Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2245554	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clear Choice Dermatology Lab Salem	1610 12th Street Se, Salem, OR	

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**
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 review of testing personnel (TP) educational documentation, competency assessments and interview with the Laboratory Director (LD), the LD failed to ensure that the person listed on the CMS 209 form as General Supervisor (GS) and as a testing personnel (TP) had the requisite education and documentation required by CLIA on file for this laboratory. Findings include: 1. While on site for survey 12/12 /2023, the LD could not produce educational documentation or clinical experience for TP 1, listed on the CMS 209 form as a TP and as the General Supervisor (GS). 2.The LD and GS / TP1 confirmed during interview 12/12/2023 at 12:15 pm that they did not have the competency assessments for the person listed on the CMS 209 formTP2 readily available for my review. 3. Upon review of the grossing competency assessments for TP2 submitted to me after the survey 12/12/2023 by email 12/15 /2023, the grossing competencies dated 4/14/2023 and 10/3/2023 failed to include the 6 elements of assessment required for competency assessment for those performing

	moderate and high complexity testing, in this case, grossing of human tissues.. 4. The laboratory reports performing 880 Mohs surgical procedures and 7975 Histopathology specimens processed and interpreted annually
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Based on review of educational documents and competencies produced for my review during survey and interview with testing personnel (TP1) and the Laboratory Director (LD), the LD failed to ensure the person listed on the CMS 209 form as the General Supervisor (GS) was qualified to perform the duties of a GS, by education and / or experience. Findings include: 1. Upon review of the educational documents provided for my review during survey, no documentation of education or experience for the GS (also TP1) could be produced. 2. When asked to provide evidence of education for the GS /TP1 twice (2x) post survey, the laboratory failed to provide evidence of education or experience within the 10 day post survey time line. 3. Interview with the LD during survey at 12:15 pm confirmed the laboratory did not have evidence of education or experience for GS/TP1 listed on the CMS 209 form. 4. Received by email from TP1 on 12/20/2023, GS/TP1 confirmed that she had no evidence of education or experience to provide to me. 5. The laboratory reports performing 880 Mohs surgical procedures and 7975 Histopathology specimens processed and interpreted annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual provided for my review during survey and interview with the General Supervisor (GS, / TP 1) and the Laboratory Director (LD), the LD failed to ensure an approved and current procedure manual, signed and dated indicating his approval was available to all testing personnel (TP). Findings include: 1. Upon review of the current procedure manual presented for my review during survey, I could not find a current LD approval signature/date for any of the following procedures located within this procedure manual for testing personnel use: 1. General Laboratory Safety 2. Procedure for Labeling and Storage of Chemicals 3. Quality Assessment 4. Macroscopic Tissue Processing (aka Grossing) 5. Specimen Collection 6. Microtomy 7. Tissue Embedding 2. Review of the signatures on the documents above and interview with the GS/TP1, the GS/TP1 confirmed the signatures were those of the previous LD. 3. Interview with the GS / TP1 and LD at 1230 pm 12/12/2023 confirmed that the current LD had not reviewed the procedure manual nor had he approved any of it's contents since the last survey 03/23/2023. 4. The laboratory reports performing 880 Mohs surgical procedures and 7975 Histopathology specimens processed and interpreted annually.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records indicating the duties and responsibilities of all staff performing any phase of laboratory testing and interview with the General Supervisor (GS / TP1) and the Laboratory Director (LD), the LD failed to ensure the duties and responsibilities of all laboratory personnel involved in the testing process were approved and current. Findings include: 1. Review of the job descriptions for each position described for high complexity testing in the manual presented for review during survey, the LD failed to ensure a current, signed and approved job description for each TP performing CLIA regulated testing was approved and in place for this laboratory. 2. Interview with the LD and GS / TP1 at 12:30 pm confirmed that no such current, approved and dated personnel job descriptions and policy for TP for this lab was available for review. 3. The laboratory reports performing 880 Mohs surgical procedures and 7975 Histopathology specimens processed and interpreted annually.
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 patient test reports and interview with the Laboratory Director (LD), the LD failed to ensure that testing personnel (TP 2), who is performing anatomical grossing on human tissue specimens received from other satellite Clear Choice laboratories, had his gross assessment of tissues reviewed by the Technical Supervisor (TS), or the LD or another CLIA qualified individual within 24 hours and documenting this in writing. Findings include: 1. Upon review of the grossing done by TP 2, no evidence of TS or LD review within 24 hours of performing the grossing could be provided. 2. Interview with the LD at 1:00 pm confirmed that the laboratory was not performing grossing review within 24 hours of TP 2 performing the gross assessment of human tissue samples submitted for histological interpretation by a CLIA qualified individual as described in 493.1449 (b) or (l). 3. The laboratory reports performing 880 Mohs surgical procedures and 7975 Histopathology specimens processed and interpreted annually.