Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D2043427	04/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pmg Lab- Hawthorne	551 E Hawthorne Rd, Spokane, WA	

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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of American Proficiency Testing (API) Proficiency testing (PT) records and an interview with the Laboratory Director (LD), The LD failed to sign PT attestations or delegate the responsibility for signing the attestation forms to a technical consultant designee. Findings include: 1. Review of PT records for year (s) 2021 and 2022 showed that the laboratory director failed to sign five (5) of six (6) testing event attestation forms. 2. The laboratory did not have a delegation of responsibilities assigned to the technical consultant (TC) who had signed five (5) of six (6) API PT attestation forms for year (s) 2021 and 2022. 3. Interview with LD on 04/11/2023 at 04:00 PM confirmed that there was no delegation of responsibility assigned to a technical consultant to sign PT attestations. 4. The laboratory reports performing 33,889 patient tests annually.
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 record review and interview with the Laboratory Director (LD), the

	laboratory failed to retain analyzer quality control (QC) printouts and patient test records for the month of October 2022. Findings include: 1. During record review of QC printouts and patient records revealed for the month of October 2022 laboratory documents could not be located. 2. Interview with LD on 4/11/2023 at 04:00 PM confirmed that October 2022 QC and patient records were not available during the day of the survey. 3. The laboratory reports performing 33,889 patient tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on request, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to establish and verify the accuracy of qualitative serum human Chorionic gonadotrophin (hCG) with the Medline HCG Combo. Findings include: 1. Review of the laboratory's test menu showed that qualitative Serum HCG was not enrolled in Proficiency Testing to verify accuracy. 2. Review of records showed no documentation of accuracy performed for Medline HCG Combo for the year (s) 2021 and 2022. 3. Interview with LD on 4/11/2023 at 04:00 PM confirmed that enrolment in PT or verification of accuracy for qualitative serum HCG Combo for the year (s) 2021 and 2022. 4. The laboratory records indicate the laboratory performed Serum qualitative hCG testing twice in 2021, once in 2022, and once in 2023.
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 a review of the quality assessment procedure and interview with the Laboratory Director (LD), the LD failed to include quality assessment (QA) assessments for the ongoing effectiveness of corrective actions taken to resolve problems. Findings include: 1. Review of the QA plan "Laboratory Quality Assurance Plan" did not include a process or procedure for continuous QA monitoring. 2. Request for the laboratory's quality assessment reports showed that LD failed to have documentation of ongoing reviews for year (s) 2021 and 2022. 3. Interview with LD on 4/11/2023 at 04:00 PM confirmed that they did not conduct quality assessment reports for 2021 and 2022. 4. The laboratory reports performing 33,889 patient tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 5469 Based on a record review and interview with the Technical Consultant (TC), the TC failed to establish or verify the criteria for acceptability of Quality Control (QC) in chemistry. Findings include: 1. Review of QC records showed that Multiqual QC lot numbers on Beckman Coulter DXC600 Chemistry analyzer printout did not correlate with the current Multiqual QC lot in use on the Laboratory Information System (LIS), Epic Beaker system. QC Paperwork LIS-Epic Beaker Level 1 Lot 46591 Exp: Not retrievable Level 1 Lot 56671 Exp: 06-30-2023 Level 2 Lot 46592 Exp: Not retrievable Level 2 Lot 56672 Exp: 06-30-2023 Level 3 Lot 46593 Exp: Not retrievable Level 3 Lot 56673 Exp: 06-30-2023 2. Review of QC records showed a lack of established QC acceptability criteria for Chemistry QC material. 3. Review showed a lack of documentation and TC verification of established QC acceptable parameters for chemistry QC. 4. Interview with TC on 04/11/2023 at 04:00 PM confirmed that the laboratory is unable to update the lot number on the analyzer and do not have a current mechanism for establishing QC acceptable parameters for chemistry. 5. The laboratory reports performing 20,280 routine chemistry patient tests annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory director (LD), the LD failed to evaluate annual competencies or delegate the responsibilities of Technical Consultant (TC) for evaluating annual competencies for all testing personnel in the year (s) 2021 and 2022. Findings include: 1. Review of competency records showed that the LD failed to evaluate nine (9) of nine (9) annual testing personnel (TP) competencies for the year 2021 and two (2) of two (2) semi-annual competencies in 2022. 2. Review of TP competencies showed no LD signature on competency assessments for the year (s) 2021 and 2022. 3. Review of policies and procedures

	showed no TC designee assigned by the LD for the year (s) 2021 and 2022. 4. Interview with LD on 04/11/2023 at 04:00 PM confirmed that the LD did not review competency assessments, or delegate the authority to a TC designee for year (s) 2021 and 2022. 5. The laboratory reports performing 33,889 patient tests annually.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the TC failed to review and sign pipette calibrations prior to placing pipettes into service. Findings include: 1. Review of calibration records show no review and signature for pipette calibration reports six (6) of six (6) calibrated on August 29, 2022, prior to use. Item Number Calibrated Pipette 239151-28 08/29/2022 Pipette 20120890 08/29/2022 Pipette 21120891 08/29/2022 Pipette 21120892 08/29/2022 Pipette 20120893 08/29 /2022 Pipette 20120894 08/29/2022 2. Interview with the laboratory director on 04/11 /2023 at 04:00 PM confirmed that TC review or designee review was not assigned. 3. The laboratory reports performing 33,889 patient tests annually.