

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2111952	(X3) Date Survey Completed 08/19/2024
Name of Provider or Supplier Grand Ave Urgent Care	Street Address, City, State 3236 E Grand Ave, Suite D, Laramie, WY	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to ensure the individual testing the proficiency samples and the laboratory director attested to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 3 of 5 proficiency testing events reviewed from February 2023 through July 2024. The findings were: 1. Review of the 2023 API Chemistry Core Event #3, 2024 Chemistry Core Event #1, and 2024 Chemistry Core Event #2 records showed the testing personnel and laboratory director failed to sign the attestation statements. 2. Interview with the clinic manager on 8/19/24 at 10:38 AM confirmed no further documentation was available. .</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, staff interview, and policy and procedure review, the laboratory failed to maintain a copy of each step in the testing and reporting of the API (American Proficiency Institute) proficiency samples for 3 out of 5 proficiency testing events reviewed from February 2023 through July 2024. The findings were: 1. Review of the API 2023 Chemistry Core Event #3, 2024 Chemistry Core Event #1, and the 2024 Chemistry Core Event #2 proficiency testing events failed to include the attestation statement, data submission forms, the performance summary, the comparative evaluation, and the laboratory director's signed performance evaluation form. 2. Interview with the clinic manager on 8/19/24 at 10:38 AM revealed she was unable to locate any additional documentation and confirmed the proficiency testing records were incomplete. 3. Review of the Proficiency Testing Standard Operating Procedure, with an origination date of 3/30/22, showed "...2. General Guidelines...2.3 Upon receipt of any proficiency testing materials, they should be inspected to ensure that all expected materials were received. They should then be stored according to the instructions included with the package. 2.4 PT specimens should be processed and analyzed according to patient specimen protocols throughout the process. Specimens will be rotated amongst all staff performing testing...2.6 The Laboratory Supervisor will review the data sheet and inspect the worksheets for any transcription errors. 2.7 The Laboratory Director or designee and any staff performing testing should sign and date 2.8 A copy of any data sheets, worksheets, and instrument printouts should be retained for two years in the designated Proficiency Testing binder...4. Assessment of the Proficiency Testing Report...The Laboratory Supervisor and testing personnel should review PT scores, and if all are satisfactory, the forms are signed and dated. The Laboratory Director and testing personnel must sign the forms as reviewed and reports are kept in the Proficiency Testing Manual..." .

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of documentation and staff interview, the laboratory failed to retain the quality control data for the analytes Troponin I and D-dimer performed on the Quidel Triage instrument from January 2023 until February 2024. The laboratory performed approximately 730 D-dimer and 730 Troponin I patient tests per year. The findings were: 1. Review of the laboratory's quality control documentation showed no evidence quality control had been performed between January 2023 until February 2024. 2. Interview with the clinic manager on 8/19/24 at 11:35 AM confirmed no further documentation was available. .

D5200

GENERAL LABORATORY SYSTEMS

CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of personnel files, review of the Centers for Medicare and Medicaid Services 209 Personnel Report, review of policy and procedure, lack of documentation, review of proficiency testing records, procedure manual review, and staff interview, the laboratory failed to complete the required competency assessments (D5209), failed to review and evaluate proficiency testing results (D5211), and failed to monitor, assess, and correct problems in the general laboratory system (D5291).

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 review of personnel files, review of the Centers for Medicare and Medicaid Services 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the laboratory failed to complete competency assessments for 3 of 3 testing personnel (TP #1, TP #2, TP #3) as required for 18 months reviewed from March 2023 through July 2024. The findings were: 1. Review of the laboratory's personnel files showed the following concerns: a. Review of the personnel file for TP #1 showed an initial competency assessment was completed on 8/30/22. There was no evidence the laboratory had completed any subsequent assessments. b. Review of the personnel file for TP #2 showed an unsigned and undated quiz related to the Quidel Triage analyzer. Interview with the clinic manager on 8/19/24 at 11:44 AM revealed TP #2's date of hire was 11/15/23. There was no evidence the laboratory had completed any of the required competency assessments. c. Review of the personnel file for TP #3 showed an unsigned and undated quiz related to the Quidel Triage analyzer. Interview with the clinic manager on 8/19/24 at 11:44 AM revealed TP #3's date of hire was 12/21/23. There was no evidence the laboratory had completed any of the required competency assessments. 2. Interview with the clinic manager on 8/19/24 at 11:44 AM confirmed no further documentation was available. 3. Review of the Personnel Training Plan Policy with an origination date of 3/30/22 showed "...3. Training and Competency... Personnel will be trained upon hire, and when new tests or processes are brought into the laboratory. This will be documented in their personnel binders. Personnel must be evaluated for competency in all of their respective duties initially, after the first 6 months, then annually thereafter. Competency will be evaluated in a minimum of four categories: Problem solving, Performing Quality Control, Processing Patient Specimens, and Proficiency testing (or other blind specimens)." .

