Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0976961	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
University Of Miami Pathology Specialty Services	1400 Nw 12th Ave, Miami, 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 unannounced complaint survey, #2019004080, was conducted on 5/20-22/2019 at University of Miami Pathology Specialty Services. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D5400-Analytic Systems-493.1250 D6076-Laboratory Director--493.1411
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of College of American Pathologists (CAP) proficiency testing records and interview with the General Supervisor(GS), the laboratory director failed to sign the attestation of 1 out of 6 events reviewed for Immunohistochemistry PM2. Findings included: Review of the CAP proficiency testing records for 2017 and 2018 revealed, the laboratory director failed to sign the attestation for the 2nd event of PM2-B Immunohistochemistry TMA of 2018. During an interview on 05/21/2019 at 2:30 PM, the GS confirmed that the laboratory failed to sign the attestation of reference.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on observation and interview with the Laboratory Director and Cytotech #A,

	the laboratory failed to have sufficient equipment, instruments, reagents, materials, and supplies for testing performed at the laboratory for Cytology testing. Findings Included: There are 2 laboratories located at the same physical address, this laboratory and another Certificate of Accreditation laboratory (to be referred to as Lab A). During a tour of the cytology laboratory on 05/22/19 at 4:15 PM, it was observed instruments were not labled for which the laboratory is was being used or hours of operation of each laboratory. The supplies, reagents, materials were not labled for a specific laboratory nor where they separated. Interview with the Laboratory Director and Cytotech #A on 05/22/19 at 4:15 PM confirmed, the two labs (2 different CLIA numbers) did not separate specimens, reagents, supplies, instruments, or equipment. It was also confirmed that patient testing was performed together (grouped together with their own laboratory and ran together) then separated afterwards. There was no separation made for testing at this laboratory or Lab A testing either through physical separation or scheduling.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on Occupational Safety and Health Administration (OSHA) regulation for Nitrogen storage, observation and interview with Building Safety Manager (BSM), the laboratory failed to have an Oxygen sensor in the Liquid Nitrogen Storage Area for an undetermined amount of time. Findings included: Review of the OSHA procedure for Nitrogen storage revealed, it is a requirement that for any indoor Nitrogen storage to have a Oxygen level sensor. Observation of the laboratory revealed that: The laboratory has 2 large Nitrogen Tanks in a shared area with another laboratory. There was no sensor for Oxygen level detection available. During an interview on 05/21/2019 at 3:30 PM, the BSM confirmed, there was no Oxygen level sensors available.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to document room temperature and humidity (See D5413) and did not follow quality assurance (QA) policy (See D5791).
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 record review and interview with the general supervisor (GS), the laboratory failed to document the room humidity for 2 out of 2 years (2017-2019) reviewed. Findings included: Review of the cryostat manual Leica CM1850 indicated a requirement for room temperature not greater than 35 Celsius and humidity not above 60 %. The quality control records of the renal room revealed, there was no documentation of the room temperature and humidity during 2017-2019. During an interview on 05/21/19 at 2:00 pm., the GS confirmed that there was no record of room temperature and humidity for the years of reference.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) policy and interview with the Laboratory Director (LD), the laboratory failed to follow the QA policy for 2 out of 2 years (2017-2019) reviewed. Findings Included: The review of the Intradepartmental Quality Assurance policy (VN 01/21/10) stated: Daily Surgical Pathology Staff Conference on interesting, unusual and difficult cases, with logbook control of the cases reviewed. The assigned pathologist brings the case to the conference before signing them out for review/opinion/diagnosis by the staff pathologists of the Department, that a log is kept which details the date, specimen, accession number, organ, and attendees and the review is noted in the respective pathology reports. Review of the laboratory records revealed, the log of reference was not kept during 2017-2019. During an interview on 05/22/19 at 3:30 PM, the LD confirmed that there was no log of the intradepartmental activity for the years of reference.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on the review of patient reports and interview with Laboratory Director (LD), the laboratory failed to include the correct laboratory name and address on 3 out of 3 patient reports. Findings included: Patient reports dated US19-5880, US19-6312, and US19-6808 were reviewed. The 3 Patient final reports did not have the Laboratory Name that is on their CLIA certification and did not have the correct address of where the testing was conducted. During an interview on 05/22/19 at 5:30 PM., the Laboratory Director confirmed that the final report did not include the correct laboratory name and address.
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 staff interview, the Laboratory Director failed to have oversight of the laboratory (see D6079), failed to ensure quality assurance (See D6094) and failed to ensure Residents had competency evaluations (See D6103)
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 observation, record review, and staff interview, the Laboratory Director failed to have oversight of the laboratory since October 2018 (See D5400).
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 the review of the quality assurance (QA) policy and interview with the Laboratory Director (LD), the LD failed to ensure the QA policy was followed for 2 out of 2 years (2017-2019) reviewed. Findings Included: The review of the Intradepartmental Quality Assurance policy (VN 01/21/10) stated: Daily Surgical Pathology Staff Conference on interesting, unusual and difficult cases, with logbook control of the cases reviewed. The assigned pathologist brings the case to the conference before signing them out for review/opinion/diagnosis by the staff pathologists of the Department, that a log is kept which details the date, specimen, accession number, organ, and attendees and the review is noted in the respective pathology reports. Review of laboratory records revealed, the log of reference was not kept during 2017-2019. During an interview on 05/22/19 at 3:30 PM, the LD confirmed that there was no log of the intradepartmental activity for the years of reference.
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 interview with Pathologist #C, the Laboratory Director failed to ensure competency evaluations were performed on 20 out of 20 residents who performed grossing of histology specimens for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of the employee records of the 20 residents (R#A-R#T) who perform grossing of histology specimens, revealed no six part competency evaluations. Interview on 05/22/19 at 4:00 PM Pathologist #C confirmed, the Laboratory Director did not perform a six part competency evaluation on the Residents who performed grossing.