Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1073594	08/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Skin Cancer Center Of Nm	5120 Masthead St Ne, Albuquerque, NM	

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	During a recertification survey completed on 08/12/2020 for 42 CFR part 493 Laboratory Requirements, the laboratory was found out of compliance with the following conditions: 42 CFR Part 493.801 Enrollment in Proficiency Testing 42 CFR Part 493.1441 Laboratory Director, high complexity 42 CFR Part 493.1487 Testing Personnel, high complexity
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the review of the CMS(Centers for Medicare & Medicaid Services) Form 116 (Application for Certification), Annual Test Volume Spreadsheet, CMS CASPER Report 96 (Facility History including Proficiency Testing), laboratory policies /procedures and interviews with laboratory staff, the laboratory failed to enroll in Proficiency Testing for gram stains (chemical stain used to identify bacteria). The laboratory reported performing 12 gram stains per year. Findings are: A. Review of the CMS Form 116 signed by the Laboratory Director on 08/04/2020 and the Annual Test Volume Spreadsheet (used to report test volumes for survey) revealed the laboratory had added gram stains to the laboratory's test menu. B. During interview on 08/12/2020 at 3:00 pm, TP (Testing Person) #2 confirmed the laboratory performed "a couple of gram stains" since he was hired in August 2019. C. During interview on 08

	/12/2020 at 3:20 pm, the General Supervisor stated the laboratory added gram stains in 2016, about the same time as PAS (Periodic Acid Schiff stain). The General Supervisor also stated the laboratory was not enrolled in Proficiency Testing for gram stains. D. Review of the CMS Form 116 from the prior survey on 07/17/2018 had no documentation that the laboratory performed gram stains at that time. E. Review of the laboratory's policy and procedure manual revealed the gram stain and PAS procedures were not signed by the Laboratory Director nor were they dated. F. Review of the CMS CASPER Report 96 dated 08/06/2020 revealed no enrollment in Proficiency testing for Bacteriology.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, manufacturer instructions, CMS (Centers for Medicare & Medicaid Services) Form 116, Annual Test Volume Spreadsheet and interview with the General Supervisor, the laboratory failed to establish performance specifications for the modified gram stain procedure. The laboratory reported performing 12 gram stains per year. Findings are: A. Review of the CMS Form 116 signed by the Laboratory Director on 08/04/2020 and the Annual Test Volume Spreadsheet (used to report test volumes for survey) revealed the laboratory had added gram stains (chemical stain used to identify bacteria) to the laboratory's test menu. B. During interview on 08/12/2020 at 3:00 pm, TP (Testing Person) #2 confirmed the laboratory performed "a couple of gram stains since been here." C. During interview on 08/12/2020 at 10:40-11:00 am, the General Supervisor stated: 1. He did not have hard copies of the manufacturer's instructions for the Cancer Diagnostics Inc Gram Stain Kit. Copies were printed from the manufacturer's website during the survey on 08/12/2020 at 11:00 am. 2. The laboratory did not follow the procedure as shown in the Cancer Diagnostics Inc Gram Stain Kit. The laboratory used a Crystal Violet stain instead of the Gentian Violet Solution and Safarin O instead of the Carbol Fuchsin Counterstain. 3. This change to the Gram Stain kit procedure was based on his previous job experience and the laboratory did not establish performance specifications for the modified staining method. D. During interview on 08/12/2020 at 3:20 pm, the General Supervisor stated the laboratory added gram stains in 2016, about the same time as PAS (Periodic Acid Schiff stain). D. Review of the laboratory's policy and procedure manual revealed the gram stain and PAS procedures were not signed or dated by the Laboratory Director, or identify the reagents used in the staining process.
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 the review of maintenance records and logs for 2020 and the Nikon Microscope Use Protocol, the laboratory failed to establish and follow written maintenance protocol for their microscope. Findings are: A. Review of the Microscope Use Protocol dated August 1, 2014 indicated the microscope stage (platform where a slide is placed for examination) and ocular eyepiece are to be cleaned once per day. B. Review of the January-August 2020 Microscope daily maintenance log, effective date August 1, 2014, revealed weekly ocular eyepiece cleaning and no documentation for cleaning the microscope stage.
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 the review of personnel records, CMS (Centers for Medicare & Medicaid Services) Laboratory Personnel Report form 209, CMS Form 116 (Application for Certification), CASPER Report 96 (Facility History including Proficiency Testing), Annual Test Volume Spreadsheet, laboratory policies/procedures and interviews with laboratory staff, the laboratory director failed to provide overall direction and management of the laboratory. Findings are: A. The Laboratory Director failed to ensure the laboratory enrolled in Proficiency Testing for gram stains. See D6088 B. The Laboratory Director failed to ensure that 1 (TP #2) of 3 testing personnel, met the educational requirements for high complexity testing personnel. Repeat deficiency from 07/17/2018. See D6102 C. The Laboratory Director failed to ensure policies were established and followed to assess competency of laboratory personnel. Repeat deficiency from 07/17/2018. See D6103
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the review of the CMS(Centers for Medicare & Medicaid Services) Form 116 (Application for Certification), Annual Test Volume Spreadsheet, CMS CASPER Report 96 (Facility History including Proficiency Testing), laboratory policies /procedures and interviews with laboratory staff, the laboratory director failed to ensure the laboratory enrolled in Proficiency Testing for gram stains. Findings are: A. Review of the CMS Form 116 signed by the laboratory director on 08/04/2020 and the Annual Test Volume Spreadsheet (used to report test volumes for the survey) revealed

