

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0663011	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Grover C Dils Medical Center	Street Address, City, State 700 N Spring Street, Caliente, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 5, 2026. The findings and conclusions of any investigation by the Division of Healthcare Purchasing and Compliance shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of instrument printouts and laboratory records for American Proficiency Institute (API) Proficiency Testing (PT) 2025 Chemistry Core test events two and three, API PT 2026 Chemistry Core test event one, an interview with the laboratory supervisor on August 5, 2026, at approximately 12:00 PM, email correspondence received from the laboratory supervisor on August 18, 2026, at 12:12 PM PDT, and a telephone conversation on August 21, 2026, at approximately 9:45 AM PDT, the laboratory failed to ensure that proficiency testing specimens were tested in the same manner as patient samples for test results outside the assay range for High Sensitivity Troponin I (TNHI) for three of the six test events reviewed. Findings include: 1. The laboratory supervisor indicated that proficiency testing

specimens are not diluted when results exceed the assay's upper range, and that patient specimens are diluted when High Sensitivity Troponin I results fall above the upper limit of the assay's analytical measurement range (AMR) (4.0 - 25,000 pg/mL). 2. The printouts revealed an error code of "assay range" indicating that the results were outside of the analytical measurement range of the instrument for TNHI. The laboratory failed to resolve the error code for the following proficiency test events: a. The laboratory reported TNHI results of 27,000 pg/mL for 2025 API Chemistry Core Event 2 sample CM-06. The instrument print outs indicated results of 27.298 ng/mL or 27,298 pg/mL which is above the AMR. b. The laboratory reported TNHI results of 69,816 pg/mL for 2025 API Chemistry Core Event 3 sample CM-12. The instrument print outs indicated results of 69.816 ng/mL or 69,816 pg/mL which is above the AMR. c. After receiving the PT evaluation, the laboratory re-ran sample CM-12 and obtained a result of 35.857 ng/mL (35,857 pg/mL) with the same ' assay range ' error code. The laboratory did not correct the error code or document any dilutions performed. d. The laboratory reported TNHI results of 34,283 pg/mL for 2026 API Chemistry Core Event 1 sample CM-01. The instrument print outs indicated results of 34.283 ng/mL or 34,283 pg/mL which is above the AMR. 3. There was no documentation of dilution and re-running of the PT samples with the Troponin I (CTNI) diluent in accordance with the manufacturer's instructions prior to reporting the results, as the laboratory indicated they did with patient samples. 4. The laboratory supervisor confirmed during an interview conducted on August 5, 2026, at approximately 11:45 AM that the High Sensitivity Troponin I PT results outside the high end of the analytical range were not manually diluted and repeated to ensure that the results were accurate and reliable. 5. The laboratory supervisor confirmed via email correspondence received on August 18, 2026, at 12:12 pm PDT, and during a telephone conversation on August 21, 2026, at approximately 9:45 am PDT that PT specimens are not diluted if they are outside the assay range high prior to reporting the results to API. The supervisor stated in both the email correspondence and during the telephone conversation that patient specimens are diluted when the High Sensitivity Troponin I results are outside the upper end of the assay range. According to the submitted CMS-116 form, the laboratory performs 5,835 chemistry tests annually.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

(a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of manufacturer ' s instructions, instrument printouts and laboratory records for the American Proficiency Institute (API) Proficiency Testing (PT) 2024 Chemistry Core test event three through 2026 Chemistry Core test event two, a review of a patient report and the corresponding instrument print out from January 16, 2025

