

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0939484	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Crystal Run Healthcare Physicians Llp	Street Address, City, State 2 Centerock Road, West Nyack, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration records and an interview with the laboratory supervisor, the laboratory failed to calibrate the hematology analyzer every six months in year 2017. Findings Include: It was confirmed with the laboratory supervisor on August 16, 2018 at approximately 12:15 pm that, 1. The Manufacturer requires that calibration be performed every six months; 2. Calibration was performed on February 15, 2017 and January 18, 2018; 3. Calibration was due August 15, 2017; 4. The Sysmex XP 300 was out of calibration from August 16, 2017 to January 18, 2018. Approximately 1015 patient specimens were tested and reported for hematology testing when calibration was not performed.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must</p>

have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on a lack of correlation records and an interview with the laboratory supervisor, the laboratory failed to have a system in place to monitor, evaluate and define twice a year the relationship between the Beckman Coulter AU 480 chemistry analyzer and the Abbott I Stat Point of Care testing instrument for chemistry from April 27, 2017 through the date of this survey. Approximately 1463 patient specimens were test and results were released during that time.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a review of calibration records and an interview with the laboratory supervisor, the laboratory director failed to ensure that the QC program was maintained for hematology testing. Refer to D5437

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on a lack of correlation records, and an interview with the laboratory supervisor, the laboratory director failed to ensure that the QA program for the chemistry testing was maintained to ensure quality laboratory services. Refer to: D5775