

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407438	(X3) Date Survey Completed 09/16/2019
Name of Provider or Supplier Avera Grassland Diagnostic	Street Address, City, State 1900 Grassland Drive, Mitchell, 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 9/16/19. The Avera Grassland Diagnostic laboratory was found not in compliance with the following requirements: D6028, D6051, and D6052.
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on review of employee files, the CMS 209 Laboratory Personnel Report Form, policy review, and interview with the laboratory director, the laboratory director failed to ensure competency evaluations for eight of twelve laboratory staff (B, C, D, E, F, G, H, and I) were completed by qualified personnel for the nonwaived test methods they performed under the laboratory's certificate. Findings include: 1. Review of employees' files for laboratory staff revealed: * Laboratory staff B had a competency evaluation performed on 6/28/18 and 6/25/19. * Laboratory staff C had a competency evaluation performed on 8/2/18, 2/13/19 and 8/22/19. * Laboratory staff D had a competency evaluation performed on 3/13/19. * Laboratory staff E had a competency evaluation performed on 9/12/18 and 3/21/19. * Laboratory staff F had a competency evaluation performed on 5/1/19. * Laboratory staff G had a competency evaluation performed on 10/23/17 and 10/23/18. * Laboratory staff H had a competency evaluation performed on 12/12/18 and 6/6/19. * Laboratory staff I had a competency</p>

evaluation performed on 3/19/18 and 9/24/18. The above competency evaluations had been conducted and signed by laboratory staff A (B) and laboratory staff B (C, D, E, F, G, H, and I). There was no indication the laboratory director was involved in the competency assessment process. Review of the the CMS 209 Laboratory Personnel Report Form signed by the laboratory director on 7/17/19 revealed the laboratory director was also serving as the technical consultant. Laboratory staff A and B had been listed as testing personnel and not listed as technical consultants. Review of the Associate Evaluation and Competency policy, last revised 3/17 and reviewed by the laboratory director on 2/26/19, revealed: *F. The attached form (competency assessment form) will be utilized when completing competency assessments. It will be signed by the reviewer, a technical consultant, and the laboratory director. Interview on 9/16/19 at 3:00 p.m. with the laboratory director revealed she was not aware laboratory staff A and B were not qualified to perform employee competencies.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of personnel competency records, policy review, and interview with laboratory staff B and the laboratory director, the technical consultant failed to ensure annual competency assessments included assessment of test performance through previously analyzed specimens for eight of twelve laboratory staff (B, C, D, E, F, G, H, and I). Findings include: Review of employees' files for laboratory staff revealed: * Laboratory staff B had a competency evaluation performed on 6/25/19. * Laboratory staff C had a competency evaluation performed on 8/2/18 and 8/22/19. * Laboratory staff D had a competency evaluation performed on 3/13/19. * Laboratory staff E had a competency evaluation performed on 3/21/19. * Laboratory staff F had a competency evaluation performed on 5/1/19. * Laboratory staff G had a competency evaluation performed on 10/23/17 and 10/23/18. * Laboratory staff H had a competency evaluation performed on 12/12/18 and 6/6/19. * Laboratory staff I had a competency evaluation performed on 9/24/18. a. The above competency assessment forms did not include the assessment of test performance through previously analyzed specimens to ensure the proper performance and resulting of patient specimens. b. The column designated as Assayed Test Performance by PT (proficiency testing) or Blind Sample Review had been left blank on the above competency assessments. c. The above competencies had been completed and signed by laboratory staff A (B) and laboratory staff B (C, D, E, F, G, H, and I). There was no indication the technical consultant had performed the above competencies. Review of the Associate Evaluation and Competency policy, last revised 3/17 and last reviewed by the laboratory director on 2/26/19, revealed: *D. Items to be included in each one of the above categories include: - Direct observation of properly performing task. - Review of the records and reporting of results. - Reviewing documentation, QC (quality control), PT, PMs (preventative maintenance), etc. - Directly observing calibrations, PMs, and other function checks - Performance of proficiency testing. - Assessment of trouble shooting skills. Interview with laboratory staff B on 9/16/19 at 3:00 p.m. revealed she was not aware it was necessary to document the assessment of testing previously analyzed specimens as part of the competency assessment. Interview with the laboratory director at the above time revealed she was not aware the assessment of

testing previously analyzed specimens had not been documented on the competency assessments.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of personnel competency records, policy review, interview with laboratory staff B and the laboratory director, the technical consultant failed to ensure annual competency assessments included assessment of problem solving skills for eight of twelve laboratory staff (B, C, D, E, F, G, H, and I). Findings include: Review of employees' files for laboratory staff revealed: * Laboratory staff B had a competency evaluation performed on 6/28/18 and 6/25/19. * Laboratory staff C had a competency evaluation performed on 8/2/18 and 8/22/19. * Laboratory staff D had a competency evaluation performed on 9/2/18 and 3/13/19. * Laboratory staff E had a competency evaluation performed on 9/12/18 and 3/21/19. * Laboratory staff F had a competency evaluation performed on 5/1/19. * Laboratory staff G had a competency evaluation performed on 10/23/17 and 10/23/18. * Laboratory staff H had a competency evaluation performed on 12/12/18 and 6/6/19. * Laboratory staff I had a competency evaluation performed on 9/24/18. a. The above competency assessment forms did not include the assessment of problem solving skills related to the performance of laboratory testing. b. The column designated as Assessed Problem Solving Skills had been left blank on the above competency assessments. c. The above competencies had been completed and signed by laboratory staff A (B) and laboratory staff B (C, D, E, F, G, H and I). There was no indication the technical consultant had performed the above competencies. Review of the Associate Evaluation and Competency policy, last revised 3/17 and reviewed by the laboratory director on 2/26/19, revealed: *D. Items to be included in each one of the above categories include: - Direct observation of properly performing task. - Review of the records and reporting of results. - Reviewing documentation, QC (quality control), PT, PMs (preventative maintenance), etc. - Directly observing calibrations, PMs, and other function checks - Performance of proficiency testing. - Assessment of trouble shooting skills. Interview with laboratory staff B on 9/16/19 at 3:00 p.m. revealed she was not aware it was necessary to document the assessment of problem solving skills on the competency assessments. Interview with the laboratory director at the above time revealed she was not aware the assessment of problem solving skills had not been documented on the competency assessments.