| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 13D0522286 | 03/19/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gritman Medical Center | 623 S Main St, Moscow, ID | |

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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) documentation from the College of American Pathologists (CAP), Wisconsin State Laboratory of Hygiene (WSLH) and American Proficiency Institute (API), and an interview with the technical consultant (TC) on 3/19/2024, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2022 and 2023. The findings include: 1. A review of PT results from CAP and WSLH for 2022 identified that the laboratory failed to have the performing testing personnel and the laboratory director attest that the PT samples were tested with patient samples for three of three events in 2022 for hematology, bacteriology /virology, chemistry/endocrinology, and immunology and two of two events for HIV. 2. A review of PT results from API for 2023 identified that the laboratory failed to have the laboratory director attest that the PT samples were tested with patient samples for immunology and chemistry miscellaneous for events one and two, and three of three events for hematology, general chemistry and microbiology. 3. An interview with the TC on 3/19/2024 at 7:49 am confirmed the above findings. 4. The laboratory reports performing 197,050 tests annually. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(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. |

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| | 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 system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) documentation from the Wisconsin State Laboratory of Hygiene (WSLH) and the College of American Pathologists (CAP), a lack of laboratory documentation and an interview with the technical consultant (TC) on 3/19/2024, the laboratory failed to retain PT documents for 2022. The findings include: 1. A review of PT documents for 2022 from WSLH identified that the laboratory failed retain documentation of attestation forms, raw testing data, graded results and review of results for the following: chemistry/endocrinology events one and two, hematology events one and two, bacteriology/virology events one, two and three, HIV combo events one and three and immunology events one and two. 2. A review of PT documents for 2022 from CAP identified that the laboratory failed retain documentation of attestation forms, raw testing data, graded results and review of results for the following: rheumatic disease event one and clinical microscopy event one. 3. An interview with the TC on 3/19/2024 at 7:49 am confirmed that the laboratory failed to have documentation of attestations, raw data, graded results and results review for the above PT events. 4. The laboratory reports performing 197,050 tests annually. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment records and an interview with the technical consultant (TC) on 3/19/2024, the laboratory failed to follow written policies and procedures to assess testing personnel and technical consultant competency in 2022 and 2023. The findings include: 1. A review of the CMS 209 form identified two testing personnel and one technical consultant. 2. A review of competency assessment records identified the laboratory failed to have adequate documentation of annual competency for testing personnel 1 in 2022 and 2023. 3. A review of competency assessment records identified the laboratory failed to have adequate documentation of six month and annual competency assessments for testing personnel 2 in 2023. 4. A review of competency assessment records identified the laboratory failed to have documentation of competency for the TC with a start date of November 2022. 5. An interview with the TC on 3/19/2024 at 8:10 am confirmed the above findings. 6. The laboratory reports performing 197,050 tests annually. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE |

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| | CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) documentation from the Wisconsin State Laboratory of Hygiene (WSLH), the College of American Pathologists (CAP) and American Pathology Institute (API), lack of laboratory documentation and an interview with the technical consultant (TC) on 3/19/2024, the laboratory director or delegated designee failed to review PT results in 2022 and 2023. The findings include: 1. A review of PT documents for 2022 from WSLH identified that the laboratory director failed to review results for the following: three of three events for chemistry /endocrinology, hematology events, bacteriology/virology, two of three events for immunology and two of two events for HIV combo. 2. A review of PT documents for 2022 from CAP identified that the laboratory director failed review results for the following: rheumatic disease events one and two and clinical microscopy event one. 3. A review of PT documents for 2023 from API identified that the laboratory director failed to review results for the following: chemistry miscellaneous event two. 4. An interview with the TC on 3/19/2024 at 7:49 am confirmed that the laboratory director failed review the above PT results. 5. The laboratory reports performing 197,050 tests annually. |
| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) documents from the American Proficiency Institute (API), Wisconsin State Laboratory of Hygiene (WSLH) and College of American Pathologists (CAP), and an interview with the technical consultant (TC) on 3/19/2024, the laboratory failed to review and evaluate PT scores that were given an artificial score of 100% in 2022 and 2023. The findings include: 1. A review of PT documents from API for the specialty of chemistry for 2023 event one identified that the laboratory failed to evaluate results for alanine aminotransferase sample CH-01 that was given an artificial score of 100% due to lack of consensus. 2. A review of PT documents from WSLH for the specialty of hematology for 2022 event three identified that the laboratory failed to evaluate results for leukocytes samples AF5-11 through AF5-15 that were given artificial scores of 100% due to insufficient peer group. 3. A review of PT documents from WSLH for the specialty of immunology for 2022 event three identified that the laboratory failed to evaluate results for rubella samples XU-11 through XU-15 and immunoproteins samples IMP-11 through IMP-15 that were given artificial scores of 100% due to insufficient peer group. 4. A review of PT documents from CAP for clinical microscopy for 2022 event two identified that the laboratory failed to evaluate results for urine sediment identification sample CMP-14 that was given an artificial score of 100% due to lack |

