Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2032689	01/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners	5026 Tennyson Parkway, Plano, TX	

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 investigation of complaint TX00328642 and a recertification survey was conducted on site. An entrance conference was held 01/07/2020 with the laboratory assistant. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 01/07/2020, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1441 Laboratory Director High Complexity 493.1487 Testing Personnel High Complexity Complaint TX00328642 was substantiated. An exit conference was held on 01/07/2020 with the laboratory assistant. The exit conference attendee was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: This STANDARD was not met as evidenced by: Based on review of laboratory records and interview the laboratory failed to verify the accuracy of Dermatologic pathology and Mohs micrographic analyses twice annually to ensure accurate and reliable results in 2018 and 2019. The findings were: 1) Based on review of the laboratory's Proficiency QA records the last peer review assessment for accuracy in Dermatology pathology analysis was performed on 12/4/2017. The last peer review assessment for accuracy in Mohs surgery analysis was performed on 1/15/2017. 2) Proficiency QA records for 2018 and 2019 were requested at 1052 hours 1/7/2020. 3) Based on interview with the laboratory assistant at 1320 hours the proficiencies (peer reviews) were unable to be found.

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 review of patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in preanalytic systems. Findings included: 1. Random review of patient test requisitions with their corresponding patient test reports were requested and included the following: Patient #CS17-08115; collected 11/07/2017; received 11/07/2017; report date 11/08/2017 included documented grossing results without initials of the person who performed the grossing. Patient #CS17-08111; collected 11/07/2017; received 11/07/2017; report date 11/08/2017 included documented grossing results without initials of the person who performed the grossing. The grossing results did not include initials of the testing person or of Testing Person -2 (TP-2), who was the only testing person that qualified to perform grossing. During an interview on 01/07/2020 at 4:20 pm, the laboratory assistants were asked who documented the above grossing results, one of the laboratory assistants stated, he may have written the grossing results from a previous requisition and the one documented on was the corrected requisition. He stated the previous requisitions may have been submitted with errors such as the "wrong site" (of the specimen) and that requisition with errors was shredded. He reviewed and confirmed it was his handwriting for the above documented grossing results (Patients CS17-08115 and CS17-08111). 2. During an interview on 01/07/2020 at 4:20 pm, the laboratory assistants were asked for documentation of corrective action for the above test requisitions submitted with errors, documentation could not be provided. The laboratory did not establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in preanalytic systems.
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:
I. Based direct observation, review of the laboratory's procedure, quality control documentation, patient test reports and in interview with staff, the laboratory failed to implement a policy/procedure that was consistent with their current Periodic acid-Schiff (PAS) stain practice. Findings included: 1. On 01/07/2020 at 2:15 pm, the laboratory assistant provided their PAS procedure and it stated, "This procedure is available in kit form from: Poly Scientific R&D Corp. 70 Cleveland Avenue Bay Shore, NY 11706 (631) 586-0400 cat#k047. PERIODIC ACID SCHIFF REACTION: ...SOLUTIONS: 1. Schiff Reagent cat# s272 2. Periodic Acid 0.5% Aqueous cat# s1860 3. Acid Alcohol 0.5% cat# s103B 4. Harris Hematoxylin cat# s212 5. Bluing Solution 1% Lithium Carbonate cat# s127. STAINING PROCEDURE: 1. Deparaffinize and hydrate water. 