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, staff interview, and policy and procedure review, the laboratory failed to review and evaluate proficiency testing results for 4 of 5 testing events reviewed from February 2023 through July 2024. The findings were: 1. Review of the American Proficiency Institute proficiency testing (PT) documentation failed to include documentation the laboratory had reviewed and evaluated the PT results for the following events: a. 2023 Chemistry Core Event #1 b. 2023 Chemistry Core Event #3 c. 2024 Chemistry Core Event #1 d. 2024 Chemistry Core Event #2 2. Interview with the clinic manager on 8/19/24 at 10:38 AM revealed she was unable to locate any additional documentation and confirmed the proficiency testing documentation was incomplete. 3. Review of the Proficiency Testing Standard Operating Procedure with an origination date of 3/30/22 showed "...The Laboratory Supervisor and testing personnel should review PT scores, and if all are satisfactory, the forms are signed and dated. The Laboratory Director and testing personnel must sign the forms as reviewed and reports are kept in the Proficiency Testing Manual..." .

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on procedure manual review, lack of documentation, and staff interview, the laboratory failed to establish a quality assessment plan for general laboratory, pre-analytic, and post-analytic systems for the Quidel Triage test system for the analytes of D-dimer and Troponin I. The laboratory estimated it would perform approximately 730 D-dimer and 730 Troponin I patient tests per year. The findings were: 1. Review of the laboratory's records showed no evidence an ongoing quality assessment program was in place which included the items the laboratory reviewed, the frequency of the review, and the method used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, and specimen labeling. c. Analytic tasks which include review of quality control and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the clinic manager on 8/19/24 at 11:35 AM confirmed no further documentation was available. .

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	<p>This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services)-116 form, procedure manual review, and staff interview, the current laboratory director failed to sign, and date as approved, 8 out of 12 policies and procedures (Standard Operating Procedures, FDA Adverse Event Reporting, Reportable Pathogens Policy, Personnel Job Description, Personnel Training Plan, IQCP policy, Proficiency Testing policies, Delegation of Duties) reviewed. The findings were: 1. Review of the CMS-116 form showed a change of the laboratory director, effective 5/9/23, was approved on 5/15/23. 2. Review of the laboratory's procedure manual showed 8 out of 12 policies and procedures reviewed had not been signed by the current laboratory director. 3. Interview with the clinic manager on 8/19/24 at 11:35 AM confirmed the procedures had not been signed by the current laboratory director. .</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on Review of the CMS (Centers for Medicare and Medicaid Services)-209 Laboratory Personnel Report, review of the laboratory's records, review of proficiency testing records, review of policy and procedures, personnel file review, and staff interview, the laboratory director failed to attest to the routine integration of the American Proficiency Institute proficiency tests into the patient workload (D6016), failed to review and evaluate proficiency testing results (D6018), failed to establish a quality assessment plan (D6021), failed to ensure competency assessments were completed as required (D6029), and failed to sign and date as approved the laboratory's policy and procedures (D6031). .</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of the American Proficiency Institute proficiency tests into the patient workload for 3 of 5 proficiency testing events reviewed from February 2023 through July 2024. Refer to D2009. .</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute proficiency testing records, staff interview, and policy and procedure review, the laboratory director failed to review and evaluate proficiency testing results for 4 of 5 testing events reviewed from February 2023 through July 2024. Refer to D5211. .

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on procedure manual review, lack of documentation, and staff interview, the laboratory director failed to establish a quality assessment plan for general laboratory, pre-analytic, and post-analytic systems for the Quidel Triage test system for the analytes of D-dimer and Troponin I. The laboratory estimated it would perform approximately 730 D-dimer and 730 Troponin I patient tests per year. Refer to D5291. .

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel files, review of the Centers for Medicare and Medicaid Services 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the laboratory director failed to ensure competency assessments for 3 of 3 testing personnel (TP #1, TP #2, TP #3) were performed, as

required, for 18 months reviewed from March 2023 through July 2024. Refer to D5209. .

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services 116 form, procedure manual review, and staff interview, the current laboratory director failed to sign, and date as approved 8 out of 12 policies and procedures (Standard Operating Procedures, FDA Adverse Event Reporting, Reportable Pathogens Policy, Personnel Job Description, Personnel Training Plan, IQCP policy, Proficiency Testing policies, Delegation of Duties) reviewed. Refer to D5407. .

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on lack of documentation and staff interview, the laboratory failed to employ one or more individuals who were qualified by education and either training or experience to provide technical consultation for moderate complexity laboratory testing (D6034). .

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on lack of documentation and staff interview, the laboratory failed to employ one or more individuals who were qualified by education and either training or experience to provide technical consultation for moderate complexity laboratory testing. The findings were: 1. Review of the laboratory's records failed to show evidence a technical consultant was employed. 2. Interview with the clinic manager

on 8/19/24 at 11:45 AM confirmed the laboratory did not have a technical consultant.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on lack of documentation, review of the Centers for Medicare and Medicaid Services 209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure testing personnel met the qualifications to perform moderate complexity laboratory testing (D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on lack of documentation, review of the Centers for Medicaid and Medicare Services 209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure 2 of 3 testing personnel (TP #2, TP #3) met the qualifications to perform moderate complexity laboratory testing. The findings were: 1. Review of the laboratory's records failed to show evidence TP #2 and TP #3 were qualified to perform moderate complexity testing. 2. Interview with the laboratory manager on 8/19/24 at 11:45 AM confirmed documentation of the testing personnel's qualifications was not available.