

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2152829	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Cristina Matera Md Pc	Street Address, City, State 50 East 77th Street, New York, 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 a phone conversation with the laboratory director and a Proficiency Test (PT) desk review, the laboratory failed to obtain a CLIA certificate for the new laboratory that continued testing patient specimens and performing PT when the director of the facility took the CLIA number with her to a new location. Refer to D3009</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 a phone conversation with the laboratory director and a PT desk review, the laboratory was found to be testing patient specimens without a valid CLIA certificate</p>

from October 25, 2017 until August 17, 2018. Finds Include: 1) During a PT desk audit it was discovered that the CLIA # for Madison Women's Health and Fertility had moved to a new location along with a laboratory name change. 2) the director of that laboratory confirmed on August 13, 2018 at approximately 10:30 am, that the endocrinology analyzer had remained at the old address with the partner of the director. Testing and PT continued at the old office and that office failed to have a CLIA number. 3) On August 13, 2018 at approximately 1:30 pm, it was confirmed with the clinical consultant (the director's partner at the former Madison Women's Health and Fertility laboratory), that the clinical consultant continued to perform patient testing and PT and failed to apply for a CLIA certificate.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

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 did not have a procedure for determining the presence or absence of sperm . Finding: It was confirmed with the laboratory director on September 27, 2018 at approximately 1:15 pm, that the laboratory director failed to have a complete procedure for the microscopic reading of sperm viability (presence or absence).

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedure records and confirmed by the laboratory director in an interview on September 27, 2018 at approximately 1:15 PM, the laboratory director failed to ensure that the QA program for sperm viability testing was maintained to ensure quality laboratory services. Refer to D5403

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 review of personnel records and an interview with the laboratory director, the laboratory director failed to ensure that documentation of education was available at the time of the survey for 1 of 2 testing personnel. 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 review of personnel records and an interview with the laboratory director, the laboratory did not have documentation of education available for review for one of two testing personnel. Finding Include: It was confirmed by the laboratory director on September 27, 2018, at approximately 12:45 pm 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.