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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0879841 | (X3) Date Survey Completed 05/14/2018 |
| 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 Henry Schein Rapid Strep 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 and each new kit of Henry Schein Rapid Strep. FINDINGS: 1. The packet insert for the Siemens Multistix requires that external controls be performed with each new Vial of Multistix opened. On May 14, 2018 at approximately 10:30 AM the laboratory director/testing person confirmed surveyor's findings that documentation for the required external control testing was not available for calendar years 2016 and 2017. 2. The packet insert for the Henry Schein Rapid Strep requires that external positive and negative controls, included in each test kit, be performed for each kit prior to use for patient testing. Documentation for the required external control testing was not available for the Henry Schein Rapid Strep in calendar years 2016, 2017 and up to survey date. 3. Approximately 200 patients specimens were tested and reported for urinalysis and approximately 30 patients specimens were tested and reported for Rapid Strep during above time frame. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON JUNE 9, 2014 AND ON AUGUST 4, 2016.</p> |
| D6000 | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</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.

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 and on 8/4/2016; 2. The QC program was maintained, refer to D6020. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEYS CONDUCTED ON JUNE 9, 2014 AND ON AUGUST 4, 2016.

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 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 AND ON AUGUST 4, 2016.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a surveyor review of personnel records and confirmed in an interview with the laboratory director/testing person, the laboratory director failed to ensure that one of two testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a surveyor's review of personnel records and confirmed in an interview with the laboratory director/testing person at the time of the survey, the laboratory director failed to ensure that one of two testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.