on qualifying for technical supervisor. 6. A review on 6/12/18 at 2:35 p.m. of the CMS-209 form did not list any other staff as technical supervisor. Qualifications of the providers trying to qualify as technical consultant were not provided.