Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2054717	02/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Denison Pllc	5130 Pool Road Suite 200, Denison, 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	Noted deficiencies and plans of correction were discussed with laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 45 CFR 493.1230 General Laboratory Systems; 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) 493.1487 Testing Personnel (high complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of American Proficiency Institute (API) proficiency testing (PT) records 2018 (1st, 2nd, 3rd Events), 2019 (1st, 2nd, 3rd Events), and staff interview, the laboratory failed to have documentation of the laboratory director signing 3 of 6 attestation statements and testing personnel signing 3 of 6 attestation statements (2019 Mycology 1st, 2nd, 3rd Events). Findings included: 1. Review of API proficiency testing records from 2018 (1st, 2nd, 3rd Events) and 2019 (1st, 2nd, 3rd Events) revealed the laboratory did not have documentation of the laboratory director and the

	testing personnel signing the attestation statement for the following 3 of 6 PT events: 2019 Mycology 1st Event 2019 Mycology 2nd Event 2019 Mycology 3rd Event 2. The above findings were confirmed by Testing Person 2 in an interview on 02/21 /2020 at 0930 hours in the breakroom.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and confirmed in interview, the laboratory failed to meet the requirements of general laboratory systems as evidenced by: 1. The laboratory failed to have documentation of laboratory director review for 3 of 3 proficiency testing events. Refer to D5211. 2. The laboratory failed to verify the accuracy of non-regulated Potassium hydroxide (KOH) preps twice annually to ensure accurate and reliable test results in 2018 and 2019. Refer to D5217.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) Mycology proficiency testing records from 2019 (1st, 2nd, 3rd Events), and staff interview, it was revealed the laboratory failed to have documentation of laboratory director review for 3 of 3 proficiency testing events. Findings included: 1. Review of API proficiency testing records from 2019 (1st, 2nd, 3rd Events) revealed the laboratory did not have documentation of laboratory director review for the following 3 of 3 PT events: 2019 Mycology 1st Event 2019 Mycology 2nd Event 2019 Mycology 3rd Event 2. The above findings were confirmed by Testing Person 2 in an interview on 02 /21/2020 at 0930 hours in the breakroom. This is a REPEAT DEFICIENCY from the survey conducted 05/26/2017
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: Based on review of American Proficiency Institute (API) proficiency testing records, laboratory records, and confirmed by staff interview, the laboratory failed to verify the

	accuracy of non-regulated Potassium hydroxide (KOH) preps twice annually to ensure accurate and reliable test results in 2018 and 2019. Findings included: 1. Review of American Proficiency Institute (API) proficiency testing records from 2018 and 2019 revealed the laboratory had not performed proficiency testing for KOH using API proficiency testing materials. Further review of laboratory records revealed NO documentation of twice annual accuracy assessment for KOH preps in 2018 and 2019. The laboratory was asked to provide documentation of twice annual accuracy assessment for KOH preps. No documentation was provided. 2. In an interview on 02 /21/2020 at 0930 hours in the breakroom, Testing Person 2 confirmed the above findings. The laboratory has an annual volume of 3 KOH preps.
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 review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to ensure the optimal cutting temperature for specimen testing for 114 of 124 days. Refer to D5413 I. 2. The laboratory failed to have documentation of monitoring the operating conditions (humidity) for the cryostat and automatic stainer for 124 of 124 testing days. Refer to D5413 II. 3. The laboratory failed to check each new lot of testing media for its ability to support growth and produce a biochemical response. Refer to D5477 4. The laboratory's Quality Assurance (QA) system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of Histopathology and Mycology. Refer to D5793.
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 review of laboratory's policy, Avantik QS 12 Cryostat environmental logs (2018 and 2019) and staff interview, it was revealed the laboratory failed to ensure the optimal cutting temperature for specimen testing for 114 of 124 days. Findings included: 1. Review of the laboratory policy titled "Histopathology-Mohs Surgery" stated the following: "D ... ...2. The temperatures for the cryostats are recorded