(the date of the 2025 Chemistry Core Test Event one), an interview and a telephone conversation with the laboratory supervisor, the laboratory failed to follow the manufacturer's calibration frequency requirements for multiple analytes across six of six API Chemistry Core PT events and related patient testing. Findings include: 1. A review of the retained instrument printouts and performance evaluations for API PT Chemistry Core events from 2024 through 2026 revealed that the following analytes were performed and reported for the following events with expired calibrations: a. HBA1C: 2024 Event 3; 2025 Event 2 b. Vitamin D: 2024 Event 3; 2025 Events 1, 2, 3; 2026 Events 1, 2 c. Blood Urea Nitrogen: 2024 Event 3; 2025 Event 1 d. Phosphorus: 2024 Event 3; 2025 Event 1 e. Thyroid Stimulating Hormone: 2024 Event 3 f. Acetaminophen: 2024 Event 3; 2025 Event 3; 2026 Event 1 g. Salicylate: 2024 Event 3 h. Lipase: 2025 Event 1; 2026 Event 1 i. Amylase: 2025 Events 1, 2; 2026 Event 2 j. Cholesterol: 2025 Event 1 k. Carbon Dioxide: 2025 Event 1 l. Glucose: 2025 Event 1 m. Triglycerides: 2025 Events 1, 2 n. Total Bilirubin: 2025 Event 1 o. High Sensitivity Troponin I: 2025 Event 2; 2026 Events 1, 2 p. Ethanol: 2025 Event 2 q. Ferritin: 2025 Event 2 r. Free T4: 2025 Event 2; 2026 Event 2 s. Total Iron Binding Capacity: 2025 Event 2 t. High Density Lipoprotein: 2026 Event 1 u. Total Prostate Specific Antigen: 2026 Event 1 v. Creatine Kinase: 2026 Event 1 w. N-Terminal Pro-Brain Natriuretic Peptide: 2026 Event 2 2. The manufacturer's instructions from Siemens indicate the following calibration frequencies: a. Every 7 days Vitamin D (VITD) b. Every 21 days High Sensitivity Troponin I (TNIH) c. Every 30 days Hemoglobin A1c (A1C) Blood Urea Nitrogen (BUN) Thyroid Stimulating Hormone (TSHL) Free T4 (FT4L) N-Terminal Pro-Brain Natriuretic Peptide (LNTP) d. Every 45 days Lipase (LIP) e. Every 90 days Acetaminophen (ACTM) Carbon Dioxide (ECO2) Glucose (GLU) Triglycerides (TGL) Total Bilirubin (TBI) Ethanol (ETOH) Total Iron Binding Capacity (IBCT) Total Prostate Specific Antigen (TPSA) Creatine Kinase (CKI) f. Every 3 months Phosphorus (PHOS) Amylase (AMY) Cholesterol (CHOL) Ferritin (FERR) High Density Lipoprotein (AHDL) Salicylate (SAL) 3. A patient test report and instrument print out for a Comprehensive Metabolic Panel and Lipid Panel performed on January 16, 2025, on the same day as the API 2025 Chemistry Core PT Event 1 revealed that the calibrations for the following tests were expired: Cholesterol, Triglycerides, Carbon Dioxide (CO2), Glucose, Blood Urea Nitrogen (BUN), and Total Bilirubin. The results were reported for the patient's test order. 4. The findings were confirmed during an interview with the laboratory supervisor conducted on August 5, 2026, at approximately 3:30 PM and a telephone conversation with the laboratory supervisor on August 21, 2026, at 9:45 AM PDT. According to the submitted CMS-116 form, the laboratory performs 5,835 chemistry tests annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on a review of the director approved quality assessment policy, a review of the laboratory semi-annual quality assessment between the dates of reports, a review of instrument printouts and laboratory records for the American Proficiency Institute (API) Proficiency Testing (PT) 2024 Chemistry Core test event three through the 2026 Chemistry Core test event two, a review of a patient report and the

corresponding instrument print out from January 16, 2025 (the date of the 2025 Chemistry Core Test Event 1), an interview and a telephone conversation with the laboratory supervisor, the laboratory failed to ensure that the director approved quality assessment policy and procedure was effective to detect and correct the failure to ensure that the calibration procedures for multiple analytes were performed in accordance with the manufacturer's instructions, and the failure to ensure that troubleshooting was performed to resolve error codes associated with test results from the Siemens Dimension EXL 200 prior to reporting proficiency testing results. Findings include: 1. A review of the instrument printouts for the API PT Chemistry Core 2024 test event three, 2025 events one, two and three, and the 2026 events one and two, and a review of a patient report and the corresponding instrument print out from January 16, 2025 (the date of the 2025 Chemistry Core Test Event 1) revealed that the laboratory failed to ensure that calibrations were current and not expired prior to reporting PT and patient results for multiple analytes. A review of the printouts and the manufacturer ' s instructions revealed that the calibrations were expired at the time of reporting. (Refer to D5437) 2. A review of the semi-annual Quality Assurance Reports between the dates of July 2024 and July 2026 revealed that four of four reports incorrectly stated that the calibration for the Siemens Dimension EXL 200 was 100% in compliance. 3. A review of the instrument printouts for the API PT Chemistry Core 2025 events two and three, and the 2026 test event one revealed that the laboratory failed to resolve the high assay range error codes for the High Sensitivity Troponin I (TNHI) prior to reporting the PT results. (Refer to D5781) 4. A review of the director approved quality assessment policy revealed that the established policy and procedure was not effective to detect and correct the failure of the laboratory to follow the manufacturer's instructions for the calibration of analytes prior to reporting results and resolution of error codes prior to reporting proficiency testing results. 5. The findings were confirmed during an interview with the laboratory supervisor conducted on August 5, 2026, at approximately 11:45 AM, via email correspondence received on August 18, 2026, at 12:12 pm PDT and a telephone conversation on August 21, 2026, at approximately 9:45 am PDT. According to the submitted CMS-116 form, the laboratory performs 5,835 chemistry tests annually.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on a review of manufacturer's instructions, instrument printouts and laboratory records for the American Proficiency Institute (API) Proficiency Testing (PT) 2024 Chemistry Core test event three through 2026 Chemistry Core test event two, a review of a patient report and the corresponding instrument print out from January 16, 2025 (the date of the 2025 Chemistry Core Test Event 1), an interview and a telephone conversation with the laboratory supervisor, the laboratory director failed to ensure that the manufacturer ' s calibration frequency requirements for multiple analytes across six of six API Chemistry Core PT events and related patient testing. Findings include: 1. A review of the retained instrument printouts of the instrument printouts and performance evaluations for the API PT 2024 Chemistry Core test event three, 2025 Chemistry Core test events one, two and three, 2026 Chemistry Core test events one and two revealed that the laboratory director failed to ensure that the laboratory performed calibration procedures according to the manufacturer's instructions for the