	the laboratory had added gram stains (chemical stain used to identify bacteria) to the laboratory's test menu. B. During interview on 08/12/2020 at 3:00 pm, TP (Testing Person) #2 confirmed the laboratory performed "a couple of gram stains since he's been here." C. During interview on 08/12/2020 at 3:20 pm, the laboratory supervisor stated the laboratory added gram stains in 2016, about the same time as PAS (Periodic Acid Schiff stain). The laboratory supervisor also stated the laboratory was not enrolled in Proficiency Testing for gram stains. D. Review of the CMS Form 116 from the prior survey on 07/17/2018 had no documentation that the laboratory performed gram stains at that time. E. Review of the laboratory's policy and procedure manual revealed the gram stain and PAS procedures were not signed by the laboratory director nor were they dated. F. Review of the CMS CASPER Report 96 dated 08/06 /2020 revealed no enrollment in Proficiency testing for Bacteriology.
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 personnel records, CMS (Centers for Medicare & Medicaid Services) Laboratory Personnel Report form 209, CMS Form 116 (Application for Certification), CASPER Report 96 (Facility History including Proficiency Testing), Annual Test Volume Spreadsheet, laboratory policies/procedures and interviews with laboratory staff, the Laboratory Director failed to ensure a quality assessment was established and followed by the laboratory. Findings are: A. The Laboratory Director failed ensure the laboratory enrolled in Proficiency Testing for gram stains. See D6088 B. The Laboratory Director failed to ensure that 1 (TP#2) of 3 testing personnel met the educational requirements for high complexity testing personnel. See D6102 Repeat deficiency from 07/17/2018 C. The Laboratory Director failed to ensure policies were established and followed to assess competency of laboratory personnel. See D6103 Repeat deficiency from 07/17/2018 D. The laboratory failed to establish performance specifications for the modified gram stain procedure. See D5423 E. The laboratory failed to establish and follow written maintenance protocol for their microscope. See D5429
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of personnel records and CMS (Centers for Medicaire & Medicaid)Laboratory Personnel Report Form 209, the Laboratory Director failed to ensure that 1 (TP#2) of 3 (TP#1-TP #3) testing personnel met the educational requirements for high complexity testing personnel. Findings are: This is a repeat

