

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0993642	(X3) Date Survey Completed 08/23/2018
Name of Provider or Supplier Samuel Cho Md Pc	Street Address, City, State 150-11 Northern Boulevard, Flushing, 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on an interview with the laboratory director on August 23, 2018 at approximately 11:30 am, the director stated, "the office is small and when I have difficulty reading slides in the office, I take it home to read." The laboratory director began reading slides at the Physician Office Laboratory in March 2017. Refer to 3009.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the laboratory director, the laboratory director failed to read the patient slides at the Physician Office Laboratory which holds the CLIA certificate located at 150-11 Northern Blvd, Flushing, NY. Findings Include: On</p>

	<p>August 23, 2018 at approximately 11:30 am, the director was asked if he takes the patient slides to his home located in Monmouth Beach, NJ to be read. The director stated, "the office is small and when I have difficulty reading slides in the office, I take it home to read." The laboratory director began this practice of patient testing at his home in March 2017 through the date of this survey.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of verification records and an interview with the laboratory director, the laboratory did not complete the twice annual verification for 2017. Findings Include: It was confirmed with the laboratory director on August 23, 2018 at approximately 11:15 am, the laboratory director failed to complete the twice annual verification of patient slides for 2017. The only verification performed was in November 2017. The director stated. "I began patient testing in March 2017 not January and did not need to do verification twice for 2017". Approximately 25,000 patient specimens were read and results released during that time.</p>
<p>D5433</p>	<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 a review of the laboratory procedure manual and an interview with the laboratory director, the laboratory failed to have a complete maintenance protocol or procedure for histopathology. Findings Include: On August 23, 2018, at approximately 11:15 AM, it was confirmed by the laboratory director that the laboratory failed to have a procedure available for service and maintenance of the laboratory Microscope to include the interval between service performance.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a surveyors review of the laboratory's records and an interview with the</p>

laboratory director/technical supervisor, the laboratory director failed to fulfill his/her responsibilities and provide overall management of the laboratory and assure compliance with all CLIA regulations and standards. Refer to D6079, D6094

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a conversation and admission by Laboratory Director, the laboratory director approved taking slides out of the Physician Office laboratory to read at home. The Director's home office does not have a CLIA certificate.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review of procedures and confirmed in an interview with the laboratory director, the director failed to have a procedure for the microscope maintenance and schedule and to perform twice annual verification in 2017. Refer to: D5217 and D5433