

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2081192	(X3) Date Survey Completed 05/12/2021
Name of Provider or Supplier Delaware County Women's Center	Street Address, City, State 1 Medical Center Blvd, Pob Ii, 2nd Fl, Ste 224, Upland, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the testing personnel (TP) #1, the laboratory failed to establish a maintenance policy to assess the maintenance /function for 1 of 1 Taylor NSF 5924 thermometer used to monitor the temperature for the only refrigerator in the laboratory from 03/27/2019 to the day of survey. Findings Include: 1. On the day of the survey, 05/12/2021, the laboratory could not provide a maintenance policy for the thermometer. 2. The laboratory could not provide maintenance records for the thermometer used to store RH factor assay (Albaclone) reagents. 3. A due date for calibration of 03/20 was observed on the sticker posted on the Taylor NSF 5924 thermometer. The last calibration was performed on 03/27/2019. 4. TP #1 confirmed the findings above on 05/05/2021 at 12:00 p.m.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on review of personnel qualification records and interview with Testing Personnel (TP)#1., the laboratory failed to have a technical consultant who meets the qualification requirements for Rh factor assay (moderate complexity) from 11/01/2018 to the date of survey. Refer to 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 review of personnel qualification records and interview with Testing Personnel (TP)#1., the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for Rh factor assay (moderate complexity) from 11/01/2018 to the date of survey. Findings include: 1. On the date of survey, 05/12/2021 at 09:22 a.m., reviewed of TC credentials who performed competency assessment for the other testing personnel in the laboratory from 11/01/2018 to the day of survey. TP#1 did not meet the qualifications (493.1411) to be a Technical Consultant for the RH factor assay. 2. During an interview on 05/12/2021 around 09:

22 a.m., the TP#1 confirmed that TP#1 has a Bachelor of Art in Fine Art. 3. The TP#1 confirmed the findings above at the time of survey.