Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2044477	10/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cmc-Dhk Dermatology Mohs	51 Railroad St, Keene, NH	

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
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 record review and staff interview, the laboratory director failed to ensure that testing personnel performing inking and mapping have the appropriate education for performing high complexity testing prior to patient testing in 2019 and 2020. Findings include: 1) Review on 10/13/2020 of the laboratory's procedure revealed the Moh's technician performed inking and mapping of specimens for histopathology. 2) Review on 10/13/2020 of the laboratory's competency assessments revealed 3 of 3 Moh's technicians performed inking and mapping. Staff A completed their first competency assessment in 2020. Staff B completed their first competency assessment in 2019. 3) Review on 10/13/2020 of personnel records revealed 2 of 2 new testing personnel (Staff A & B, Moh's technicians) failed to include documentation of educational qualifications. 4) Interview with Staff A and B (Moh's Technicians) on 10 /13/2020 revealed Staff A and Staff B did not have the required coursework or degree to perform high complexity testing. Staff A and B confirmed they performed inking and mapping. 5) The laboratory performed an annual test volume of 1,129 for inking and mapping in 2019.
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 record review and staff interview, the 2 of 3 testing personnel performing inking and mapping failed to educational qualification requirements to perform high complexity testing prior to patient testing in 2019 and 2020. Refer to tag D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and

	verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the 2 of 3 testing personnel performing inking and mapping failed to meet educational qualification requirements to perform high complexity testing prior to patient testing in 2019 and 2020. Findings include: 1) Review on 10/13/2020 of the laboratory's procedure revealed the Moh's technician performed inking and mapping of specimens for histopathology. 2) Review on 10/13/2020 of the laboratory's competency assessments revealed 3 of 3 Moh's technicians performed inking and mapping. Staff A completed their first competency assessment in 2020. Staff B completed their first competency assessment in 2019. 3) Review on 10/13/2020 of personnel records revealed 2 of 2 new testing personnel (Staff A & B, Moh's technicians) failed to include documentation of educational qualifications. 4) Interview with Staff A and B (Moh's Technicians) on 10/13/2020 revealed Staff A and Staff B did not have the required coursework or degree to perform high complexity testing. Staff A and B confirmed they performed inking and mapping. 5) The laboratory performed an annual test volume of 1,129 for inking and mapping in 2019.