

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0709006	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Pchc	Street Address, City, State 376 Main St, Jackman, ME	
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
D6010	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)</p> <p>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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the technical consultant (TC), the laboratory failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. Findings include: 1. Record review on 5/2/2024 of the laboratory Quality Assurance documentation revealed: "PCHC lab reviews quality assurance activities, problems, and corrective actions taken. Quality assurance is reviewed with the laboratory staff and Laboratory Director. 2. Record review on 5/2/2024 of the laboratory Temperature Chart for February 2024, revealed the following: a. February 12, 57 degrees Fahrenheit. b. February 20, 53 degrees Fahrenheit. c. February 22, 53 degrees Fahrenheit. 3. Interview with the TC on 5/2/2024 at 9:00am revealed: a. The temperature of the laboratory had dropped below the Sysmex 1000i hematology analyzer manufacturer's required operating temperature (59-86 degrees Fahrenheit) on 3 days in February 2024. b. The TC stated that testing had continued, the heating system reset, results reported, no corrective action had been documented, and the laboratory director (LD) had not been notified. 4. The laboratory performs 300 tests per year in the specialty of hematology.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p>

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on documentation and interview with the technical consultant (TC) the laboratory director (LD) failed to perform observation of the TC for annual competencies. Findings include: 1. Record review of the laboratory "Competency Assessment" policy on 5/2/2024 revealed competency to be performed "Annually for all Laboratory personnel ..." including "Direct observations of routine patient test performance ..." and "Direct observation of performance of instrument maintenance function checks and calibration". 2. Record review on 5/2/2024 of the TC annual competencies for 2022-2023 revealed the LD to have signed the competencies. 3. Interview with the TC on 5/2/2024 at 9:30am revealed that the LD had signed the competencies based on documentation but had not performed direct observations.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the technical consultant (TC), the TC failed to ensure that patient test results were not reported until all corrective actions have been taken for the test system to function properly in the specialty of hematology. Findings include: 1. Record review on 5/2/2024 of the laboratory policy and procedure documentation revealed the TC to assigned: " resolving technical problems and ensuring that remedial actions are taken when ever test systems deviate " , " Ensuring that patient test results are not reported until all corrective actions have been taken " , " adherer to manufacturer ' s instructions " . 2. Record review on 5/2 /2024 of the laboratory Temperature Chart for February 2024, revealed the following: a. February 12, 57 degrees Fahrenheit. b. February 20, 53 degrees Fahrenheit. c. February 22, 53 degrees Fahrenheit. 3. Interview with the TC on 5/2/2024 at 9:00am revealed: a. The temperature of the laboratory had dropped below the Sysmex 1000i hematology analyzer manufacturer ' s required operating temperature (59-86 degrees Fahrenheit) on 3 days. b. The TC stated that testing had continued, the "boiler" was reset, results reported, no corrective action had been documented, and the laboratory director (LD) had not been notified. 4. The laboratory performs 300 tests per year in the specialty of hematology.