

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0954636	(X3) Date Survey Completed 01/30/2020
Name of Provider or Supplier Central Wyoming Skin Clinic	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to verify dermatophyte culture and histopathology testing at least twice a year for 2 of 2 years of testing reviewed, (2018 and 2019). The laboratory performed approximately 20 dermatophyte test media (DTM) cultures and 2700 histopathology biopsy and frozen section tests per year. Findings include: 1. The laboratory failed to document they verified the accuracy of dermatophyte presence or absence by culture using media with chloramphenicol and gentamicin for inhibition of bacterial contaminants and red color indicator, Dermatophyte Test Media (DTM), for dermatophyte presence or absence at least twice a year in 2018 and 2019. 2. The laboratory failed to document histopathology biopsy and Mohs surgery frozen section specimens diagnostic test accuracy was verified at least twice annually in 2018 and 2019. 3. In an interview conducted on 01/30/2020 at approximately 3:45 P.M., staff stated they failed to document histopathology cases sent to reference laboratories for test accuracy verification and failed to verify DTM culture accuracy at least twice a year in 2018 and 2019.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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</p>

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 lack of documentation and interview with staff, the laboratory director failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of histopathology and mycology testing to assure they are competent and maintain their competency to perform and report tests results promptly and proficiently for 2 of 2 test systems, mycology culture, and potassium hydroxide (KOH) tests for two of two testing personnel, and for histopathology diagnosis for one testing person. Findings include:

1. The laboratory lacked a procedure to monitor and document that testing personnel were competent to perform dermatophyte test media culture interpretation, KOH slide interpretation for the presence or absence of fungal elements for two testing persons, and for histopathology biopsy diagnosis of skin pathology and frozen section slide interpretation for the presence or absence of previously diagnosed tumor cells for one person.
2. In an interview on 01/30/2020 at approximately 3:30 P.M., the laboratory director confirmed the laboratory did not have a policy and procedure for professional testing personnel competency.