Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0908280	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Robert A Norman Do Pa	10820 Sheldon Rd, Tampa, FL	

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
D0000	An announced CLIA recertification survey was conducted at Robert A Norman DO PA on 07/02/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6076 - 42 C.F.R. 493.1441: Laboratories performing high complexity testing; laboratory director
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with Dermatopathologist, the laboratory failed to have a written preanalytic quality assessment policy. Findings include: Review of the procedure manual revealed no preanalytic quality assessment procedure was present to monitor, assess, and correct problems identified with preanalytic systems. Interview on 07/02/19 at 12:15 PM with the Dermatopathologist revealed she did now know the laboratory was without a preanalytic quality assessment procedure and confirmed that quality assessment procedures were not being documented.
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 review of laboratory procedures and interview with the Dermatopathologist, the laboratory did not have written procedures for Acid-Fast Bacilli (AFB) stain and Periodic acid-Schiff (PAS) stain. Findings included: A review of the procedure manual showed the laboratory did not have a written procedure in place for AFB and PAS stains. On 07/02/19 at 12:45 p.m., the Dermatopathologist confirmed the laboratory performed AFB and PAS stains and could not provide a written procedure for these stains.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to have an acting Laboratory Director. Refer to D6078.
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 record review and interview with the office staff, the laboratory failed to have a Laboratory Director since the last recertification survey conducted 07/12/2017. Findings Included: Review of the policy and procedure manual revealed the "Yearly Staff Procedure Manual Sign Off Sheet" was signed and dated by a Laboratory Director on 01/09/2017. Review of the quality control and maintenance records from July 2017 through 07/02/2019 revealed no evidence that a Laboratory Director had reviewed these documents. Review of the previous CMS 209, Laboratory Personnel Report, and CMS 116, Application for CLIA Certification, signed and dated on 07/11 /17 revealed Staff C, Medical Doctor (MD), served as the Laboratory Director. Interview on 07/02/2019 at 10:00 AM with the Office Manager revealed the former Laboratory Director, Staff C, had left the provider and no notification of a change in Laboratory Director was ever made.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to implement a program that monitors the competency of the laboratory staff performing the preanalytic systems Histopathology slide preparation for two of two years reviewed (2017-2019). Findings included: Record review of the procedure manual, quality control logs, and maintenance records revealed no evidence of a Laboratory Director since the last recertification survey conducted 07/12/17. Record review of the policy and procedure manual revealed that the facility was unable to provide documentation that showed a personnel competency program was in place since July of 2017. Interview on 07/02/19 at 12:15 PM with the Dermatopathologist confirmed that the laboratory failed to have a personnel competency program in place. During

	the 07/02/19, recertification survey, the Dermatopathologist was appointed to the position of Laboratory Director as evidenced by a letter signed by the owner of the laboratory on 07/02/19.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Dermatopathologist, the laboratory failed to have a Technical Supervisor review the quality control slides for hematoxylin and eosin (H&E) stain and for special stains which included Acid-Fast Bacilli (AFB) and Periodic acid-Schiff (PAS) from July 2017 to 07/02/19, the date of survey. Findings included: Review of the Quality Control logs from July 2017 to 07/02/19 revealed the log for H & E Quality Assurance was not being signed by a Technical Supervisor and Quality Control logs were not present for AFB and PAS. Interview on 07/02/2019 at 12:15 PM with the Dermatopathologist revealed quality control for H&E had been performed and documented by a histologist or histotechnician, and quality control for AFB and PAS had not been performed and documented.