Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1073594	07/17/2018
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 07/17/2018 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.1441 Laboratory director, high complexity 42 CFR Part 493.1487 Testing personnel, high complexity The laboratory director was unavailable during the survey and the findings were discussed with the office manager on 07/17 /2018 at 2:14 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of 2016-2018 temperature logs and interview with the laboratory supervisor, the laboratory failed to perform and document corrective actions for unacceptable temperatures in the laboratory. Findings are: A. Review of the drying oven temperature records revealed unacceptable temperatures for 3 months in 2016. According to the temperature log, the drying oven should be 65 - 70 degrees C (Celsius). There was no documentation of corrective actions on the logs. 1. August 2016 For 18 of 23 days, the temperature was recorded as 48 degrees C. 2. September 2016 For 22 of 22 days, the temperature was recorded as 48 degrees C. 3. October 2016 For 15 of 22 days, the temperature was recorded as 48 degrees C. B. Review of the water bath temperature records revealed unacceptable temperatures for 4 months in 2016. According to the temperature log, the water bath should be 36 - 42 degrees C.

	There was no documentation of corrective actions on the logs. 1. July 2016 2 of 19 days 07/17/2016 = 43.9 C 07/18/2016 = 44.0 C 2. August 2016 20 of 23 days 08/08 /2016, 08/09/2016, 08/11/2016 - 08/17/2016, 08/19/2016 - 08/31/2016 = 44.0 C 08/10 /2016 and 08/18/2016 = 48.0 C 3. September 2016 22 of 22 days 09/01/2016 - 09/30 /2016 = 44.0 C 4. October 2016 15 of 21 days 10/03/2016 - 10/14/2016 = 44.0 C 10/17 /2016 - 10/21/2016 - 41.0 C C. During interview on 07/17/2018 at 1:04 pm, the general supervisor confirmed that no corrective actions were documented elsewhere in the laboratory.
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 Laboratory Personnel Report form 209 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 that 1 (TP #3) of 3 testing personnel met the educational requirements for high complexity testing personnel. See D6102 B. The laboratory director failed to ensure policies were established and followed to assess competency of laboratory personnel. See D6103
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, CMS Laboratory Personnel Report form 209 and interviews with laboratory staff, the laboratory director failed to ensure that 1 (TP #3) of 3 testing personnel met the educational requirements for high complexity testing personnel. Findings are: A. Review of the CMS Laboratory Personnel Report form signed by the laboratory director on 07/16/2018 indicated the addition of a new high complexity testing person (TP #3) to the laboratory staff since the previous survey on 03/14/2016. B. During interview on 07/17/2018 at 9:25 am, TP#3 confirmed that he performed gross examinations (the process by which pathology specimens are inspected with the bare eye to obtain diagnostic information, while being processed for further microscopic examination). C. Review of the personnel records revealed no documentation of training, job description or competency evaluations since TP#3 was hired on 07/08/2016. The only rewords provided during the survey were a copy of a resume and Histology Board of Registry Certification dated 2003. D. TP#3's resume indicated he worked as a histotechnologist in clinical laboratories April 2001 - May 2007. From May 2007 - June 2016 he worked for an animal research laboratory. E. During interview on 07/18/2018 at 01:40 pm, the

	general supervisor stated that the training for TP #3 was not documented. F. Review of TP#3's secondary education transcripts and high school diploma sent by email on 07 /18/2018, revealed that TP#3 had earned his high school diploma and 23 college credit hours but did not have an Associate's degree in Science.
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, CMS Laboratory Personnel Report form 209 and interviews with laboratory staff, the laboratory director failed to ensure policies were established and followed to assess competency of laboratory personnel. Findings are: A. Review of personnel files for 3 of 3 (TP #1 - #3) and the general supervisor revealed no documentation of competency assessments for any aspect of the processing or gross examinations. B. During interview on 07/17/2018 at 01:15 pm, the general supervisor stated there was no written policies for performing competency evaluations.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on the review of personnel records, and interviews with laboratory staff, the general supervisor failed to perform and document competency evaluations for 3 of 3 (TP#1 - TP#3) Findings are: A. Review of personnel records revealed no documentation of competency evaluations for 3 of 3 (TP #1 - TP #3) testing personnel performing gross examinations of tissues in the laboratory. B. During interview on 07 /18/2018 at 01:15 pm, the general supervisor stated that he did not perform competency evaluations of the testing personnel. He further stated that the laboratory did not have a written policy for performing competency evaluations.
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, 1 (TP #3) of 3 testing personnel failed to meet the educational requirements for high complexity testing personnel. Findings are: The laboratory failed to ensure all testing personnel met 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, CMS Laboratory Personnel Report form 209 and interviews with laboratory staff, 1 (TP #3) of 3 testing personnel failed to meet the educational requirements for high complexity testing personnel. Findings are: A. Review of the CMS Laboratory Personnel Report form signed by the laboratory director on 07/16/2018 indicated the addition of a new high complexity testing person (TP #3) to the laboratory staff since the previous survey on 03/14/2016. B. During interview on 07/17/2018 at 9:25 am, TP#3 confirmed that he performed gross examinations (the process by which pathology specimens are inspected with the bare eye to obtain diagnostic information, while being processed for further microscopic examination). C. Review of the personnel records revealed no documentation of training, job description or competency evaluations since TP#3 was hired on 07/08/2016. The only rewords provided during the survey were a copy of a resume and Histology Board of Registry Certification dated 2003. D. TP#3's resume indicated he worked as a histotechnologist in clinical laboratories April 2001 - May 2007. From May 2007 - June 2016 he worked for an animal research laboratory. E. Review of TP#3's secondary education transcripts and high school diploma sent by email on 07/18/2018, revealed that TP#3 had earned his high school diploma and 23 college credit hours. 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.