

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233859	(X3) Date Survey Completed 10/02/2020
Name of Provider or Supplier Pro Lab, Llc	Street Address, City, State 10401teays Valley Road Ste 1b, Scott Depot, WV	
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
D0000	An announced, on-site CLIA recertification survey was conducted at Dunbar Medical Associates on 10/02/2020 by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the CLIA regulations under 42 CFR 493. Specific deficiencies are explained below.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports, laboratory PT records, and interview with the Laboratory Manager (LM), the laboratory failed to satisfactorily participate in PT for the specialty of Hematology. Findings: 1. Review of the API PT evaluation report that covers Hematology PT for events 2 and 3 of 2019 and event 1 of 2020 demonstrated the following unsatisfactory scores: a. 2019 event 2 i. 40% for MCV ii. 20% for Monocytes b. 2020 event 1 i. 60% for Granulocytes ii. 0% for Monocytes iii. 20% for Prothrombin Time iv. 60% for INR 2. Review of the laboratory's API records for event 2 of 2019 and event 1 for 2020 demonstrated an adequate investigation and corrective action for the PT failures. 3. During interview on 10/2/2020 at approximately 1:30pm, the LM described the causes of error in all unsatisfactory analytes and the corrective actions taken.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p>

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) Proficiency Testing (PT) evaluation reports, laboratory PT records, and interview with the Laboratory Manager (LM), the laboratory failed to successfully participate in PT for Monocytes in the specialty of Hematology. Findings: 1. Review of the API PT evaluation report that covers Hematology PT for events 2 and 3 of 2019 and event 1 of 2020 demonstrated the following unsuccessful participation: a. First unsuccessful (unsatisfactory scores in 2 of 3 consecutive testing events) participation for Monocytes i. 20% in 2019 event 2 ii. 0% in 2020 event 1 2. Review of the laboratory's API records for event 2 of 2019 and event 1 for 2020 demonstrated an adequate investigation and corrective action for the PT failures. 3. During interview on 10/2/2020 at approximately 1:30pm, the LM described the causes of error in testing and the corrective actions that were taken.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a tour of the laboratory, review of reagent package inserts, instrument owner's manuals, and laboratory records, and interview with the Laboratory Manager (LM), the laboratory failed to accurately monitor the (2) temperatures of the laboratory. Findings: 1. During a tour of the laboratory, a FisherBrand NIST Traceable thermometer was found to be monitoring the lab's room temperature and humidity. The thermometer had expired in May of 2020. a. A package insert for one of the reagents stored at room temperature, Coulter AcT diff Pak Reagent Kit, states to store the reagent between 2 and 30 degrees Celsius. 2. The Futura under-counter freezer, which is used for storage of calibrators and quality control materials, is monitored by a built-in thermometer that is not NIST traceable or calibrated. a. The owner's manual for the freezer states the following: "Please be sure you have a NIST traceable and calibrated thermometer." b. A package insert for one of the calibrators stored in the freezer, Anemia Cal, states that it must be stored between -25 and -15 degrees Celsius. 3. During an interview on 10/2/2020 at approximately 9:50am, the LM stated that she did not realize the room temperature thermometer had expired. 4. During an interview on 10/2/2020 at approximately 2:00pm, the LM stated that the Futura freezer temperature is monitored only by the built-in thermometer.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of past survey documents, personnel records, laboratory policies and procedures, and interview with the Laboratory Manager (LM), the laboratory director (LD) failed to specify in writing the the responsibilities and duties of each consultant. Findings: 1. A review of the CMS-2567 Statement of Deficiencies from the survey completed on 9/5/2018 found that this is a repeat deficiency. a. The laboratory director in place at the time of the last survey is no longer directing the laboratory. b. The laboratory manager in place at the time of the last survey is no longer overseeing this laboratory location. 2. During review of personnel records and the policy/procedure manuals, written job descriptions for the Laboratory Director and Testing Personnel were found. No written job descriptions for the Clinical Consultant or Technical Consultant were seen during the records review. 3. During interview on 10/2/2020 at approximately 1:45pm, the LM stated she was not sure if written job descriptions for the two consultant positions had been created after the last survey due to the change in laboratory staffing/leadership.