

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1078013	(X3) Date Survey Completed 01/14/2020
Name of Provider or Supplier Northlakes Community Health Center	Street Address, City, State 7665 Us Hwy 2, Iron River, WI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of competency assessment procedures and laboratory records, and interview with the technical consultant, the laboratory has not evaluated or developed procedures to assess the competency of the technical consultant to meet position requirements. Findings include: 1. Review of laboratory procedures showed no evidence of policies or procedures to assess the competency of the technical consultant in meeting the position responsibilities listed in Subpart M. 2. Review of laboratory records showed no documented evaluation of competency of the technical consultant. 3. Interview with the technical consultant on January 14, 2020 at 10:30 AM confirmed that the laboratory does not have a procedure to evaluate the competency of the technical consultant in meeting position responsibilities and the laboratory has not assessed the competency of the technical consultant. This is a repeat deficiency previously cited October 30, 2013 and November 16, 2017.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory does not have a process established for documenting general laboratory operation problems to allow monitoring and evaluation of the corrective actions taken. Findings include: 1. Review of laboratory records show no documentation of general laboratory issues. 2. Interview with the technical consultant on January 14, 2020 at 1:15 PM confirms the laboratory does not have a process to identify, document, and correct general laboratory problems. This is a repeat deficiency previously cited November 16, 2017.

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 laboratory records and procedures, and interview with the technical consultant, the laboratory did not calibrate the Emerald hematology analyzer every six months as required in the laboratory's procedures. Findings include: 1. Review of the Cell-Dyn Emerald "CellDyne Procedure" shows to calibrate using commercial calibrators every six months as required by the manufacturer. 2. Review of laboratory records shows the Cell-Dyn Emerald had calibrations performed January 29, 2018, February 13, 2018, and January 7, 2020. 3. Interview with the technical consultant on January 14, 2020 at 1:25 PM confirms there are no records to show the analyzer was calibrated every six months in 2018 and 2019. This is a repeat deficiency previously cited November 16, 2017.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor review of laboratory records, laboratory information system records, laboratory procedures, and interview with testing personnel and the technical consultant, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory director has not assigned the duties of the technical consultant in writing. See D6004 Item 1. 2. The laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations. See D6004 Item 2. 3. The laboratory

director did not ensure that the laboratory information system reported test results that included appropriate reference ranges required for interpretation as defined by the laboratory procedures. See D6026.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Item 1: Based on laboratory record review and interview with the technical consultant, the laboratory director has not designated in writing responsibilities to the qualified technical consultant. Findings include: 1. Review of laboratory records show that the laboratory director has not delegated duties in writing to the qualified technical consultant. 2. Interview with the technical consultant on January 14, 2020 at 10:30 AM confirms the laboratory director has not delegated in writing the duties that the technical consultant may perform. This is a repeat deficiency previously cited November 16, 2017. Item 2: Based on surveyor comparison of previous CMS (Centers for Medicare and Medicaid Services) Form 2567 (Statement of Deficiencies and Plan of Correction) and deficiencies cited on the current CMS Form 2567, and interview with the technical consultant, the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations. Findings include: 1. The following deficiencies have been cited on the CMS Form 2567 from prior surveys and are also cited on this CMS Form 2567: D5209: The laboratory director did not evaluate the competency of the technical consultant, previously cited October 30, 2013 and November 16, 2017. D5291: The laboratory does not have a process to identify, document, and correct general laboratory problems., previously cited November 16, 2017. D5437: The laboratory director did not ensure that the hematology analyzer was calibrated every six months as required by the instrument manufacturer and laboratory procedure, previously cited November 16, 2017. 2. Interview with technical consultant on January 14, 2020 at 1:30 PM confirms that the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on surveyor review of reference (normal) ranges in the hematology procedure with those on patient test reports, and interview with the technical consultant, reference (normal) ranges on patient reports are not consistent with the reference ranges in the approved procedure. Findings include: 1. Comparison of the reference (normal) ranges shown in the "Cell Dyne Procedure" with the reference ranges on the patient reports from the EPIC Ochin electronic medical record (EMR) show that reference ranges available on patient reports are not consistent with reference ranges in the approved procedure. Reference Ranges from the EMR patient report versus the hematology procedure: (All reference ranges listed in the procedure are not gender specific): White Blood Cell (WBC) count: Procedure: 4.6-10.2 per cubic millimeter EMR Report: 4.8-10.8 per cubic millimeter Red Blood Cell (RBC) count: Procedure: 3.50-6.13 per cubic millimeter EMR Report: 4.7-6.2 per cubic millimeter Red Cell Distribution Width (RDW): Procedure: 11.5-14.5 % EMR Report: 11-14.5 % 2. Interview with the technical consultant and Staff A on January 14, 2020 at 2:00 PM confirms the reference ranges on patient reports used for the evaluation of test results are not consistent with the reference ranges in the approved laboratory procedure.