	everyday. A temperature range is in place for each cryostat and if the temperature deviates from these ranges corrective action is taken, ranging from adjusting the temperature in the machine manually, or calling the manufacturer if the problem is severe. The temperature is between -10 to -30 degrees centigrade. This range provides optimum cutting temperature for skin specimens ... F. Test Procedure/processing of tissue ... .The tissue is cut into 5-8-micron thick sections in the cryostat which is between -24 and -30 degrees centigrade." This policy states TWO different acceptable temperature ranges. 2. Review of the Avantik QS12 Cryostat environmental logs from 2018 and 2019 revealed an acceptable temperature range of -10 to -30 C (Centigrade). 3. Further review of the Avantik Cryostat environmental logs from 2018 and 2019 revealed the following 114 of 124 testing days with a documented cryostat temperature of -34 C: February 7, 21, 27, 28, 2018 March 7, 9, 21, 27, 28, 2018 April 4, 11, 13, 18, 24, 25, 2018 May 9, 11, 16, 23, 29, 30, 2018 June 6, 8, 13, 20, 26, 27, 2018 July 11, 13, 25, 2018 August 15, 20, 22, 28, 29, 2018 September 5, 12, 19, 25, 26, 2018 October 3, 10, 17,24, 30, 31, 2018 November 7, 14,16, 27, 28, 2018 December 12, 2018 January 2, 8, 9, 16, 23, 30, 2019 February 5,6,13, 2019 March 5, 6, 13, 20, 27, 2019 April 2, 3, 10, 17, 23, 26, 2019 May 1, 7, 8, 14, 15, 17, 21, 22, 2019 June 5, 19, 25, 26, 2019 July 2, 3, 9, 10, 17, 2019 August 7, 14, 21, 23, 27, 28, 30, 2019 September 3, 4, 10, 11, 18, 25, 2019 October 2, 9, 16, 22, 30, 2019 November 6, 13, 20, 2019 December 4, 11, 17, 18, 2019 This temperature was NOT within either temperature range of -10 to -30 C or -24 to -30 C defined in the laboratory policy. The laboratory failed to ensure the optimal cutting temperature for specimen testing of 114 of 124 days. 4. In an interview on 02/21/2020 at 1045 hours in the breakroom, Testing Person 2 was asked to provide corrective action for the out of range temperature readings. No documentation was provided. This confirmed the above findings. II. Based on review of the manufacturer's instructions for the Avantik QS12 Cryostat, the Linistat Linear Stainer, and laboratory environmental logs (2018 - 2019), and staff interview, it was revealed the laboratory failed to have documentation of monitoring the operating conditions (humidity) for the cryostat and automatic stainer for 124 of 124 testing days. Findings included: 1. A review of the manufacturer's instructions for the Avantik QS 12 Cryostat under the section titled "Technical Specifications" revealed the manufacturer required the following conditions for operation: "15C to 30C (59-86F) (at a maximum relative humidity of 60%)". 2. A review of the manufacturer's instructions for the Linistat Linear Stainer under the section titled "System Specification" revealed the manufacturer required the following conditions for operation: "5C to 40C (41-104F) (at a maximum relative humidity 80% up to 31 C (87.8 F)". 3. Review of laboratory environmental logs (2018 - 2019) revealed the laboratory had an acceptable humidity range of 60% - 75%. This range does NOT ensure humidity levels were within manufacturer's specifications for the Avantik QS 12 cryostat. Further review of the environmental logs revealed no humidity readings documented for 124 of 124 testing days in 2018 and 2019. 4. The laboratory was asked to provide documentation of monitoring the humidity of the laboratory for compliance with the manufacturer's instructions. No documentation was provided. Laboratory reported 765 histopathology tests performed annually. 5. In an interview on 02/21/2020 at 1045 hours in the breakroom, Testing Person 2 confirmed the above findings. This is a REPEAT DEFICIENCY from the survey conducted 05/26/2017.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory records (2018 and 2019) and confirmed in staff interview, it was revealed that the laboratory failed to check each new lot of testing media for its ability to support growth and produce a biochemical response. Findings included: 1. On 02/21/2020 at 1000 hours in the breakroom, one package of 24 vials of DTM medium (Lot number D1333-0719, Expiration date 07/08/2021) was observed in a small refrigerator in the breakroom area. 2. The manufacturer's instructions for Acuderm Dermatophyte Test Medium (DTM) stated the following: "DTM is a selective medium intended for use in the detection of dermatophytes from cutaneous sources." In the section titled "Quality Control" the manufacturer states, "CLIA requires the end user to perform a minimum of a positive and negative control on each new lot or batch purchased." 3. In an interview on 02/21/2020 at 1000 hours in the breakroom, Testing Person 2 was asked to provide documentation of quality control for each new lot or batch of DTM. No documentation was provided. She stated that the laboratory did not perform new lot or batch quality control. This confirmed the above findings. This is a REPEAT DEFICIENCY from the survey conducted 05/26/2017.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy manual, laboratory records and staff interview, the laboratory's Quality Assurance (QA) system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of Histopathology and Mycology for 12 of 12 months in 2018 and 12 of 12 months in 2019. Findings included: 1. Review of the laboratory policy titled "Histopathology---Mohs Surgery" stated the following: "Corrective Actions: All out of control situations not resolved by a simple repeat analysis will be reported and reviewed by the direction. The director will prescribe the corrective action to be taken and assure the appropriate action was taken and proper procedures were followed. The appropriate individual will fill out a corrective action form whenever a problem arises in calibration or an out-of-control situation ... ." 2. The laboratory failed to ensure the optimal cutting temperature for specimen testing for 114 of 124 days. No corrective action documentation was provided. Refer to D5413 I. 3. The laboratory failed to have documentation of monitoring the operating conditions (humidity) for the cryostat and automatic stainer for 124 of 124 testing days. No corrective action documentation was provided. Refer to D5413 II. 4. The laboratory failed to check each new lot of testing media for its ability to support

