Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0120662	07/25/2023
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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for 2023. The Program Manager for the Clinical Laboratory Improvement Services (CLIS) confirmed on 7/24/23, prior to the recertification survey, that the laboratory did not have a NJCLL license for 2023 or any prior years. The Laboratory Director confirmed on 7/25/23 at 12:30 pm that the laboratory did not maintain a NJCLL for 2023 or any prior 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 for the calendar years 2021, 2022 and 2023. The LD confirmed on 7 /25/23 at 10:30 am that the CA was not performed as stated above.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of patient work records, review of the Beckman Coulter AcT diff 2 Operator's Guide (OG) and interview with the Laboratory Director (LD), the laboratory failed to follow the OG for the Hematology testing performed on the Beckman Coulter AcT diff 2 from 5/18/21 to the date of survey. The findings include: 1. 6 out of 10 patient work records had flags but there was no corrective action taken per the OG. 2. For the asterick (*) flag, manufacturer states, "See instructions for +++++, +, or -----" which each provide detailed instructions under suggested actions. a. Patient specimen's Accn # 2459 from 7/12/23, Accn # 6700 and 6744 from 7/13/23, Accn # 9809 from 7/18/23 and Accn # 7065 from 7/21/23, a total of 5 patient specimens, had results with astericks but those results were reported without further action being taken and/or documented. 3. For the X flag, manufacturer requires to check the specimen for clots and.or fibrin strands and then perform a bleaching and zap aperture function on the analyzer. a. Patient specimen Accn # 6744 from 7/21/23 had results with an X but those results were reported without further action being taken and/or documented. 4. For the 1, 2, 3, 4, M (multiple regions) flags, the maufacturer states, "Differential parameters failed the internal regional size distributional criteria at one specific region (1, 2, 3 or 4) or multiple regions (M). Verify results according to your laboratory's protocol." The Laboratory added, "Send out to reference lab, or document that these results not used for dx purposes." a. Patient specimen Accn # 2459 from 7/12/23 had results with a 1 flag but those results were reported without further action being taken and/or documented. b. Patient specimen's Accn # 6700 from 7/13/23, Accn # 9809 from 7/18/23 and Accn # 0967 from 7/21/23, a total of 3 patient specimens, had results with a 2 flag but those results were reported without further action being taken and/or documented. c. Patient specimen's Accn # 6700 from 7/13/23 and Accn # 7065 from 7/21/23, a total of 2 patient specimens, had results with a 3 flag but those results were reported without further action being taken and/or documented. d. Patient specimen's Accn # 9809 from 7/18/23 and Accn # 0967 from 7/21/23, a total of 2 patient specimens, had results with an M flag but those results were reported without further action being taken and/or documented. 5. The LD confirmed on 7/25/23 at 11:30 am that the laboratory failed to take correction action for any of the aforementioned flags and/or messages based on the OG.