Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0954636	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Central Wyoming Skin Clinic	2546 E 2nd St Suite 400, Casper, WY	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, staff interview, lack of documentation, and policy and procedure review, the laboratory director and/or the testing personnel (TP) failed to attest to the routine integration of proficiency tests into the patient workload for 3 of 3 American Academy of Family Physicians (AAFP) and 2 of 2 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing events reviewed from January 2022 through December 2023. The findings were: 1. Review of the AAFP 2022-A, AAFP 2022-B, and AAFP 2022-C proficiency testing records for the potassium hydroxide (KOH) slide preparations the attestation statement failed to include the signatures of TP #1 and TP #2. 2. Review of the WSLH 2023-Micro QA1 proficiency testing records showed for the KOH slide preparation the attestation statement failed to include the signature of TP #1. 3. Review of the WSLH 2023-Micro QA2 proficiency testing records showed for the KOH slide preparations the attestation statement failed to include the signature of the laboratory director. 4. Interview with the office manager on 1/10/24 at 4:01 PM revealed she was unaware signatures were required on the proficiency testing attestation statements. 5. Review of an undated and unsigned "Proficiency Testing Policy" provided by the laboratory showed "Results will be recorded on the provided report form, which will be signed by the testing personnel and the director." 6. The laboratory director acknowledged the deficiency during a telephone interview on 1/10/24 at 4:39 PM.
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 personnel files, review of the CMS 209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory directory failed to complete an annual competency assessment for 1 of 1 (testing personnel (TP) #3). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed TP #3 was listed as performing high complexity testing. 2. Review of the personnel file for TP #3 showed a hire date of January 2022 for the position of histotechnician. Review of the "Employee Evaluation & Wage Review" annual evaluation showed "37. Lab-Completes cases with accuracy & urgency, does not leave cases unmarked or unfinished" was marked as "Exceeds" and was signed by the office manager. Further review showed the evaluation failed to include the direct observation of specimen processing, the monitoring and reporting of test results, review of quality control records; direct observation of the performance of instrument maintenance and function checks, an assessment of grossing competency, and an assessment of problem solving skills. 3. Review of the laboratories policies and procedures showed no policy had been developed for the competency assessment of high complexity testing personnel. 4. Interview on 1/10/24 at 1:39 PM with the office manager confirmed she had signed the annual employee evaluation with input from the laboratory director; however, there was no documentation of the laboratory director's input. Further interview at 4:01 PM with the office manager confirmed a competency assessment policy and procedure for high complexity testing personnel was not available. 5. The laboratory director acknowledged the deficiency during a telephone interview on 1/10/24 at 4:39 PM.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) and the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 5 of 5 testing events from January 2022 through December 2023. The findings were: 1. Review of the AAFP 2022-A, AAFP 2022-B, AAFP 2022-C, WSLH-Micro QA1, and WSLH-Micro QA2 proficiency testing records failed to show documentation the laboratory director (LD) had reviewed the results. 2. Review of the WSLH-Micro QA1 results showed the laboratory scored a 66% on the KOH slide preparation. There was no documentation the laboratory had evaluated the test result. 4. Interview with the office manager on 1/10/24 at 4:01 PM revealed she was unaware of the requirement. 5. Review of an undated and unsigned "Proficiency Testing Policy" provided by the laboratory showed "...The graded report will be reviewed immediately and submitted to the director and/or technical consultant for review...Every unsuccessful challenge will be investigated to determine the root cause. Corrective actions will be implemented if appropriate." 6. The

	laboratory director acknowledged the deficiency during a telephone interview on 1/10 /24 at 4:39 PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the histopathology log book, staff interview, and review of policy and procedure, the laboratory failed to at least twice annually verify the accuracy of histopathology testing for 2 of 2 years reviewed (2022, 2023). The laboratory interpreted approximately 5,357 histopathology cases per year. The findings were: 1. Review of the histopathology log book showed an occasional specimen had been referred to a pathology laboratory; however, there was no evidence the accuracy of internally processed specimens had been verified twice yearly as required. 2. Review of the undated and unsigned "Proficiency Testing Policy" showed "...At least twice yearly, accuracy of backup instruments or any non-waived tests that are not included in proficiency-testing program will be verified. This will be done by running at least three split specimens (a specimen that is divided into two parts after collection-the laboratory analyzes one portion and the other is sent to a reference laboratory for analysis) and comparing our results with those of the reference laboratory. The score of this testing will be handled the same way as formal proficiency testing, complete with documentation and indicated corrective actions. This information will be recorded and kept with other proficiency testing records." 3. Interview on 1/10/24 at 4: 01 PM with the office manager revealed she was unaware of the requirement. 4. The laboratory director acknowledged the deficiency during a telephone interview on 1/10 /24 at 4:39 PM.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to ensure the hematoxylin and eosin stains were tested for their intended reactivity each day of use and the results documented for 2 of 2 years of testing reviewed (2022, 2023). The laboratory processed approximately 5,357 biopsies per year. The findings were: 1. Review of the laboratory's documentation showed no evidence the quality of the hematoxylin and eosin stains were evaluated for their intended reactivity. 2. Interview with TP #3 on 1/10/24 at 2:54 PM confirmed the quality of the stains had not been evaluated each day of patient testing. 3. The laboratory director acknowledged the deficiency during a telephone interview on 1/10/24 at 4:39 PM
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 proficiency testing records, personnel records, and policy and procedure review, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of proficiency tests into the routine patient workload (D6089); failed to ensure proficiency testing events were reviewed and evaluated (D6091); failed to ensure a quality control program was established to ensure the quality of laboratory results (D6093); failed to ensure a quality assurance program was maintained (D6094); and failed to ensure policy and procedures were developed and followed to ensure the competency of testing personnel (D6103).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, staff interview, lack of documentation, and policy and procedure review, the laboratory director failed to attest to the routine integration of proficiency tests into the patient workload for 1 of 5 proficiency testing events reviewed from January 2022 through December 2023. The findings were: 1. Review of the WSLH 2023-Micro QA2 proficiency testing records showed the KOH slide preparation event attestation statement failed to include the signature of the laboratory director. 2. Interview with the office manager on 1/10/24 at 4:01 PM revealed she was unaware the signatures of the laboratory director and the testing personnel were required on the proficiency testing attestation statements. 3. Review of an undated and unsigned "Proficiency Testing Policy" provided by the laboratory showed "Results will be recorded on the provided report form, which will be signed by the testing personnel and the director." 4. The laboratory director acknowledged the deficiency during a telephone interview on 1/10/24 at 4:39 PM.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) and the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to review and evaluate proficiency testing results for 5 of 5 testing events from January 2022 through December 2023. Refer to D5211.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 lack of documentation and staff interview, the laboratory director failed to ensure a quality control program was established and maintained to ensure the quality of laboratory services provided. Refer to D5473.
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 procedure manual review, lack of documentation, and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems for the specialty of histopathology. The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan that included the items the laboratory reviews, the frequency of review, and the method they used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, specimen labeling, storage, and transportation. c. Analytic tasks which include review of quality control, instrument preventive maintenance, reagent replacement and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview on 1/10/24 at 4:01 PM with the office manager confirmed the laboratory had not established a quality assessment plan. 3. The laboratory director acknowledged the deficiency during a telephone interview on 1/10 /24 at 4:39 PM.
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 review of personnel files, review of the CMS 209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory director failed to

	ensure policy and procedures were developed to ensure competency assessments for testing personnel included all of the required elements and were performed by qualified staff. Refer to D5209.