

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0966357	(X3) Date Survey Completed 11/19/2020
Name of Provider or Supplier Community Care Physicians Pc	Street Address, City, State 2125 River Road, Suite 100, Niskayuna, NY	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of 2019 and 2020 American Proficiency Institute (API) proficiency testing (PT) attestation statements and an interview with the general supervisor, the laboratory failed to rotate the testing of PT samples among five personnel who routinely perform patient testing on the Sysmex XN-450 hematology analyzer. The same person performed all three 2019 Hematology events as indicated by the signed attestation statements. FINDINGS. The general supervisor confirmed on November 19, 2020 at approximately 11:00 AM, the surveyor found the following attestation events recorded the same testing person performed the test events. There were five other testing personnel that routinely perform hematology testing on Sysmex XN-450 analyzer. 2019 first event Hem01- Hem05 2019 second event Hem06- Hem10 2019 third event Hem11-Hem15</p>
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's review of competency assessment records for the five of five</p>

testing personnel , the laboratory's competency assessment policy and an interview with the general supervisor, the laboratory failed to follow their written policies for competency assessment for five of five testing personnel and the technical consultant for the calendar year 2019 and 2020. FINDINGS: The general supervisor confirmed on November 19, 2020 at approximately 11:30 AM, the surveyor's findings that the laboratory failed to follow their written competency assessment polices for the following: a. five of five personnel who routinely perform hematology testing failed to be evaluated at their six-month period after completing their training in 2019. b. three of five personnel failed to be evaluated for their annual 2020 review on their anniversary date of hire. c. The technical consultant failed to be evaluated based on her duties and responsibilities in 2019.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

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.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of records and confirmed in an interview with the general supervisor at the time of this survey, the laboratory failed to follow their written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing. Refer to D2007, D5209 and D5437. FINDINGS: The laboratory failed to identify and take actions to prevent reoccurrence for the following failures: a. follow the laboratory's API PT protocol b. follow their competency assessment policy c. maintain the Quality control program for hematology

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's review of hematology analyzer Sysmex XN-450 validation records, maintenance and service records and an interview with the general supervisor, the laboratory failed to perform the required six month calibration in 2019 and 2020. FINDINGS: The general supervisor confirmed on November 19, 2020 at approximately 12:00 PM, that the laboratory did not perform the required six month calibration after the new analyzer was validated on July 9, 2018. a. The laboratory's

	<p>calibration policy and the manufacturer policy for the Sysmex XN-450 hematology analyzer requires the analyzer to be calibrated every six months and/or as needed after preventative maintenance b. The validation records indicated the calibration was performed on July 9, 2018. The next calibration was due on January 9, 2019. c. The analyzer was therefore out of calibration from January 9, 2019 through this survey date. d. Approximately 2000 patient specimens were tested and reported for hematology during the time period when analyzer was out of calibration.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the: 1. Laboratory performed and followed their established PT policy, Refer to D6016 2. QA program was maintained for all phases of laboratory testing, Refer to 6021 3. Remedial action was taken and documented when the laboratory failed to follow their QC policy, Refer to D6024 3. The new testing personnel were evaluated at six month after completing their training, Refer to D6053 4. The testing personnel and the technical consultant were evaluated annually, Refer to D6054.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of 2019 and 2020 API PT attestation statements and confirmed in an interview with the general supervisor, the laboratory director failed to ensure that PT samples were tested in the same manner as patient samples are tested. Refer to D2007.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

	<p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's Quality Assessment (QA) policy and confirmed in an interview with the general supervisor, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5291</p>
<p>D6024</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of hematology analyzers validation records, lack of calibration records and confirmed in an interview with the general supervisor, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D5437.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the personnel records and confirmed in an interview with the general supervisor, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation during the calendar year 2019 for five of the five testing personnel during the first year of patient testing. Refer to D5209.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the personnel files and confirmed in an interview with the general supervisor, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for three of the five testing personnel and the technical consultant in calendar year 2020. Refer to D5209</p>