2. Periodic Acid 0.5% Solution for 5 minutes. 3. Rinse in 4 changes of distilled water. 4. Schiff Reagent for 15 minutes. 5. Wash well in water for 10 minutes. 6. Harris Hematoxylin for 5 minutes. 7. Wash well in water. 8. Quick dip in Acid Alcohol 0.5%. 9. Wash well in water. 10. Saturated Lithium Carbonate - 2 dips. 11. Wash 5 minutes in water. 12. Dehydrate in 95% Alcohol, Absolute, and clear in Xylene, two changes each. 13. Mount with Poly Mount (cat# 2153) or any other acceptable mounting medium." Note: this procedure was in a binder with documents of PAS stain quality control from 2014. 2. During a tour of the laboratory on 01/07/2020 at 2:34 pm, the following was observed: Stain holder from left to right had containers with labels: Xylene, Xylene, 100% alcohol, 100% alcohol, Periodic Acid (no container at time of observation), DI H2O, DI H2O, Schiff's, Light Green, 100% alcohol, 100% alcohol, and Xylene. In small refrigerator beneath the PAS station counter included: 1 pint of American MasterTech Scientific Light Green (lot #083766, expiration date 08/01/2020), 100 ML of StatLab Schiff's Reagent (Lot #091546, expiration 12/31/2020), 500 ML Periodic Acid 1% (Lot #089616, expiration date 04/30/2021). The laboratory's written procedure was not consistent with the reagents used and the PAS stain practice. The laboratory had not implemented a current written PAS stain procedure, as required. 3. Review of a random sampling of patient test records for PAS stain use included Patient #DA19-19009 (collected 12/20 /2019; received 12/23/2019; reported 12/31/2019; "A PAS stain is negative for fungal organisms"). 4. During an interview on 01/07/2020 at 2:35 pm, the laboratory assistant stated the PAS stain had been brought back about 2 to 3 months ago. The PAS stain was a stain they had used in the past, stopped using and brought it back recently. The laboratory had not implemented a written PAS stain to align with their current practices and current reagents. II. Based on review of laboratory's procedure manual, manufacturer's instructions, environmental/equipment logs, and in interview with staff, the laboratory failed to ensure their written procedures were consistent with their logs defined temperature/humidity ranges. Findings included: 1. Review of the laboratory's procedure manual included a "Title: Instrument and Equipment Maintenance and Schedules/Uses and QC" that stated, "III. Flotation Baths: b. Water bath temperatures are monitored daily for tolerance limits and recorded on the water bath functions verification log. Range is 45C - 50C....V. Embedding Center: Dispenser and Cold Plate: ...Cold Plate range is -6 to -14 degrees Celsius. Paraffin holding tank 58-68 degrees Celsius." Review of the laboratory's procedure manual included a "Title: Temperature and Humidity Monitoring for Histology" that stated, "Ranges: Refer to the ranges listed on the quality control log sheets. Laboratory temperature: range 20-28C or 68-82F; Laboratory humidity: range 15-65%." 2. Random review of "Microtome/Water bath QC chart's" for 01/2019 and 02/2019 included water bath defined temperature range of 42C-48C. Random review of

	"Embedding Chart's" for 01/2019 and 02/2019 included cold plate defined temperature of -4C - 10C and paraffin holding tank defined temperature of 56C-68C. Random review of environmental logs from 11/2018, 01/2019, 02/2019, 10/2019, 11 /2019, and 12/2019 included defined humidity range of 15-60%. The humidity range was not consistent with manufacturer's instructions for equipment used for histopathology procedures. Refer to D5413. Random review of environmental logs from 11/2018, 01/2019, 02/2019, 10/2019, 11/2019, and 12/2019 included defined temperature range of 68-73F. The laboratory did not ensure their written procedures were consistent with temperature/humidity ranges used for day-to-day acceptability. 3. During an interview on 01/07/2020 at 4:30 pm, the laboratory assistant reviewed and confirmed the above findings.
