Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657006	03/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Upmc Dermatopathology Lab	Medical Arts Bldg Dept Of Dermatology, Pittsburgh, PA	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD), the laboratory failed to document proficiency testing evaluation and verification activities provided by The American Society of Dermatopathology for 3 of 4 Testing Personnel (TP) performing Histopatholgy slide examinations from 08/07/2018 to the day of survey. Findings Include: 1. On the day of survey, 03/17/2021 the laboratory could not provide documentation of proficiency testing evaluation and verification activities for 3 of 4 TP (#2, #3, and #4) performing The American Society of Dermatopathology proficiency testing for Histopatholgy slide reading in 2018, 2019 and 2020. 2. The LD confirmed the findings above on 3/17/2021 at 10:20 a.m.
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 observation of the laboratory and interview with Laboratory Director (LD), the laboratory failed to ensure 23 of 23 gallon bottles of ethyl alcohol 190 proof ACS

	/USP grade were labeled to indicate their received and expiration dates at the day of survey. Findings Include: 1. On the day of survey, 03/17/2021, observations of the laboratory revealed, the laboratory did not label the received and expiration dates on 23 of 23 gallon bottle of ethyl alcohol 190 proof ACS/USP grade lot#020Kl200200E190KG01. 2. The LD confirmed the finding above on 3/17/2021 at 11:10 a.m.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with Testing Personnel (TP) #5, the laboratory failed to calibrate 1 of 1 room temperature thermometer and 1 of 1 unlabeled refrigerator thermometer from 2018 to the day of survey. Findings include: 1. On the day of survey, 03/17/2021, while touring the laboratory the surveyors observed the following thermometers were due for calibration: - 1 of 1 Fisher Scientific Traceables room temperature thermometer was due for calibration on August 05, 2018. - 1 of 1 unlabeled refrigerator thermometer was due for calibration on December 9, 2012. 2. TP #5 confirmed the findings above on 03/17/2021 at 10:58 am
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 review of UPP Dermatopathology criteria for Pass/failed of special stains procedure, review of stain quality control (QC) records, and interview with the Laboratory Director (LD), the laboratory failed to document QC for Histology stain examinations performed from 2020 through the day of survey. Findings include: 1. The UPP Dermatopathology criteria for Pass/failed of special stains procedure states, "The technician, daily will fill our and assigned a grade of 3 for pass, 2 for pass with comments or 1 for stain failure". "The responsible pathologist will review each positive control slide individually. The Pathologist will accept the graded sheet as is and will sign the Quality assurance (QA) form to document that they have personally checked each slide and agree with the technicians' assessment". 2. On the day of survey, 03/17/2021, a sampling of Histology QC records revealed, testing personnel failed to document the graded QC for the Histology stains for the following stains: - 12 /11/2020: Graccot (GMS), GRAM and Periodice Acid Shiff (PAS) - 02/24/2020 : SOX-10, K167 3. The pathologists did not sign QC records for special stains for the following dates: - 06/10/2020 - 06/15/2020 - 07/22/2020 - 09/14/2020 - 10/30/2020 -

	12/08/2020 - 12/11/2020 - 12/14/2020 - 12/18/2020 - 12/21/2020 - 12/24/2020 4. The LD confirmed the findings above on 03/17/2021 at 10:46 a.m.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of temperature logs and interview with Laboratory director (LD), the laboratory failed to document all corrective actions taken when room temperature ranges were unacceptable for 11 of 355 days in 2020. Findings include: 1. On the temperature log sheets, the acceptable room temperature range is 68 -77 Fahrenheit (F). 2. On the day of survey, 03/17/2021 review of room temperature logs revealed, the following dates were out of range: - 06/24/2020: temperature - 67 F. - 06/29/2020: temperature - 64 F. - 07/10/2020: temperature - 67 F. - 07/13/2020: temperature - 66 F. - 07/14/2020: temperature - 66 F. - 07/17/2020: temperature - 67 F. - 09/03/2020: temperature - 67 F. - 09/04/2020: temperature - 67 F. - 11/10/2020: temperature - 67 F. - 11/20/2020: temperature - 67 F. 3. The laboratory was unable to provided corrective action documentation for the temperatures out of range. 4. The LD confirmed the findings above on 03/17/2021 at 11:10 a.m.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Laboratory Director (LD), the laboratory director failed to delegate Technical Supervisor (TS) duties for 2 of 8 Testing Personnel (TP) performing supervisory responsibilities from 08/07/2018 to the day of survey. Findings include: 1. On the Laboratory personnel Report from, (CMS 209), testing personnel #5 and #6 were not listed as a TS. 2. On the day of survey, 03/17/2021, review of laboratory records revealed, TP#5 and #6 performed the following roles as a TS from 08/07/2018 to 03/17/2021: - Signed testing personnel competency assessment records for 4 of 8 TP. -Reviewed maintenance documents. 3. The LD confirmed finding above on 03/17/2021 around 09:45 a.m.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education

	appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, personnel competency assessment records, and interview with Laboratory Director (LD), the Technical Supervisor (TS) failed to ensure the competency of 3 of 4 testing personnel (TP) performing dermatopathology slide reading and 1 of 5 TP performing inking and grossing examinations were assessed for competency in 2018, 2019, and 2020. Findings Include: 1. On the day of survey, 03/17/2021, the LD could not provide documentation of competency assessments performed for 3 of 4 TP who examined dermatopathology slides and 1 of 5 TP who performed inking and grossing examinations in 2018, 2019, and 2020. 2. The LD confirmed the findings above on 03 /17/2021 around 09:55 am.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Testing Persinnel #5, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 9) is qualified. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At

least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on record review and interview with Testing Personnel (TP) #5, the laboratory failed to provide the appropriate educational credentials for 2 of 9 TP who performed inking and grossing of tissue specimens from 08/07/2018 to the date of survey. Findings Include: 1. On the day of survey, 03/17/2021, the laboratory was unable to provide appropriate educational credentials for 2 of 9 TP (TP# 6 and TP#9) who performed inking and grossing of tissue specimens from 08/07/2018 to the day of survey. 2. TP#5 was given until 03/25/2021 to provide the appropriate educational records. 3. TP#5 was contacted on 03/26/2021, in regards to not receiving the appropriate educational records for TP#6 and TP#9, and was given until 12:00 p.m. to retrieve the documents. 4. TP#5 was unable to provide the appropriate educational records for TP#6 and TP#9 on 03/26/2021 at 12:00 pm.