Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2245554	01/06/2026
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the current CMS 209 form, the CMS 209 form from the previous survey dated 12/12/2023, and interview with the Laboratory Manager, the Laboratory Director (LD) failed to ensure that a procedure for assessing all personnel who are listed on the CMS 209 form as holding a Federal Title (TC, Technical Consultant, TS, Technical Supervisor, GS, General Supervisor) was established and that competency assessment of those personnel holding such titles was performed annaully or as stated in the procedure for Federal Title Assessments. Findings include: 1. Upon request for a procedure for assessing personnel who hold a federal title, none could be produced. 2. Upon request for documentation for assessment for all personnel listed on either CMS 209 forms, holding a federal title (TS), none could be produced. 3. The CMS 209 form from the survey conducted 12/12/2023 listed one (1) person as a TS. (TS #1). The CMS 209 form from current survey listed one (1) person as the TS. This is not the same person as listed on the previous survey's CMS 209 form. (TS #2). 4. Interview with the Lab Manager confirmed that there was no procedure or policy for assessing laboratory personnel who hold a federal title of TS, TC, or GS, nor was he aware of any competencies by federal title of the personnel in question (TS #1 and TS #2). 5. The laboratory reports performing 31,990 histological stains and grossing procedures annually.
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 competency assessments, laboratory procedures, peer review records and current CMS 209 form, the Laboratory Director (LD) failed to fulfill the duties of the LD. Findings include: 1. See D6093, D6103, D6107
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 lack of peer review documentation for each Pathologist reading and interpretting histological slides, interview with the Lab Manager and interview with the Laboratory Director (LD) by phone 01/15/2026, the LD failed to ensure that each Pathologist listed on the CMS 209 form for surveys dated 12/12/2023 and 01/06/2026 had written evidence of peer review at least twice per year. Findings include: 1. Upon request for twice yearly peer review documentation for three (3) individuals listed on the 12/12/2023 CMS 209 form for reading and interpretting histological slides for 2024 & 2025, none could be produced for TP #5 & TP #6. One (1) documented peer review in 2025 was reviewed for TP#4, none could be produced for 2024. 2. Upon request for twice yearly peer review documentation for the four (4) individuals listed on the 01/06/2026 CMS 209 form, (TP #4, TP #5, TP #7 and TP #8) for reading and interpretting histological slides for 2024 and 2025, some could not be produced. TP #6 had no testing in 2024 & 2025, according to the LD by phone 01/15/2026 at 3:00 pm. a. TP # 4 lacked documentation for twice annually peer review for 2024 and one for 2025. b. TP # 5 lacked documentation for twice annually peer review for 2024 (on leave for 2025). c. TP # 7 lacked training documentation and evidence of twice annually peer review for 2025. d. TP #8 lacked documentation for twice annually peer review for 2024 & 2025. (TP #8 left this facility for Alaska 12/2025). 3. Interview with the Lab Manager at 1:30 pm confirmed that there was no other peer review documentation to his knowledge. 4. Phone interview with the LD on 01/15/2026 at 3: 00 pm confirmed that there were missing peer review competencies for all of the seven (7) TP reading and performing histological slide interpretation for 2024 and 2025. 5. The laboratory reports performing 31,990 histological stains and grossing procedures annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 testing personnel (TP) competency assessments submitted for review during survey, lack of a detailed procedure for the assessment of TP performing grossing on human tissues, TP performing interpretation of stained histological tissues on slides and interview with the Lab Manager, the Laboratory Director (LD) failed to ensure approved written policies and procedures for the assessment of all testing personnel (TP) involved with any of the three (#) phases of laboratory testing were established and being followed. Findings include: 1. Upon review of the procedure manual, competency assessments submitted for review during survey for TP performing grossing or microscopic interpretation of histological slides the LD failed to ensure all TP had access to a competency assessment procedure for all persons performing high complexity testing, including initial training and written records of cases reviewed and used in assessment applicable to this training and that it was being followed. 2. Review of the competency assessments for the six (6) TP currently performing grossing revealed no detail as to how competency was determined for each of the six (6) elements for personnel performing grossing on human tissues. Further review revealed an unqualified person was performing the competency assessments for grossing TP, including his own competency assessment. 3. Request for a written policy or procedure for monitoring TP who perform grossing on human tissues failed to yield such policy or procedure. 4. Requests for bi-annual peer review policy and 2024 & 2025 peer review records for the four (4) providers listed on the CMS 209 form failed to yield two (2) peer review documents / year for each TP for 2024 & 2025. See D6093 5. No written record of cases reviewed for each of the six (6) individual's performing grossing prior to being allowed to do grossing un-assisted could be produced. 6. Interview with the Lab Manager at 12:30 pm confirmed that there was no procedure or policy for performing competencies on persons performing grossing nor was there a specific number of cases required to be performed for grossing, before that specific TP was approved to gross on his or her own. 7. Interview by phone with the LD on 01/15/2026 at 3:00 pm confirmed there was no policy or procedure that stated the required number of successful grossing cases required for competence and be deemed competent to gross human tissues without oversight. 8. The laboratory reports performing 31,990 histological stains and grossing annaully.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) 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 personnel documents, CMS form 209 and interview with the Lab Manager, the Laboratory Director (LD) failed to provide a current and complete list of all persons involved in any of the three (3) phases of laboratory testing, including pre-analytic, analytic and post analytic and to what extent each person is allowed to perform the test and if oversight or supervision is required, since last survey 12/12

	/2023. Findings include: 1. This is a repeat citation. 2. A current list of all laboratory personnel, including lab assistants, performing any phase of testing and "who was allowed to do what" since the last survey could be produced. 3. Interview with the Lab Manager at 1230 pm confirmed that the requested document could not be found. 4. The laboratory reports performing 31,990 histological stains and grossing of human tissues annaully.