Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0121725	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Princeton Medical Group - Princeton	419 N Harrison St, Princeton, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), a lack of Smear Acceptability Records for Manual Differential Smears and interview with the Technical Supervisor (TS), laboratory personnel failed to follow the procedure for "Evaluation of Smear Acceptability" for Hematology tests performed from 4/10/22 to 4/10/24. The findings include: 1. There was no documented evidence TP evaluated Manual Differential smears for acceptability each day the procedure was performed. 2. The TS confirmed on 4/10/24 at 11:00 am, laboratory personnel failed to follow the PM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to have all applicable procedures for Hematology tests in the PM from 4/10/22 to 4/10/24. The findings include: 1. The laboratory failed to include Reference Intervals (RI) for both male and females for Complete Blood Count tests performed on the Horiba Pentra XL80 in the PM. 2. The laboratory failed to have a complete flagging guide procedure for the Horiba Pentra XL80 in the PM. a. Sample ID 6394408 had an analyzer alarm for LMNE+. b. There was no procedure to resolve the alarm. 3. The TS confirmed on 4/10/24 at 12:00 pm, that the PM failed to have all applicable procedures for Hematology tests. B) Based on surveyor review of the Procedure Manual (PM), Test Records and interview with the Technical Supervisor (TS), the laboratory failed to have all applicable procedures for Urine Microscopic (UM) tests in the PM from 4/10/22 to 4/10/24. The findings include: 1. The laboratory failed to have a written quality control procedure for UM tests in the PM. 2. The laboratory failed to have a pertinent literature reference for the RI used for UM tests in the PM. 3. The TS confirmed on 4/10/24 at 12:30 pm, that the PM failed to have all applicable procedures for UM tests.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient Test Records (PTR) and interview with the Technical Supervisor (TS), the laboratory failed to make available and failed to follow the Corrective Action (CA) policy for morphology flags for Hematology tests performed from 1/30/24 to 4/10/24. The finding includes: 1. The PM stated "! indicates suspicious result, evaluate the result and confirm if necessary". a) Sample ID 6394408 had "!" flags and was repeated 4 times. b) Sample ID 639880 had "!" flags and was repeated 2 times. 2. The PM failed to indicate the acceptability criteria if a result was repeated. 3. The TS confirmed on 4/10/24 at 11:45 am that the laboratory failed to follow the laboratory's CA policy.