

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0369410	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Planned Parenthood Of Michigan	Street Address, City, State 3100 Professional Drive, Ann Arbor, MI	
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: . Grand Rapids and Lansing locations Based on record review and interview, the laboratory failed to test the immunohematology proficiency testing (PT) samples for five (3rd event 2016, 1st-3rd events 2017, and 1st event 2018) of five events reviewed in the same manner as patient samples. Findings include: 1. On June 5, 2018 at 12:15 PM and 1:45 PM, record review of the final graded American Proficiency Institute (API) proficiency testing reports for five (3rd event 2016, 1st-3rd events 2017, and 1st event 2018) of five events reviewed the laboratory did not document the proficiency testing samples on the "AB Services Rh Laboratory Log" for the Grand Rapids and Lansing sites. 2. On June 5, 2018 at 12:15 PM and at 6:40 PM when queried, the Regional Patient Services Manager and the Regional Director of Patient Services were not able to provide documentation to show the PT samples were tested in the same manner as patient samples. 3. During the interview on June 5, 2018 at 12:15 PM and 6:40 PM, the Regional Patient Services Manager and the Regional Director of Patient Services confirmed the PT samples were not recorded on the "AB Services Rh Laboratory Log" for the Grand Rapids and Lansing sites.</p>
D2010	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:

. Traverse City Location Based on record review and interview, the laboratory failed to test the immunohematology proficiency testing samples the same number of times that it routinely tests patient samples for one (1st event 2018) of five events reviewed. Findings include: 1. On June 5, 2018 at 1:23 PM, record review of the American Proficiency Institute (API) proficiency testing reports revealed for one (1st event 2018) of five events reviewed, the testing personnel (TP) that signed the attestation statement sheet shows the specimens were run by multiple people for the same specimen on the same day of testing as follows: a. TP #1 - ran specimens #1, #3, and #5 b. TP #2 - ran specimens #2, #4, and #5 c. TP #3 - ran specimens #2, #3, and #4 2. During the interview on June 5, 2018 at 1:23 PM, the Regional Patient Services Manager confirmed the test samples were not run the same number of times that it routinely tests patient samples. ***Repeat Deficiency from August 2, 2012 survey***

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to ensure written competency policies were implemented for 19 (#34 - #48 and #50 - #53) of 76 testing personnel performing the moderately complex mycology, parasitology, and the microscopic urinary sediment testing for two years. Findings include: 1. On June 5, 2018 at 4:00 PM, record review of the competency evaluations revealed for 19 (#34 - #48 and #50 - #53) of 76 testing personnel the competency requirements from subpart M containing the six required categories were not included in the assessment for the mycology, parasitology, and microscopic urinary sediment testing as following: a. Direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performances through testing previously analyzed specimens, internal blind testing samples or external proficiency testing specimens. f. Assessment of problem solving skills. 2. On June 5, 2018 at 4:00 PM when queried, the Regional Director of Patient Services was not able to provide the surveyor with the annual competency evaluations with the six requirements for 19 (#34 - #48 and #50 - #53) of 76 testing personnel in 2016 and 2017. 3. During the interview on June 5, 2018 at 4:00 PM, the Regional Director of Patient Services confirmed the annual competencies did not contain the required categories. ***Repeat Deficiency from May 4, 2016 survey***