	growth and produce a biochemical response. Refer to D5477 The laboratory's QA system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of histopathology and mycology.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate competency annually in 2019 for 2 of 2 Testing Persons (TP-3 and TP-4) who perform moderate complexity testing. Findings included: 1. Review of CMS 209 form revealed moderate complexity KOH preps were performed by Testing Person 3 and Testing Person 4. 2. Review of personnel records from 2019 competency assessments revealed no documentation of annual competency in 2019. The Technical Consultant had not performed and documented competency assessment for TP-3 and TP-4 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficienct testing samples. f) Assessment of problem solving skills. 3. In an interview on 02/21 /2020 at 1045 hours in the breakroom, Testing Person 2 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 laboratory policy, manufacturer's instructions, and staff interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Histopathology. Refer to D6079 2. The laboratory director failed to ensure quality assurance programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to 6094. 3. The laboratory director failed to ensure policies were established and competency assessment was maintained for individuals who perform high complexity testing. Refer to 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 a review of laboratory general laboratory and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Histopathology. Refer to D5211, D5217 (Repeat Deficiency), D5413 I, D5413 II (Repeat Deficiency), D5477 (Repeat Deficiency), and D5793.
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 review of the laboratory's quality assurance records and staff interview, it was revealed the laboratory director failed to ensure quality assurance programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5793
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 review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and in interview with staff, the laboratory director failed to ensure policies were established and competency assessment was maintained for individuals who perform high complexity testing, as evidenced by: 1. The laboratory failed to evaluate and document performance of 1 of 1 Testing Persons responsible for high complexity testing at least semiannually during the first-year testing persons analyze patient specimens in 2017-2018. Refer to D6127. 2. The laboratory failed to perform the

	annual competency evaluations for 1 of 1 testing persons for the high complexity testing in the specialty of histopathology in 2019. Refer to D6128
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of 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 responsible for high complexity testing at least semiannually during the first year that testing persons analyze patient specimens. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform high complexity testing. 2. Review of personnel records from 2017 through 2019 revealed the following: a. Testing Person #2 Training documentation: 08/29/2017 No other documentation of semiannual evaluation during the first year of patient testing was provided. The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 02/21/2020 at 1045 hours in the breakroom, Testing Person 2 was asked to provide documentation of semiannual competency assessment. No documentation was provided. This 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 Centers for Medicare and Medicaid (CMS) 209 form, personnel records (2019), and interview with staff, the Technical Supervisor (TS) failed to perform the annual competency evaluations for 1 of 2 testing persons (TP-2) for the high complexity testing in the specialty of Histopathology. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform high complexity testing. 2. Review of personnel records from 2017 through 2019 revealed the following: a. Testing Person #2 Training documentation: 08/29/2017 No documentation of annual competency assessment for 2019 was provided. The Technical Consultant had NOT performed and documented competency assessment for TP-2 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficienct testing samples.

	f) Assessment of problem solving skills. 3. In an interview on 02/21/2020 at 1045 hours in the breakroom, Testing Person 2 was asked what duties she performed in the laboratory. She stated that she grosses the skin tissue, inks the tissue, and prepared the slide for evaluation. She was asked to provide documentation of annual competency assessment for 2019. No documentation was provided. This 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 CMS-209 form and personnel records, it was revealed the laboratory failed to have documentation that 1 of 2 testing persons (TP-2) met the qualifications required to perform high complexity testing. 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 review of the Centers for Medicare and Medicaid (CMS) 209 form and review of the laboratory's personnel records revealed the laboratory failed to have documentation that 1 of 2 testing persons (TP-2) met the qualifications required to perform high complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person 1 and Testing Person 2 listed to perform high complexity testing. 2. Review of personnel records revealed Testing Person 2 had an Associate degree in Nursing. The academic record revealed TP-2 did NOT have an Associate degree in a biological, chemical, physical or clinical laboratory science and did not have 24 semester hours that included 6 semester hours of chemistry, 6 semester hours of biology, and 12 hours of chemistry, biology, or medical laboratory technology.