

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0395874	<b>(X3) Date Survey Completed</b> 07/27/2018
<b>Name of Provider or Supplier</b> Peter Christensen Health Center	<b>Street Address, City, State</b> 129 Old Abe Road, Lac Du Flambeau, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and laboratory procedures, and interview with the technical consultant, the laboratory did not enroll in a PT program for mononucleosis testing as required in subpart I. Findings include: 1. Review of PT records for 2017 and 2018 showed no evidence the laboratory enrolled in a proficiency testing program that met the requirements for the non-waived mononucleosis test. 2. Review of the laboratory's "Acceava Mono Cassette" procedure showed the 'Specimen Collection and Preparation' section of the procedure identifies plasma and serum as acceptable samples for mononucleosis testing. 3. Interview with the technical consultant, staff A, on July 27, 2018 at 10:15 AM confirmed the mononucleosis procedure is non-waived when serum and plasma are used as specimens and also confirmed the laboratory was not enrolled in a PT module for non-waived mononucleosis testing as required in Subpart I.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory has not verified the accuracy of the nasal smear for eosinophils test twice annually in 2017 or 2018. Findings include: 1. Review of PT records shows the laboratory does not submit results for the nasal smear for eosinophils proficiency test. 2. Review of laboratory records shows no evidence of another means of evaluating accuracy of the nasal smear procedure twice annually. 3. Interview with the technical consultant on July 27, 2018 at 11:30 AM confirms the laboratory performs nasal smear for eosinophil testing on patient samples and has not evaluated the accuracy of the test twice annually.

**D5409**

**PROCEDURE MANUAL**

CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and interview with the technical consultant, the laboratory discontinued GGT (Gamma-glutamyl transferase) testing without including a discontinued date with the procedure. Findings include: 1. Review of laboratory procedures shows a GGT procedure for testing on the Vitros analyzer. The procedure does not show a discontinued date. 2. Interview with the technical consultant, staff A, on July 27, 2018 at 12:15 PM confirmed GGT testing was discontinued on March 22, 2018 and the procedure was not identified as discontinued.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and calibration records for the Sysmex KX-21 analyzer, and interview with the technical consultant, the laboratory did not perform calibrations at the frequency required by the laboratory from August 2017 through July 2018. Findings include: 1. Review of the "Sysmex KX-21 Operation" procedure showed calibration is required every three months. 2. Review of calibration records shows the Sysmex KX-21 analyzer was calibrated in August 2017. No records were available to show the analyzer had been calibrated again until July 2018. 3.

Interview with the technical consultant, staff A, on July 27, 2018 at 11:30 AM confirmed the Sysmex analyzer was not calibrated every three months as required in the laboratory's procedures. This is a repeat deficiency previously cited on July 27, 2010.