Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519668	06/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cheyenne Skin Clinic	123 Western Hills Blvd, Cheyenne, 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
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 potassium hydroxide (KOH) skin scraping preparations and dermatophyte test media culture (DTM) test record review, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of KOH and DTM testing at least twice annually for 2 of 2 years (2019, 2020) of testing reviewed. The laboratory performed approximately 30 KOH skin scraping preparations and 285 DTM cultures per year. The findings were: 1. Review of the laboratory's test records showed no evidence KOH preparations or DTM cultures had been verified for accuracy in 2019 and 2020. 2. Interview with the laboratory director on 6/23/21 at 4:20 PM revealed the laboratory had reviewed DTM culture and KOH skin scraping preparation testing for accuracy verification through peer review, however the laboratory had not documented the results. This is a repeat deficiency.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, procedure manual review, and staff interview, the laboratory

	failed to revise the procedure manual to include the current procedure for grossing (a macroscopic examination of tissue biopsies). The laboratory performed approximately 19,872 tissue biopsies per year. The findings were: 1. Observation on 6/23/21 at 12:20 PM showed HT (histotechnologist) #1 was preparing tissue biopsies for processing by documenting the number of pieces of tissue, the shape, length, width, and the thickness. The HT recorded the results in a log book and initialed his findings. Interview with the HT at that time revealed he was the only HT to perform the grossing procedure and his findings were used for quality assurance purposes, and were not part of the pathology report. 2. Review of the 2017 Dermatopathology Procedure manual showed...."4. No gross description is made in the lab..." 3. Interview with the laboratory director on 6/23/21 at 4:20 PM confirmed the HT performed tissue grossing in the lab and she reviewed and initialed the HT's results daily. The laboratory director stated the physician who performed the biopsy grossed the sample before placing the tissue in formalin, and those findings were used on the final report. The laboratory director confirmed the procedure manual was incorrect.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on medical record review, review of laboratory testing logs, lack of documentation, and staff interview, the laboratory failed to ensure the patients' medical record included the results of testing for dermatophyte test media cultures (DTM), potassium hydroxide (KOH) preparations, and tissue biopsies for 3 of 30 patient charts reviewed (#1, #2, #3). The laboratory performed approximately 30 KOH preparations, 285 DTM cultures, and 19,872 tissue biopsies per year. The findings were: 1. Review of the laboratory's fungus testing log showed a DTM culture had been ordered for patient #1 on 5/4/20 and was resulted on 5/18/20. Review of the patient's chart showed no documentation of the DTM culture test result. 2. Review of the laboratory's KOH testing log showed a KOH preparation had been performed for patient #2 on 12/17/19. Review of the patient's medical record showed no documentation of the result of the KOH preparation. 3. Review of the laboratory's histopathology log showed a tissue biopsy was performed on 9/3/19 for patient #3. Review of the patient's medical record showed no documentation of the biopsy results. 4. Interview with the nurse manager on 6/23/21 at 1:17 PM confirmed the test results were missing from the patient's medical record.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on patient test report review, review of testing logs, review of the laboratory's quality assurance procedure, and staff interview, the laboratory failed to monitor test results in the patient's medical record for errors related to completeness and accuracy for 4 of 30 patient records reviewed (#1, #2, #3, #4). The findings were: 1. Review of the laboratory's fungus testing log showed a dermatophyte test media (DTM) culture had been ordered for patient #1 on 5/4/20 and was resulted on 5/18/20. Review of the patient's chart showed no documentation of the DTM culture results. 2. Review of the laboratory's potassium hydroxide (KOH) testing log showed a KOH preparation had been performed for patient #2 on 12/17/19. Review of the patient's medical record showed no documentation of the result of the KOH preparation. 3. Review of the laboratory's histopathology log showed a tissue biopsy was performed on 9/3/19 for patient #3. Review of the patient's medical record showed no documentation of the biopsy results. 4. Review of the laboratory's fungus testing log showed a KOH preparation was performed on 4/7/21 for patient #4. Review of the log book showed the result was negative. Review of the patient's medical record showed the KOH was reported as positive for yeast. 5. Review of the 2017 Quality Assurance (QA) Plan stated "at least twice a year the lab manager shall evaluate QA logs and review programs for quality patient care and assurance...Patient Test Management Procedures for specimen submission and dermatopathology handling, test requisitions, test reports, timeliness of reporting accuracy shall be reviewed and documented in the Patient Test Management Log." 6. Interview with the office manager on 6/23/21 at 5 PM revealed the laboratory had not been following the QA plan and laboratory did not have a Patient Test Management Log.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on medical record review, lack of documentation, and staff interview, the technical consultant for mycology testing failed to ensure 2 of 2 testing personnel (MD (medical doctor) #4, MD #5) were evaluated semi-annually for competency in reading and reporting potassium hydroxide (KOH) preparations and dermatophyte test media agar (DTM) cultures. The findings were: 1. Review of patient test records and review of the laboratory's testing log showed the initials of the testing personnel reporting KOH and DTM test results included MD #4 and MD #5. 2. Interview with the office manager on 6/23/21 at 3:30 PM revealed MD #4 and MD #5 began practicing at the facility on 8/1/20. 2. Review of the laboratory's documentation showed no evidence MD #4 and MD #5 had been evaluated for competency prior to testing patient samples or at any time thereafter. 3. Interview with the office manager on 6/23/21 at 3:30 PM revealed she was unaware competency evaluations were required for physicians performing moderate complexity testing and confirmed the evaluations had not been completed. Interview with the laboratory director on 6/23/21 at 4:20 PM revealed the competency evaluations were completed through peer review, however it was not documented.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on medical record review, lack of documentation, and staff interview, the technical consultant for mycology testing failed to ensure 4 of 7 testing personnel (MD (medical doctor) #1, MD #2, MD #3, TP (testing personnel) #1) were evaluated annually for competency in reading and reporting potassium hydroxide (KOH) preparations and dermatophyte test media agar (DTM) cultures in 2019 and 2020. The findings were: 1. Review of patient test records and review of the laboratory's testing log showed the initials of the testing personnel reporting KOH and DTM test results included MD #1, MD #2, MD #3, and TP #1. 2. Review of the laboratory's documentation showed no evidence MD #1, MD #2, and MD #3 had been evaluated for competency in 2019 or 2020. Review of the competency evaluations for TP #1 showed no evidence a competency evaluation had been completed in 2020. 3. Interview with the office manager on 6/23/21 at 3:30 PM revealed she was unaware annual competency evaluations were required for physicians performing moderate complexity testing and confirmed the evaluations had not been completed. Interview with the laboratory director on 6/23/21 at 4:20 PM revealed the laboratory had reviewed DTM culture and KOH preparation testing for competency through peer review, however the laboratory had not documented the results. This is a repeat deficiency.