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: I. Based on direct observation, review of manufacturer's instructions, and in interview with staff, the laboratory failed to ensure proper storage of Light Green Counterstain for PAS (Periodic acid-Schiff) stain. Findings included: 1. During a tour of the laboratory on 01/07/2020 at 11:30 am, the following was observed to be stored in the refrigerator at 4.1 degrees Celsius (C): American Master Tech Scientific Light Green Counterstain, Lot #083766, expiration 08/01/2020 (1 pint); received 12/15/19. 2. Review of American Master Tech Scientific Light Green Counterstain Safety Data Sheet stated, "Section 7. Handling and Storage: Store at 15-30C." The laboratory did not ensure the American Master Tech Scientific Light Green Counterstain was stored in manufacturer's required conditions of 15-30C. 3. During an exit interview on 01/07 /2020 at 4:30 pm, the laboratory assistant reviewed and confirmed the above findings. II. Based on review of manufacturer's instructions, environmental logs, and in interview with staff, the laboratory failed to ensure their defined humidity range was consistent with manufacturer's requirements for histopathology equipment for 3 of 3 months in 2018 (09/2018, 10/2018, 11/2018) and 5 of 5 months in 2019 (01/2019, 02 /2019, 10/2019, 11/2019, 12/2019). Findings included: 1. Review of Tissue-Tek VIP 6 AI Vacuum Infiltration Processor operator's manual (page 11) stated, "1.8 Specifications...Environmental Requirements: Relative Humidity 30-85% (non-condensing)." Review of Tissue-Tek DRS 2000 Automatic Slide Stainer operator's manual (page 2.1) stated, "Environmental Factors: The ambient operating humidity range is between 30% to 85% relative humidity." 2. Review of a random sampling of environmental logs from 09/2018, 10/2018, 11/2018, 01/2019, 02/2019, 10/2019, 11 /2019, and 12/2019 included "Lab Humidity (15-60%)." The laboratory did not ensure their defined humidity range was consistent with the manufacturers lower end of the range (30-85%). 3. Review of a random sampling of environmental logs from 11 /2018, 01/2019, 02/2019, 10/2019, 11/2019, and 12/2019 revealed 97 of 125 documented days the humidity was not within manufacturer's minimum requirements (30-85%), the following is a random sample of days: 11/15/2018: 29% 11/23/2018:

	29% 01/14/2019: 25% 01/15/2019: 23% 01/16/2019: 23% 01/17/2019: 21% 01/18 /2019: 23% 02/04/2019: 25% 02/05/2019: 25% 02/06/2019: 25% 02/07/2019: 25% 02 /08/2019: 25% 10/21/2019: 24% 10/22/2019: 24% 10/23/2019: 24% 10/24/2019: 24% 10/25/2019: 24% 11/04/2019: 24% 11/05/2019: 24% 11/06/2019: 24% 11/07/2019: 24% 11/08/2019: 24% 12/09/2019: 25% 12/10/2019: 25% 12/11/2019: 25% 12/12 /2019: 25% 12/13/2019: 25% The laboratory did not ensure their humidity range was consistent with the manufacturer's minimum requirement. 4. During an interview on 01 /07/2020 at 3:00 pm, the laboratory assistant reviewed and confirmed the laboratory's defined humidity range was not consistent with the manufacturer's minimum requirement.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and in interview with staff, the laboratory failed to ensure used tissue marking dyes had not exceeded their expiration date. Findings included: 1. During a tour of the grossing room on 01/07/2020 at 11:10 am, the following was observed stored near the grossing station: Orange Tissue Marking Dye, Lot # 058088, expiration date 09/19 Green Tissue Marking Dye, Lot #049404, expiration date 10/18 2. During an interview on 01/07/2020 at 11:10 am, testing person -2 (performs grossing) reviewed and confirmed the used tissue marking dyes had expired.
