

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2079035	(X3) Date Survey Completed 01/03/2022
Name of Provider or Supplier Cancer Care Consultants	Street Address, City, State 3641 Ridge Rd, Suite 5, Highland, IN	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to establish maintenance protocol, and perform and document maintenance for one of one microscope (McKesson 6380 LED, Serial #G38L 20200791) used for manual white blood cell differentiation. Findings include: 1. On 01/03/2022 at 12:04 pm, a microscope (McKesson 6380 LED) was observed in the testing area. 2. On 01/03/2022 at 12:04 pm, upon request for maintenance logs for the microscope, SP1 indicated that no maintenance had been performed on the microscope since 12/2019. SP1 stated that this was the only microscope in the laboratory. 3. On 01/03/2022 at 12:27 pm, SP1 confirmed there was no written maintenance protocol for the microscope (McKesson 6380 LED). 4. The annual test volume for white blood cell manual differentiation is approximately four.</p>