Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2167179	12/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Radjabi Medical Pc	240 Central Park South - Suite 1p, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on a lack of laboratory quality control (QC) records and an interview with the laboratory testing person, the laboratory failed to test QC material for the Siemen' 10 SG Urine reagent strip. Findings Include: It was confirmed by the laboratory testing person on December 12, 2019, at approximately 12:30 PM that the laboratory failed to follow the manufacturer's instruction for the Siemens 10 SG Urine reagent strips which state QC material is to be performed when a new bottle is opened. Approximately 660 patient tests were performed for urinalysis and results reported during that time.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory testing person, the laboratory failed to have a complete procedure manual for all testing. Findings Include: It was confirmed with the laboratory testing person on December 12, 2019, at approximately 10:45 am that the laboratory failed to have the following procedures: 1) QC criteria to include - number/level of controls tested, frequency of control testing, acceptability of controls; 2) Verification of new controls; 3) Calibration and calibration verification procedures (frequency); 4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of sperm count QC and patient records and confirmed in an interview with the laboratory testing person, the laboratory failed to follow the Accu-beads manufacturer directions. Finding Include: 1. It was confirmed on December 12, 2019 at approximately12:30 PM, that the laboratory began sperm count testing in November 2019. 2. QC records were reviewed and it was not possible to tell if QC was performed in duplicate. The laboratory documents the "Average only". 3. The Accu-beads package insert states, " Record all results". 4. Approximately 5 patient samples were tested and reported for sperm count testing from November 2019 through the date of this survey.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) 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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a

	doctor of medicine, a 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 (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and interview with the laboratory testing person, and review of the CMS 209 Personnel Form, it was determined that the laboratory did not have a qualified high complexity Laboratory Director (LD). Findings Include: On December 12, 2019, at approximately 11:00 AM the laboratory testing person confirmed that the laboratory began performing sperm count, morphology and motility testing in November 2019, which is a high complexity test. The individual listed on the CMS 209 Personnel Form as the LD failed to meet the qualifications have training/ experience required to be qualified as the LD of a high complexity laboratory.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 in a review of QC procedures, records and confirmed in an interview with the laboraory testing person on December 12, 2019 at approximately 12:45 pm the laboratory director failed to ensure that the QC program for sperm count (hematology) testing was maintained to assure quality laboratory services. Refer to: D5543
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 quality control (QA) procedures and an interview with the laboratory testing person, the director failed to ensure that the laboratory's QA program for the laboratory was maintained for all phases of laboratory testing. Refer to: D1001 and D5403