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 review of the manufacturer's instructions, laboratory's policy, equipment maintenance logs, and in interview with staff, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency (monthly) specified by the manufacturer for histopathology equipment for 3 of 3 months in 2018 (09/2018, 10/2018, 11/2018) and 4 of 4 months in 2019 (01/2019, 02 /2019, 10/2019, and 11/2019). Findings included: 1. Review of Tissue-Tek DRS 2000 Auto-Stainer operator's manual (page 6.1) stated, "Monthly Maintenance: Drying Station: The drying station should be cleaned once a month or more often as needed" followed by step-by-step instructions. Review of Tissue-Tek VIP:E150 operator's manual (page 6.3) stated, "Periodic Maintenance: Fume Control System - Activated Carbon Cartridge: Replace the activated carbon cartridge on a regular basis. The recommended schedule is once a month (assuming five processing runs per week); however, this will vary depending upon the frequency and duration of your runs and on the reagents used." 2. Review of the laboratory's policy "Instrument and Equipment Maintenance and Schedules/Uses and QC" stated, "I. Tissue Processors: c. Filters are changed every 6 months." The policy was not consistent with Tissue-Tek VIP:E150

	manufacturer's instructions for the frequency of changing the carbon cartridge (filter). The policy did not include Tissue-Tek DRS 2000 Auto-Stainer manufacturer's instructions for the monthly maintenance drying station. 3. Random review of Tissue-Tek DRS 2000 Auto-Stainer equipment maintenance logs for 09/2018, 10/2018, 11 /2018, 01/2019, 02/2019, 10/2019, and 11/2019 revealed the laboratory did not perform and document monthly maintenance of cleaning the drying station, as required. Random review of Tissue-Tek VIP:E150 equipment maintenance logs for 09 /2018, 11/2018, 01/2019, 02/2019, 10/2019, and 11/2019, revealed the laboratory did not perform and document monthly maintenance of replacing the Carbon Cartridge (filter) once a month. The log included a frequency of "CHANGE FILTER (6 Months)." 4. During an interview on 01/07/2020 at 3:00 pm, the laboratory assistant reviewed and confirmed the above findings.
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 review of the laboratory's policy, CMS 209 form, personnel records, patient test requisitions, patient test reports, and in interview with staff, the laboratory director failed to provide overall management and direction. The laboratory director failed to employ laboratory personnel with the appropriate education required for high complexity testing. Refer to D6101.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, CMS 209 form, personnel records, patient test requisitions, patient test reports, and in interview with staff, the laboratory director failed to employ laboratory personnel with the appropriate education required for high complexity testing. The laboratory failed to ensure an individual performing high complexity testing (grossing) met one of the qualifying requirements. Refer to D6171.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, CMS-209 form, personnel records, and in interview with staff, the technical supervisor failed to ensure all components were included in procedures for competency evaluation. Findings included: 1. Review of the laboratory's policy "TITLE: GROSS ASSISTANT PERFORMANCE EVALUATION" did not include the following: 493.1451 (b)(8)(iii) - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 493.1451 (b)(8)(iv) - Direct observation of performance of instrument maintenance and function checks; 493.1451 (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; 493.1451 (b)(8)(vi) Assessment of problem solving skills; 2. Review of the CMS-209 form included TP-2 as the individuals who performs grossing on patient skin specimens. Review of TP-2 records for annual performance evaluations included "Grossing Personnel Competency Testing" signed by the laboratory director (TS) 12/15/2015. The documentation used for performance evaluations did not include all required components: 493.1451 (b)(8)(iii) - TP reviewing intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 493.1451 (b)(8)(iv) - Direct observation of TP performance of instrument maintenance and function checks; 493.1451 (b)(8)(v) Assessment of TP test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; 493.1451 (b)(8)(vi) Assessment of TP problem solving skills; 3. During an interview on 01/07/2020 at 12:15 pm, the laboratory assistant confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, CMS 209 form, personnel records, and interview with staff, the technical supervisor (TS) failed to evaluate and document performance of 1 of 2 testing persons (TP-2) for high complexity testing (grossing), at least annually for 2018 and 2019. Findings included: 1. Review of the laboratory's policy "TITLE: GROSS ASSISTANT PERFORMANCE EVALUATION" stated, "PROCEDURE: 1. The GA (gross assistant) will have performance evaluations done by the Director of Anatomic Pathology with input from the pathologist staff." The policy did not define frequency of conducting and documenting performance evaluations for grossing TP's. 2. Review of the CMS 209 for included TP-2 as the individual who performs grossing for patient skin specimens. According to documentation provided by the laboratory, TP-2 hire date for part time was in 2011 and transitioned into full time on 01/01/2017. 3. Review of TP-2 records for annual performance evaluations included "Grossing Personnel Competency Testing" signed by the laboratory director (TS) 12/15/2015. The TS had not performed and documented annual evaluations for TP-2 since 2015. Records for 2018 and 2019 were never provided. 4. During an interview on 01/07/2020 at 12:15 pm, the laboratory assistant confirmed the above findings.

