Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0954636	04/04/2018
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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on patient test requests review, accession log review, lack of documentation, and interview with staff, the laboratory failed to document the specimen date and time of receipt from off-site clinics. The laboratory received 13 of 22 specimens reviewed from clinic visits from Gillette, Riverton, Thermopolis, and Rawlins without recording the time specimens were received into the laboratory. Findings include: 1. Patient test requests included the date the specimens were collected at the off-site clinics. The laboratory accession log recorded the date specimens were accessioned into the laboratory test system. 2. The laboratory failed to document the date and time the specimens arrived at the laboratory from the off-site clinics. 3. In an interview with staff on 04/04/2018 at approximately 12:30 P.M., staff stated that specimens were returned to the laboraotry when staff returned from the clinic visits. Laboratory staff accessioned specimens the next working day as the date specimens were received.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to

	ensure they provided written instructions to one client sending referral specimens for histopathology processing and diagnosis. Findings include: 1. The laboratory lacked a copy of written instructions provided for histopathology specimen collection, preservation and transportation of specimens sent from one laboratory located in Colorado referring specimens for testing. The number of specimens received was not determined. 2. In an interview conducted on 04/04/2018 at approximately 10:45 A.M., staff stated the laboratory received referral specimens from one laboratory. Staff also confirmed they did not have written instructions available to provide to the referral laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on package insert review, lack of documentation, and interview with staff the laboratory failed to ensure Dermatophyte Test Media (DTM) incubation temperature ranges were maintained during the two week incubation period for culture media for 2 years of testing reviewed (April 2016 to April 2018). The laboratory tested approximately 5 to 10 cultures per month. Findings include: 1. DTM package inserts state media incubation range is at a room temperature range of 65 to 75 degrees F. 2. The laboratory failed to document the culture's room temperature incubation temperature was monitored to ensure the cultures were incubated within the DTM manufacturer's instructions. 3. In an interview conducted on 04/04/2018 at approximately 12:00 noon, staff confirmed they did not monitor the temperature of the room where cultures were incubated for up to two weeks for determination of presence or absence of dermatophytes.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on media quality control records review and interview with staff, the laboratory failed to check the sterililty of each new lot number or shipment of dermatophyte test media (DTM) for two years of mycology test records reviewed. The laboratory performed approximately 10 cultures per month. Findings include: 1. DTM quality

	control record review failed to include documentation the laboratory checked each new lot number of media to verify media sterility prior to patient specimen inoculation for media received from April 2016 to April 2018. The laboratory received approximately 2 media shipments per year. 2. In an interview with staff on 04 /04/2018 at approximately 11:00 A.M., staff confirmed sterility checks were not performed for media shipments received from April 2016 to April 2018.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on patient test reports review and interview with staff, the laboratory failed to ensure the laboraotry test system had a signature system to ensure the electronic signature on histopathology test reports reviewed from 05/06/2016 to 03/02/2018 were accessible only to personnel that qualified as histopathology diagnostic personnel. Findings include: 1. Test reports reviewed for 16MG-0339, 16SB-0703, 16SB-100, 16MG-05271, 16MG-0926, 17SB-0028, 17SB-0414, 17SB-0263, 17SB-0619, 17SB-0860, 17SB-0028, 17MG-0261, 17MG-0550, and 17MG-0728, included a type printed note the histopathology microscopic diagnosis report was electronically signed by the director and the technical supervisor by name without a time stamp, followed by another signature of a staff member that did have an electronic timestamp who was not qualified to sign histopathology test reports. 2. In an interview with staff on 04/04/2018 at approximately 2:00 P.M., staff confirmed the reporting system prior to January 2018 failed to ensure the test reports were signed using password protected electronic signature available only to personnel qualified to sign histopathology microscopic test reports. THIS IS A REPEAT DEFICIENCY.