Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0280714	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
University Of Miami Hospitals And Clinics	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, #2019004076, was conducted on 5/20-22/19 at University of Miami Hospital and Clinics. 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 493.1441
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 B). During a tour of the cytology laboratory on 05/22/19 at 4:15 PM, it was observed instruments not labled for which the laboratory was being used or hours of operation of each laboratory. The supplies, reagents, and materials were not labled for a specific laboratory nor were 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 B 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 the 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 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 that no Oxygen level sensors were available.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Histology Supervisor, the laboratory failed to complete the annual competency for 1 (#D) out of 6 IHC (immunohistochemical) testing personnel for 1 (2019) out of 2 years (2017-2019) reviewed. Findings Included: Review of the annual competency evaluations revealed, Testing Personnel had competency performed on 02/23/17 and 02/23/18. The competency for 02/21/19 was not signed by the Supervisor. Interview on 05/21/19 at 10:00 AM, the Histology Supervisor confirmed that the signature of the supervisor was missing.
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 have the Laboratory Director sign the policies and procedures (See D5407), failed to document room temperature and humidity (See D5413), failed to label a container on cryostat (See D5415), failed to document stain quality (See DD5601), and did not follow the quality assurance policy (See D5791).

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of policy and procedures and interviews with the Laboratory Director (LD), the LD failed to sign all of the Tumor Board Interdepartmental Policy since adopted 01/07/19. Findings include: Review of the Policies and procedures revealed that the current Laboratory Director did not sign the "Tumor Board Interdepartmental Policy" that was adopted 01/07/19. Interview on 5/22/19 at 9:00 AM the Laboratory Director confirmed that she did not sign all the policies.
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 Histology Supervisor, the laboratory failed to document the temperature and humidity of the room where testing was performed for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of the manufacturers instructions for the cryostat state the operating conditions must be 5-35 degrees Celsius and at a maximum humidity of 60%. Review of the temperature logs revealed no room temperature or humidity recorded. Interview on 05/20/19 at 11:00 AM the Histology Supervisor confirmed, the room temperature and humidity had not been recorded in the room where the cryostat was being used.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations and interview with the Histology Supervisor, the laboratory had an unlabeled container on top of 3 cryostats for an undetermined amount of time. Findings Included: During a tour of the laboratory on 05/20/19 at 11:15 AM it was

	observed an unlabeled container sitting on each of the 3 cryostats. Interview on 05/20 /19 at 11:15 AM the Histology Supervisor confirmed, the container contained rapid fix and was supposed to be changed every morning, however there was no label.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with the Histology Supervisor, the laboratory failed to document the stain quality of the Hematoxylin and Eosin stained slide for 4 out of 4 months (March 2019, October 2018, April 2018, and December 2017) reviewed. Findings Included: Review of the Quality Control (QC) logs for March 2019, October 2018, April 2018, and December 2017 revealed, the QC slide was not identified each day of patient testing and the Pathologist who reviewed the slide for stain quality was not documented. Interview on 05/22/19 at 9:00 AM, the Histology Supervisor confirmed that the first case of the day was used for the stain quality check and the slide was not indicated on the QC report nor did the Pathologist reviewing the slides sign off that the stain quality was acceptable.
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 the 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 the patient reports and interview with Laboratory Director (LD), the laboratory failed to include the correct laboratory name and address on 5 out of 5 patient reports. Findings included: Patient reports dated 11/24/17, 04/11/18, 10/10 /18, 02/22/19, and 03/26/19 were reviewed. The five 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 4:00 p.m., 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) and failed to have separation of the Laboratory with another laboratory (See D3007).

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 the laboratory records revealed that 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 the 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.