Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2123371	03/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Avera Medical Group - Pierre Mohs Laboratory	The Helmsley Center, Pierre, 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 3/30/21. The Avera Medical Group - Pierre Mohs Laboratory was found not in compliance with the following requirements: D2000, D2011, D2013, D6076, and D6089.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records, the American Academy of Family Physicians (AAFP) 2021 PT catalog, the laboratory's procedure manual, and interview, the laboratory failed to implement policies to ensure the laboratory did not engage in inter-laboratory communication regarding PT prior to the cutoff date for submission of PT results for one of one PT event (AAFP 2021-A). This failure resulted in PT specimens being referred to another laboratory for evaluation. Refer to D2011 and D2013.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any

	inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, the American Academy of Family Physicians (AAFP) 2021 PT catalog, the Centers for Medicare and Medicaid Services (CMS) form 209, the laboratory's procedure manual, and interview, the laboratory failed to implement policies to ensure the laboratory did not engage in inter-laboratory communication regarding PT prior to the cutoff date for submission of PT results for one of one PT event (AAFP 2021-A). Findings include: 1. Review of the PT records revealed: *Avera Medical Group - Dermatology located in Sioux Falls, South Dakota (SD) had subscribed to KOH [potassium hydroxide] (glass slides)-2 specimens (KOH) PT program through AAFP. *Avera Medical Group - Pierre Mohs Laboratory located in Pierre, SD had not subscribed to a PT program. *Records of the 2021-A KOH (glass slides)-2 specimens (KOH) PT event contained results for PT specimens one and two reported by the laboratory director and physician A completed on 3/24/21. Review of the AAFP 2021 PT catalog shipment schedule revealed the cutoff date for submission of results for the KOH (glass slides)-2 specimen (KOH) 2021- A PT event was 3/24/21. Review of the CMS form 209 revealed the laboratory director and physician A were designated as testing personnel. Review of the laboratory's procedure manual on 3/30/21 revealed the facility did not have a policy or procedure for the processing of PT specimens. Interview on 3/30/21 at 9:40 a.m. with laboratory personnel B revealed: *The Avera Medical Group- Pierre Mohs laboratory and the Avera Medical Group- Dermatology laboratory were part of the same health facility group. *She worked primarily in the Avera Medical Group- Dermatology laboratory. *She traveled to the Avera Medical Group- Pierre Mohs laboratory three times a month to process Mohs surgical specimens. *She confirmed she had hand carried the 2021-A KOH (glass slides)-2 specimen KOH PT event specimens from the Avera Medical Group- Dermatology laboratory to the Avera Medical Group- Pierre Mohs laboratory on 3/24/21 for the laboratory director and physician A to examine and report. The laboratory director was unavailable for interview at the time of the survey.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to

	alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, the American Academy of Family Physicians (AAFP) 2021 PT catalog, the laboratory's procedure manual, and interview, the laboratory failed to implement policies to ensure the laboratory notified the Centers for Medicare and Medicaid Services (CMS) of PT specimens received from another laboratory for one of one PT event (AAFP 2021-A). Findings include: 1. Review of the PT records revealed: *Avera Medical Group - Dermatology laboratory located in Sioux Falls, South Dakota (SD) had subscribed to the KOH [potassium hydroxide] (glass slides)-2 specimens (KOH) PT program through AAFP. *Avera Medical Group - Pierre Mohs Laboratory located in Pierre, SD had not subscribed to a PT program. *Records of the 2021-A KOH (glass slides)-2 specimens (KOH) PT event contained results for PT specimens one and two reported by the laboratory director and physician A on 3/24/21. *There was no documentation that CMS had been notified of the receipt of PT specimens from another laboratory. Review of the AAFP 2021 PT catalog shipment schedule revealed the cutoff date for submission of results for the KOH (glass slides)-2 specimen (KOH) 2021- A PT event was 3/24/21. Review of the laboratory's procedure manual on 3/30/21 revealed the facility did not have a policy or procedure for the processing of PT specimens. Interview on 3/30/21 at 9:40 a.m. with laboratory personnel B revealed: *She confirmed she had hand carried the 2021-A KOH (glass slides)-2 specimen KOH PT event specimens from the Avera Medical Group - Dermatology laboratory to the Avera Medical Group - Pierre Mohs Laboratory on 3/24/21 for the laboratory director and physician A to examine and report. The laboratory director was unavailable for interview at the time of the survey.
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 (PT) records, the American Academy of Family Physicians (AAFP) 2021 PT catalog, the laboratory's procedure manual, and interview, the laboratory director failed to ensure policies had been implemented to ensure the laboratory followed the CLIA regulations concerning PT for one of one PT event (AAFP 2021-A). This failure resulted in PT specimens being referred to another laboratory for testing. Refer to D6089.
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 (PT) records, the American Academy of Family Physicians (AAFP) 2021 PT catalog, the laboratory's procedure manual, and interview with laboratory personnel B, the laboratory director failed to ensure policies had been implemented to ensure the laboratory followed the CLIA regulations concerning PT for one of one PT event (AAFP 2021-A). Findings include: 1. Review of the PT records revealed: *Avera Medical Group - Dermatology laboratory located in Sioux Falls, South Dakota (SD) had subscribed to KOH [potassium hydroxide] (glass slides)-2 specimens (KOH) PT program through AAFP. *Avera Medical Group - Pierre Mohs Laboratory located in Pierre, SD had not subscribed to a PT program. *Records of the 2021-A KOH (glass slides)-2 specimens (KOH) PT event contained results for PT specimens one and two reported by the laboratory director and physician A on 3/24/21. *There was no documentation that CMS had been notified of the receipt of PT specimens from another laboratory. Review of the AAFP 2021 PT catalog shipment schedule revealed the cutoff date for submission of results for the KOH (glass slides)-2 specimen (KOH) 2021- A PT event was 3/24/21. Review of the laboratory's procedure manual on 3/30/21 revealed the facility did not have a policy or procedure for the processing of PT specimens. Interview on 3/30/21 at 9:40 a.m. with laboratory personnel B revealed: *She confirmed she had hand carried the 2021-A KOH (glass slides)-2 specimen KOH PT event specimens from the Avera Medical Group - Dermatology laboratory to the Avera Medical Group - Pierre Mohs Laboratory on 3/24/21 for the laboratory director and physician A to examine and report. The laboratory director was unavailable for interview at the time of the survey.