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| | of consensus. 5. An interview with the TC on 3/19/2024 at 7:49 am confirmed that the laboratory failed to evaluate PT results with artificial scores in 2022 and 2023. 6. The facility reports performing 197,050 tests annually. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory maintenance logs and an interview with the technical consultant (TC) on 3/19/2024, the laboratory failed to perform maintenance as required by the instrument manufacturers in 2022. The findings include: 1. A review of Sysmex XS-1000i maintenance logs identified that the laboratory failed to have documentation of daily, weekly and monthly maintenance performance for April 2022 and July 2022. 2. A review of Sysmex XS-1000i maintenance logs identified that the laboratory failed to have documentation of the monthly rinse performance for January 2022 and June 2022. 3. A review of Roche D10 maintenance logs identified that the laboratory failed to have documentation of daily and monthly maintenance performance for April 2022 and July 2022. 4. A review of Dimension EXL200 maintenance logs identified that the laboratory failed to have documentation of daily, weekly and monthly maintenance performance for April 2022 and July 2022. 5. An interview with the TC on 3/19/2024 at 8:40 am confirmed the above findings. 6. The laboratory reports performing 149,842 chemistry and 42,658 hematology tests annually. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of calibration records, calibration verification records for the Dimension EXL200 and an interview with the technical consultant (TC) on 3/19 /2024, the laboratory failed to verify the reportable range at least once every six months for 2022. The findings include: 1. A review of calibration records and calibration verification records for the Dimension EXL200 identified that the laboratory failed to perform verifications of the reportable range every six months in 2022 for the following chemistry analytes: potassium, sodium, carbon dioxide, chloride, creatinine, glucose calcium, urea, albumin, total bilirubin, total protein, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, iron, magnesium, gamma-glutamyl transferase and phosphorous. 2. An interview with TC on 3/19/2024 at 11:03 am confirmed that the laboratory had not verified the reportable range for the above chemistry analytes at least once every six months in 2022. 3. The laboratory reports performing 146,784 routine chemistry tests annually. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of PT documents from the American Proficiency Institute (API), College of American Pathologists and Wisconsin State Laboratory of Hygiene, instrument manintenance logs, a lack of documentation, and interviews with the technical consultant on 3/19/2024, the laboratory director failed to ensure that testing personnel were providing accurate and reliable patient results, that PT was tested and reviewed for all analytes and that testing personnel had appropriate training. See D6017, D6018, D6023 and D6029. |
| **D6017** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(ii)<br><br>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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) results from the Wisconsin State Laboratory of Hygiene (WSLH) and the American Proficiency Institute (API) and an interview with the technical consultant (TC) on 3/19/2024, the laboratory director failed to ensure that PT results were returned to the proficiency providers in 2022 and 2023. The findings include: 1. A review of PT results from WSLH identified that the laboratory failed to participate in 2022 event three for the specialty hematology, cell identification of samples XI15- XI19, resulting in a score of zero. 2. A review of PT results from API identified that the laboratory failed to participate in 2023 event two for the specialty chemistry, urine creatinine, urine microalbumin, urine total protein of |

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| | samples UC04- UC06, resulting in a score of zero. 3. An interview with the TC on 3 /19/2024 at 7:49 AM confirmed the above findings. 4. The laboratory reports performing 42,658 hematology and 1,812 urine chemistry tests annually. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) documentation from the College of American Pathologists (CAP), Wisconsin State Laboratory of Hygiene (WSLH) and American Proficiency Institute (API) and an interview with the technical consultant (TC) on 3/19/2024, the laboratory director failed to review and evaluate PT results in 2022 and 2023. See D5211 The findings include: 1. A review of PT results from CAP and WSLH for 2022 identified that the laboratory director failed to review and evaluate PT results for three of three events for hematology, bacteriology/virology, chemistry/endocrinology, two of three events for immunology, two of two events for rheumatic disease, one of two events for HIV and one of two events for clinical microscopy. 2. A review of PT results from API for 2023 identified that the laboratory director failed to review and evaluate PT results for chemistry miscellaneous event two. 3. An interview with the TC on 3/19/2024 at 7:49 am confirmed the above findings. 4. The laboratory reports performing 197,050 tests annually. |
| **D6023** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(6)<br><br>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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;<br><br>This STANDARD is not met as evidenced by:<br>Based on a record review of chemistry calibration verification documents, instrument maintenance logs and interviews with the technical consultant on 3/19/2024, the laboratory director failed to ensure the maintenance of acceptable analytic performance for chemistry and hematology testing in 2022. The findings include: 1. A review of chemistry calibration verification documents identified that the laboratory failed to perform calibration verifications in 2022. See D5439 2. A review of instrument maintenance logs identified that the laboratory failed to perform all the scheduled maintenance in 2022 for hematology and chemistry. See D5429. 3. |

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| | Interviews with the TC on 3/19/2024 at 11:03 am and 8:40 am respectively confirmed the above findings. 4. The laboratory reports performing 42,658 hematology and 149,842 chemistry tests annually. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment and training records and an interview with the technical consultant (TC) on 3/19/2024, the laboratory director failed to ensure adequate training of testing personnel and the technical consultant in 2022. The findings include: 1. A review of the CMS 209 form identified one testing personnel and technical consultant with a start date of November 2022. 2. A review of competency assessment and training records identified the laboratory failed to have documentation of initial training for testing personnel 2 in 2022. 3. A review of competency assessment records identified the laboratory director failed to document training and competency of the TC in 2022. 4. An interview with the TC on 3/19/2024 at 8:10 am confirmed the above findings. 5. The laboratory reports performing 197,050 tests annually. |