

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0879841	(X3) Date Survey Completed 12/21/2020
Name of Provider or Supplier Mitchell Berger Md Pllc	Street Address, City, State 1999 Marcus Avenue, Suite M14, New Hyde Park, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet inserts for the Siemens Multistix and interview with the laboratory director/testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the Siemens Multistix. FINDINGS: 1. The packet insert for the Siemens Multistix requires that external controls be performed with each new Vial of Multistix opened. On December 21, 2020 at approximately 10:00 AM the laboratory director/testing person confirmed surveyor's findings that documentation for the required external control testing was not available from 5/1/2018 through 12/18/2020. 2. Approximately 250 patients specimens were tested and reported for urinalysis during the above time frame. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON JUNE 9, 2014, ON AUGUST 4, 2016, AND ON MAY 14, 2018.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on the surveyor's review of Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) reports and an interview with the laboratory director/testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2019 third event: Platelets = 80% 2020 third event: Red Blood Cells (RBC) = 80% Hemoglobin (Hgb) = 80% Hematocrit (HCT) = 80%</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 a surveyor's findings and interview with the laboratory director/testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 6/9/2014, on 8/4/2016, and on May 14, 2018; 2. The QC program was maintained, refer to D6020. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON JUNE 9, 2014, ON AUGUST 4, 2016, AND ON MAY 14, 2018.</p>
<p>D6020</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 the quality control program is 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 records, and confirmed in an interview at the time of this survey with the laboratory director/testing person, the laboratory director failed to ensure that the laboratory's QC program was maintained to assure quality of laboratory services. Refer to: D1001 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON JUNE 9, 2014, ON AUGUST 4, 2016, AND ON MAY 14, 2018</p>