	deficiency from the certification survey dated 07/17/2018. A. Review of the CMS Laboratory Personnel Report Form 209 signed by the laboratory director on 08/06 /2020 indicated the addition of a new high complexity testing person (TP#2) to the laboratory staff since the previous survey on 07/17/2018. B. Review of the personnel file for TP #2 revealed the following: 1. According to the certificate issued by [Name of University], TP #2 completed a course for Health Science Laboratory Technology in August 2003 but there was no indication of the degree earned. 2. According to TP #2's resume, he earned an Associate's Degree in Health Science, April 2002- May 2003 while serving in the military. 3. There was no documentation of the DD-214 or military discharge paperwork. 4. There was no documentation that he had earned an Associate's degree in Science which is required for all high complexity testing personnel performing testing after April 24, 1995.
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 the review of personnel records, personnel competency policy, and interviews with laboratory staff, the Laboratory Director failed to ensure policies were established and followed to assess competency of 3 (TP#1-TP#3) of 3 (TP#1-TP#3) testing personnel and the General Supervisor. Findings are: This is a repeat deficiency from the certification survey dated 07/17/2018. A. Review of personnel files for 3 of 3 (TP#1-TP#3) Testing Personnel (TP) and for the General Supervisor, revealed no documentation of competency assessments at 6 months and annually thereafter. Refer to D6127. B. Review of the laboratory policies revealed three different plans for performing employee competencies and none of the three included a 6-month competency assessment for new employees. 1. An undated policy, identified as CLIA DSCCNM Communications Policy by Executive Vice President of Operations in an email dated 08/11/2020, calls for annual review of the performance of each testing personnel and documentation to be filed in their respective personnel files. 2. The Model Quality Assessment Plan, implemented 08/01/2014 indicates: "This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens. At least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency." 3. The Competency Assessment Policy dated 10/01 /2018 indicated: "The DSCCNM Laboratory will conduct quarterly competency assessments/training for all laboratory personnel. The training/reviews will cover laboratory procedures including gross examinations and laboratory safety. All training's will be documented and verified by the Lab Director. These documents along with any continuing education will be filed in the Lab Competencies binder located in the laboratory." C. During interview, on August 12, 2020 at 3:30 pm, with the General Supervisor and the Executive Vice President of Operations, were asked for personnel competency assessment records. The General Supervisor and the Executive Vice President of Operations were unable to produce proper documentation and/or policy and instead offered the employee's training checklists for each of the

	three testing personnel and for the General Supervisor. When asked to describe the process of assessing competency after an employee has been trained he stated that he did not perform competency evaluations of the testing personnel unless there is a training or performance issue. If there was an issue, they would provide more training if needed.
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 the review of personnel records, personnel competency policies, and interviews with laboratory staff, the Technical Supervisor failed to evaluate and document the semiannual performance of new testing personnel for 1 (TP #2) of 2 (TP #2 & TP #3) testing personnel hired since July 2018. Findings are: A. Review of personnel files revealed no documentation of competency assessments within 6 months of hire for TP #2, hired Aug 28, 2019. The laboratory hired TP#3 in June 2020 and not yet due for the 6-month competency evaluation. B. Review of the laboratory policies revealed three different plans for performing employee competencies and none of the three included a 6- month competency assessment for new employees. See D6103 C. During interview on August 12, 2020 at 3:30 pm, the General Supervisor and the Executive Vice President of Operations were asked for personnel competency assessment records. The General Supervisor and the Executive Vice President of Operations were unable to produce proper documentation and/or policy and instead provided the training checklists for testing personnel (TP#1 - TP#3) and for the General Supervisor. When asked to describe the process of assessing competency after an employee has been trained the General Supervisor stated that he did not perform competency evaluations of the testing personnel unless there is a training or performance issue. If there was an issue, they would provide more training if needed.
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 the review of personnel records, CMS Laboratory Personnel Report form 209 and interviews with laboratory staff, the laboratory failed to meet the condition of high complexity testing personnel. Findings are: This is a repeat deficiency from the certification survey dated 07/17/2018. The laboratory failed to ensure all testing personnel, 1 (TP #2) of 3 testing personnel, failed to meet the educational requirements for high complexity testing. See 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 the review of personnel records and CMS Laboratory Personnel Report form 209, the laboratory failed to ensure all testing personnel, 1 (TP#2) of 2 (TP #2 & TP#3), met the educational requirements for high complexity testing. Findings are: This is a repeat deficiency from the certification survey dated 07/17/2018. A. Review of the CMS Laboratory Personnel Report form 209 signed by the Laboratory Director on 08/06/2020 indicated the addition of a new high complexity testing person (TP #2) to the laboratory staff since the previous survey on 07/17/2018. B. Review of the personnel file for TP #2 revealed the following: 1. According to the certificate issued by [Name of University], TP #2 completed a course for Health Science Laboratory Technology August 2003 but there was no indication of the degree earned. 2. According to TP #2's resume, he earned an Associate's Degree in Health Science, April 2002-May 2003 while serving in the military. 3. There was no documentation of the DD-214 or military discharge paperwork. 4. There was no documentation that he had earned an Associate's degree in Science which is required for all high complexity testing personnel performing testing after April 24, 1995.