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 laboratory's policy, CMS 209 form, personnel records, patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to ensure individuals met qualification requirements for high complexity testing personnel. The laboratory failed to ensure an individual performing high complexity testing (grossing) met one of the qualifying requirements. Refer to D6168.
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 review of the laboratory's policy, CMS 209 form, personnel records, patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to ensure an individual performing high complexity testing (grossing) met one of the qualifying requirements. Findings included: 1. Review of the laboratory's policy "TITLE: GROSS ASSISTANT PERFORMANCE EVALUATION" included qualifying requirements for high complexity testing (grossing) as listed in CFR 493.1489. 2. Review of the CMS 209 form did not include the laboratory assistant as an individual who performs grossing for specimens. The only individual listed who performed grossing was the supervisor (TP-2). During the entrance interview on 01/07/2020 at 10:00 am, the laboratory assistant was asked whether he performed grossing, he stated no. 3. During a tour of the grossing room on 01/07/2020 at 11:15 am, TP-2 was asked where did she document grossing results, she stated on the patient test requisition and she documents her initials. She stated the results are then transcribed by other laboratory assistants into the LIS. During a tour of the grossing room on 01/07/2020 at 11:15 am, TP-2 was asked when she was unable to perform grossing due to leave (personnel or sick leave) who performed the grossing, she stated "[laboratory assistant's name] grosses when I am not here." 4. Review of the laboratory assistant's personnel records included a "Job Classification Form" signed and dated 08/20/2012 and was categorized as a "Lab Assistant" and "MOHS Technician." "GROSSING" section included an "X" next to "Handling of specimens not in secondary leak proof containers; Disposal of contaminated waste materials; Disposal of biohazardous [sic] waste materials to include red bagged containers and specimen archives; Cleaning and disinfecting of work areas and instruments" and a "\" next to "Gross examination and/or dissections of routine 10% formalin (or substitute) fixed biopsy specimens." The laboratory assistant's education records did not include a bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; associate degree in a laboratory science, or medical laboratory technology from an accredited institution; or enough credit hours to qualify him as high complexity testing person. Records included an Emergency Medical Technician Basic certificate, a Histotechnology Certificate Program certificate, and a transcript for a practical nursing diploma. The transcript did not have enough credit hours (chemistry, biology) to qualify as a high complexity testing person. 5. Random review of patient test requisitions with their corresponding patient test reports were requested and included the following: Patient #CS17-07912; collected 10/31/2017;

	received 11/01/2017; report date 11/02/2017 included documented grossing results without initials of the person who performed the grossing. Patient #CS17 07913; collected 10/31/2017; received 11/01/2017; report date 11/02/2017 included documented grossing results without initials of the person who performed the grossing. Patient #DA18-1600; collected 12/10/2018; received 12/12/2018; report date 12/13/2018 included documented grossing results without initials of the person who performed the grossing. Patient #DA18-1790; collected 12/14/2018; received 12 /17/2018; report date 12/18/2018 included documented grossing results without initials of the person who performed the grossing. Patient #DA18-1605; collected 12 /11/2018; received 12/12/2018; report date 12/13/2018 included documented grossing results without initials of the person who performed the grossing. The grossing results did not include initials of the testing person or of TP-2. During an interview on 01/07 /2020 at 4:07 pm, the laboratory assistant was asked who documented the above grossing results, he stated, "I may have done grossing that day. Sometimes I will gross if [TP-2 name] is out." The laboratory assistant reviewed and confirmed it was his handwriting for the above documented grossing results (patients CS17-07912, CS17 07913, DA18-1600, DA18-1790, DA18-1605). The laboratory did not ensure an individual performing high complexity testing (grossing) met one of the qualifying requirements.