Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407150	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Avera Medical Group - Dermatology	6701 S Minnesota Avenue, Sioux Falls, 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 4/20/2021. The Avera Medical Group - Dermatology laboratory was found not in compliance with the following requirements: D2000, D2011, D2013, D5209, 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.
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 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. *The cutoff date to submit results for the 2021-A-KOH (glass slides)-2 specimen KOH PT event was 3/24/2021. Review of the laboratory's procedure manual revealed the facility did not have a PT policy on 3/24/21. Interview on 4/20/21 at 1:50 p.m. with laboratory personnel A 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 physicians B and C to examine and report. Interview on 4/20/21 at 3:30 p.m. with the laboratory director revealed the laboratory had developed a new PT procedure and would be following that procedure in the future.
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. 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, laboratory records, annual test volume form, and interview the laboratory failed to establish written policies and procedures to assess the competency of testing personnel to perform preanalytical, analytical and postanalytical tasks in 2019, 2020, and to the date of the survey in 2021. Findings include: 1. Review of the annual test volume form revealed the laboratory performed non-waived Bhcg (pregnancy test), potassium hydroxide (KOH) skin preparations and dermatopathology testing. Review of the laboratory records revealed competency assessments had been performed for testing personnel in 2019 and 2020. Review of the laboratory procedure manual revealed no competency assessment procedure. Interview on 4/20/21 at 3:30 p.m. with laboratory personnel A revealed: *She confirmed that there was no written procedure for competency assessment. *She was not aware the laboratory needed to have a written policy as the competency assessments had been completed on a yearly basis. *Proficiency testing specimen review was a part of the competency assessment process. *She ensured all staff at both the Avera Medical Group - Dermatology and the Avera Medical Group - Pierre Mohs Laboratory participated in proficiency testing on a annual basis as part of the competency assessment process. Interview on 4/20/21 at 3:30 p.m. with the laboratory director revealed he was unaware a written policy for competency assessment of testing personnel was required.
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, 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. *There was no documentation that CMS had been notified of the transportation of PT specimens to another laboratory for examination and reporting. Review of the laboratory's procedure manual on 4/20/21 revealed the facility did have a policy, Procedure For Handing Out AAFP Proficiency Testing, signed by the laboratory director on 4/1/2021. Interview on 4/20/21 at 1:50 p. m. with laboratory personnel A 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 physicians B and C to report on 3/24/21. *A new PT policy had been instituted, signed by the laboratory director on 4/1/2021. Per the new policy, PT specimens would not be referred to the Avera Medical Group - Pierre Moh's laboratory until after the cutoff for submission date. Interview on 4/20/21 at 3:30 p.m. with the laboratory director revealed: *He was not aware PT specimens could not be examined by multiple personnel or at mulitiple sites prior to the cutoff date for submission of results. *The laboratory had developed a new PT procedure and would be following that procedure in the future.