

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0672466	(X3) Date Survey Completed 02/03/2022
Name of Provider or Supplier Monument Health Dermatology	Street Address, City, State 4150 5th St, Rapid City, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 2/3/22. The Monument Health Dermatology laboratory was found not in compliance with the following requirement: D5217.
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 record review and interview, the laboratory failed to verify and document the accuracy of one of four test methods reviewed (scabies examination) twice a year for thirteen of thirteen months reviewed (January 2021 through January 2022). This verification would have ensured the accuracy of the direct examination of patient specimens for the presence of scabies. Findings include: 1. Review on 2/3/22 of the laboratory's quarterly accuracy verification report revealed there had been no documentation the accuracy of the scabies examination test method had been verified twice a year for the time frame above. No other documentation of a verification of accuracy for 2021 had been available. Review of the laboratory's policy manual revealed: *The Scabies Prep policy, signed by the laboratory director January 2022, did not contain documentation of the necessity of the twice yearly verification of accuracy. *The Quality Assessment policy, signed by the laboratory director January 2022, did not contain documentation of the necessity of the twice yearly verification of accuracy for the scabies examination test method. *The laboratory did not have a separate policy regarding the twice yearly verification of the accuracy of test methods available for review at the time of the survey. Review of the laboratory test count form revealed thirteen patient scabies examination specimens had been reported in 2021 without verification of the test method's accuracy. Interview on 2/3/22 at 9:05 a. m. with laboratory personnel A revealed: *The twice yearly verification of accuracy</p>

for the scabies examination test method had not been completed in 2021. *In previous years, a second provider had reviewed the patient's scabies examination slides to ensure the accuracy of the test method. *There had been a large turnover in staff during the last year. *The new staff were not aware of the necessity of the twice yearly accuracy verification.