Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2174052	02/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Anti-Aging Clinic For Men	117 Fountains Blvd, Suite 3, Madison, MS	

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
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 review of laboratory temperature records since the IP Fast Pack Qualigen System installation and confirmation with laboratory staff at 11:30 am on the day of survey, 2/26/20, the laboratory failed to monitor and document the room and humidity temperatures of the laboratory room where the Qualigen analyzer was stored and testosterone testing performed. Findings include: 1. Observation of the laboratory where testosterone testing was performed revealed no room thermometer to monitor the temperature for optimal performance of the IP Fast Pack Qualigen analyzer. 2. Laboratory temperature records (room and humidity) available for review were documented from monitoring the thermostat in another room. 3. IP Fast Pack Qualigen manufacturer's instructions require a room temperature of 15 - 32 degrees Celsius and a relative room humidity of 10 - 80%. The instructions read "Record the temperature and humidity of the lab area on a daily basis and write values in the daily environment log." 4. Interview with the laboratory staff at 11:30 am on the day of survey confirmed the room temperature being monitored was from the thermostat on the wall down the hall and not in the laboratory room where testosterone testing was performed on the Qualigen analyzer.
D5481	CONTROL PROCEDURES

	CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the IP Fast Pack Qualigen analyzer from 12/16/19 through 2/24/20, the manufacturer's QC assay range sheet, and the patient result log, the laboratory failed to ensure that QC results met the manufacturer's acceptable range before reporting patient results. Findings Include: 1. Review of the QC records from 12/16/19 through 2/24/20 revealed on 3 days, 1 of 2 levels of QC was outside of acceptable range: a. 12/18/19 - Control 1 (C1) result was 341 mg/dl, acceptable range was 140-340 mg/dl b. 1/8/20- C1 result - 349 mg/dl, acceptable range was 140-340 mg/dl c. 1/15/20- C1 result - 362 mg/dl, acceptable range was 140-340 mg/dl 2. According to staff and patient records, only 3 patients have had testosterone testing performed since installation on 12/5/19 and 2 of the 3 patients were performed on 12/18/19 when QC was out of the acceptable range specified by the QC assay range sheet.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 Personnel form, lack of qualifying documentation for a technical consultant available on the day of survey, and confirmation by clinic staff at 12:30 pm on the day of survey, 2/26/20, the laboratory did not have a designated technical consultant who qualified in accordance with 493.1411 of this subpart that would provide technical oversight, in accordance with paragraph 493.1413 of this subpart from the initial application with CLIA, 10/17/19 through 2/26/20.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of personnel records on the initial survey, the CMS 209 personnel form, and lack of qualifying documentation available for review for the technical consultant designated on the day of survey, the laboratory did not have an individual

	who meets the qualification requirements of 493. 1411 of this subpart from the initial application with CLIA, 10/17/19 through 2/26//20. The technical consultant must-- Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located; AND Be certified in anatomic or clinical pathology, or both, by the America Board of Pathology or the America Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; OR Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service of which the technical consultant is responsible; OR Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; AND Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; OR Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; AND Have at least two years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.