

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410743	(X3) Date Survey Completed 08/28/2024
Name of Provider or Supplier Madison Valley Medical Center	Street Address, City, State 305 North Main Street, Ennis, MT	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of American Proficiency Institute records and an interview with the technical supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for partial thromboplastin time (APTT) for two out of three testing events and urine susceptibility testing for two consecutive events, resulting in unsuccessful proficiency testing performance. (See D2028 and D2130).</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p>

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of American Proficiency Institute (API) records and an interview with the technical supervisor (TS) #1, the laboratory failed to achieve a score of at least 80% for two consecutive events for urine susceptibility testing using agar disk diffusion. Findings: 1. A review of the API susceptibility testing (urine) proficiency testing scores revealed that in 2024, the 1st Event scored 67%, and the 2nd Event scored 50%. 2. An interview with TS #1 on August 28, 2024, at 10:35 AM confirmed the laboratory failed to achieve successful performance for susceptibility testing (urine) for Events 1 and 2 in 2024.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of American Proficiency Institute (API) records and an interview with the technical supervisor (TS) #1, the laboratory failed to achieve a score of at least 80% for two out of three testing events for partial thromboplastin time (APTT) performed on the Diagnostica Stago ST4 Coagulation Analyzer. Findings: 1. A review of the API partial thromboplastin time (APTT) proficiency testing scores revealed that in 2023, the 3rd Event scored 20%, and in 2024, the 2nd Event scored 20%. 2. An interview with TS #1 on August 28, 2024, at 10:30 AM confirmed the laboratory's failed APTT proficiency scores for the 2023 3rd Event and the 2024 2nd Event were due to calculation errors.

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 a record review and an interview with the technical supervisor (TS) #1, the laboratory failed to establish a procedure and perform competency assessments for the technical supervisor and general supervisor listed on the CMS-209 Personnel Report form from August 28, 2022, to August 28, 2024 and failed to follow their procedure to assess eleven out of fourteen testing personnel annually for 2023 and assess three out of six new hires prior to patient testing and/or at six months. Findings: 1. A review of the CMS-209 Personnel Report Form revealed one personnel listed as general supervisor and technical supervisor and lacked a competency assessment based on the position responsibilities from August 28, 2022, to August 28, 2024. 2. A review of the Annual Competency Review procedure lacked the frequency of the technical supervisor and general supervisor competency assessment based on their federal

regulatory responsibilities and failed to list the six required procedures as part of their annual competency for testing personnel. 3. The laboratory failed to follow their Annual Competency Review procedure to either assess new hires prior to patient testing and/or perform an assessment at 6-months of hire for three out of six laboratory testing personnel (TP) (TP# 13, 16, and 17). 4. A review of testing personnel (TP) files lacked documentation of annual competency for year 2023 for eleven out of fourteen testing personnel (TP# 5, 6, 7, 8, 9, 10, 11, 14, 15, 18, and 19) as required by their Annual Competency Review procedure. 5. An interview with TS #1 on August 28, 2024, at 9:15 AM confirmed the laboratory failed to follow their procedure to perform initial, 6-month assessments on new hires and annual competency assessments for year 2023 and lacked a procedure to perform and assess the technical supervisor and general supervisor based on the position responsibilities from August 28, 2022, to August 28, 2024.