Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0120662	06/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Robert M Goldberg Md Pa	727 Shore Road, Somers Point, NJ	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology testing participated in the American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE) PT surveys in the calendar years 2024 and 2025. The finding includes: 1. A review of AAB/MLE PT records revealed that the LD performed PT for all three events in 2024 and the 1st event of 2025. 2. The LD confirmed on 6/9/25 at 11:25 am that PT events were not rotated between all TP provided on the CMS-209 during the survey in the 2024 and 2025 calendar years.
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 the lack of Competency Assessment (CA) records and interview with the Laboratory Director (LD), the laboratory failed to perform a CA on two out of two testing personnel (TP) for the calendar years 2023, 2024 and 2025 (if due). The

	findings include: 1. Two out of two TP, provided on the CMS-209 during the survey, had no CA documentation provided. 2. The LD confirmed on 6/9/25 at 11:00 am that the CA was not performed as stated above. 3. Note: this deficiency was also cited during the 7/25/23 survey.
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 surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of all Hematology testing analytes performed on the Beckman Coulter DxH 500 from 7/25/23 to 6/9/25. The finding includes: 1. Surveyor review of PT records revealed all Hematology analytes tested by the laboratory were not included in PT events 1, 2 and 3 in 2023 and 2024 and PT event 1 in 2025 performed with PT provider American Association of Bioanalysts Medical Laboratory Evaluation (AAB /MLE). 2. The following analytes were not verified for accuracy twice annually on the Beckamn Coulter DxH 500 analyzer: a) Mean Corpuscular Hemoglobin (MCH) b) Mean Corpuscular Hemoglobin Concentration (MCHC) c Mean Corpuscular Volume (MCV) d) Red Cell Width (RDW 3. The LD confirmed 6/9/25 at at 11:00 am, the laboratory did not verify the accuracy of all analytes performed on the Beckman Coulter DxH 500.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to document the evaluation of all unsatisfactory PT scores and corrective action taken for PT performed with American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE) for the M1 2025 event in 2025. The findings include: 1. The laboratory received a 20% on Red Blood Cell (RBC) and an 80% on Lymphocytes (Lymph), Monocytes (Mono) and Eosinophils (Eos). 2. There was no documented evidence for evaluation or corrective action performed for any of the above mentioned analytes. 3. The LD confirmed on 6 /9/25 at 11:15 am, that the laboratory failed to evaluate and perform corrective action for all unsatisfactory PT scores.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-

	step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Beckman Coulter DxH 520 Operator's Manual (OM), the laboratory's Procedure Manual (PM), the laboratory's linearity summary from their validations and interview with the laboratory director (LD), the laboratory failed to provide the correct established complete blood cell (CBC) reportable ranges for the Beckman Coulter DxH 520 analyzer in the PM from 9/17/24 to 6/9/25. The findings include. 1. The laboratory failed to provide the correct established CBC reportable ranges in the PM as they failed to compare their linearity results performed during the Beckman Coulter DxH 500 install and validation performance with the OM's measuring ranges in order to determine the strictest reportable ranges between their linearity and the OM's measuring ranges as their established reportable ranges. 2. The LD confirmed on 6/9/25 at 12:30 pm that the laboratory failed to provide the correct establsihed CBC reportable ranges in the PM.