Dimension EXL 200 chemistry analyzer tests as detailed in D5437. 2. The instrument printouts and the performance evaluations for the API PT 2024 Chemistry Core test events reviewed revealed that the following analytes were performed and reported for the following events with expired calibrations: a. HBA1C: 2024 Event 3; 2025 Event 2 b. Vitamin D: 2024 Event 3; 2025 Events 1, 2, 3; 2026 Events 1, 2 c. Blood Urea Nitrogen: 2024 Event 3; 2025 Event 1 d. Phosphorus: 2024 Event 3; 2025 Event 1 e. Thyroid Stimulating Hormone: 2024 Event 3 f. Acetaminophen: 2024 Event 3; 2025 Event 3; 2026 Event 1 g. Salicylate: 2024 Event 3 h. Lipase: 2025 Event 1; 2026 Event 1 i. Amylase: 2025 Events 1, 2; 2026 Event 2 j. Cholesterol: 2025 Event 1 k. Carbon Dioxide: 2025 Event 1 l. Glucose: 2025 Event 1 m. Triglycerides: 2025 Events 1, 2 n. Total Bilirubin: 2025 Event 1 o. High Sensitivity Troponin I: 2025 Event 2; 2026 Events 1, 2 p. Ethanol: 2025 Event 2 q. Ferritin: 2025 Event 2 r. Free T4: 2025 Event 2; 2026 Event 2 s. Total Iron Binding Capacity: 2025 Event 2 t. High Density Lipoprotein: 2026 Event 1 u. Total Prostate Specific Antigen: 2026 Event 1 v. Creatine Kinase: 2026 Event 1 w. N-Terminal Pro-Brain Natriuretic Peptide: 2026 Event 2 3. The findings were confirmed during an interview with the laboratory supervisor conducted on August 5, 2026, at approximately 3:30 PM and a telephone conversation with the laboratory supervisor on August 21, 2026, at 9:45 AM PDT. According to the submitted CMS-116 form, the laboratory performs 5,835 chemistry tests annually.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of instrument printouts and laboratory records for the American Proficiency Institute (API) Proficiency Testing (PT) 2025 Chemistry Core test events two through the API PT 2026 Chemistry Core test event two, an interview with the laboratory supervisor August 5, 2026 at approximately 12:00 PM, email correspondence received from the laboratory supervisor on August 18, 2026 at 12:12 pm PDT and during a telephone conversation on August 21, 2026 at approximately 9:45 am PDT, the laboratory director failed to ensure that the proficiency testing samples are tested in the same manner as patient samples for test results outside the assay range for High Sensitivity Troponin I (TNHI) tests. Findings include: 1. The laboratory supervisor indicated that proficiency testing specimens are not diluted when results exceed the assay 's upper range, and that patient specimens are diluted when High Sensitivity Troponin I results fall above the assay's reporting limit (4.0 - 25,000 pg/mL). 2. The printouts revealed an error code of "assay range" indicating that the results were outside of the analytical measurement range of the instrument for TNHI. The laboratory failed to resolve the error code for the following proficiency test events: a. The laboratory reported TNHI results of 27,000 pg/mL for 2025 API Chemistry Core Event 2 sample CM-06. The instrument print outs indicated results of 27.298 ng/mL or 27,298 pg/mL. b. The laboratory reported TNHI results of 69,816 pg/mL for 2025 API Chemistry Core Event 3 sample CM-12. The instrument print outs indicated results of 69.816 ng/mL or 69,816 pg/mL. c. After receiving the PT evaluation, the laboratory re-ran sample CM-12 and obtained a result of 35.857 ng/mL (35,857 pg/mL) with the same ' assay range ' error code. The laboratory did not correct the error code or document any dilutions performed. d. The laboratory reported TNHI results of 34,283 pg/mL for 2026 API Chemistry Core Event 1 sample

CM-01. The instrument print outs indicated results of 34.283 ng/mL or 34,283 pg/mL. 3. There was no documentation of dilution and re-running of the PT samples with the Troponin I (CTNI) diluent in accordance with the manufacturer's instructions prior to reporting the results, as the laboratory indicated they did with patient samples. 4. The laboratory supervisor confirmed during an interview conducted on August 5, 2026, at approximately 11:45 AM that the High Sensitivity Troponin I PT results outside the high end of the analytical range were not manually diluted and repeated to ensure that the results were accurate and reliable. 5. The laboratory supervisor confirmed via email correspondence received on August 18, 2026, at 12:12 pm PDT, and during a telephone conversation on August 21, 2026, at approximately 9:45 am PDT that PT specimens are not diluted if they are outside the assay range high prior to reporting the results to API. The supervisor stated in both the email correspondence and during the telephone conversation that patient specimens are diluted when the High Sensitivity Troponin I results are outside the upper end of the assay range. According to the submitted CMS-116 form, the laboratory performs 5,835 chemistry tests annually.