

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2094497	(X3) Date Survey Completed 10/28/2019
Name of Provider or Supplier Crystal Run Healthcare Physicians Llp	Street Address, City, State 807 Route 17m, Monroe, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of several patient reports, an interview and confirmed by the laboratory manager and supervisors, patient reports reviewed failed to include the name and address of the laboratory location where the test is performed. FINDINGS: The laboratory manager confirmed the following at approximately 11:30 AM on October 28, 2019: 1. This is a Physician Office Laboratory for a large number of offices at other locations. Patient specimens are dropped off at this location for testing, no patient specimens are collected at this site. 2. The address listed on patient reports is the address where specimens are collected, not the address where the testing is performed.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate</p>

results.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the one laboratory testing personnel's education record and an interview with the laboratory manager, the laboratory director failed to ensure that the one of sixteen laboratory testing personnel had the appropriate education prior to performing laboratory testing. FINDINGS: 1. The laboratory manager confirmed, on October 28, 2019 at approximately 10:30 PM, the surveyor's findings that one of sixteen laboratory testing personnel failed to have the appropriate educational records. 2. The laboratory testing person in question had only a copy of their New York State Education medical technology license, however, CLIA requirements are a high school graduation record for moderate complexity testing or an Associates Degree in a Science for high complexity laboratory testing personnel.