Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1078232	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Princeton Medicine Physicians	5 Plainsboro Road, Plainsboro, 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) 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, Procedure Manual (PM) and interview with the Lab Supervisor (LS), the laboratory failed to ensure that all Testing Personnel (TP) who perform Hematology testing participated in the American Proficiency Institute (API) PT events in the calendar years of 2022 and 2023. The findings include; 1. The PM states " Proficiency testing will be performed on a rotating basis by testing personnel." 2. A review of PT attestation records showed that the LS performed 2 out of 3 Hematology events in 2023 in which 7 total TP failed to participate in. 3. The LS performed 2 out of 3 Hematology events in 2022 in which 5 total TP failed to participate in. 4. The LS confirmed on 1/31/24 at 11:30 am that the laboratory failed to rotate all TP to participate in the Hematology PT events in calendar years 2022 and 2023.
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 Proficiency Testing (PT) records and interview with the Lab Supervisor (LS) the laboratory failed to document the evaluation of all unacceptable scores and corrective action taken for Hematology events performed

	with the American Proficiency Institute (API) from 9/14/21 to 1/31/24. The findings include: 1. Sample XE-13 for Mean Platelet Volume (MPV) was graded as unacceptable in the 3rd Hematology event of 2023. 2. Sample XE-15 for IG- Absolute was graded as unacceptable in the 3rd Hematology event of 2022. 3. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT events. 4. The LS confirmed on 1/31/24 at 12:20 pm the laboratory failed to evaluate and perform corrective action for the failed analytes for Hematology PT events in calendar years 2022 and 2023.
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: Based on surveyor review of the Procedure Manual (PM) and interview with the Lab Supervisor (LS), the laboratory failed to have all applicable procedures for Hematology Tests performed on the Sysmex XN 540 analyzer from 11/1/21 to 1/31 /24. The findings include: 1. The laboratory failed to have the established reportable range for test results for the Sysmex XN 540 analyzer as established or verified in 493. 1253. The PM has reportable ranges that does not match the reportable ranges on the Sysmex XN 540 reports. 2. The laboratory failed to have reference intervals established with the Sysmex XN 540 analyzer. The PM has reference intervals that were established with the Beckman Coulter AcT Diff 2 Analyzer which is no longer in use. 3. The laboratory failed to have a flagging guide procedure for the Sysmex XN 540 analyzer. The PM states " Please see attached table (table 6.4) that describes the flags and suggested actions to be performed when they appear," but there was not table 6.4 in the PM. 4. The laboratory failed to have procedures for using the Sysmex Beyondcare Quality Montior for Hematology tests. 4. The LS confirmed on 1/31/24 at 12:00 pm that the PM did not have all applicable procedures for the Sysmex XN 540 analyzer.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use

	and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Lab Supervisor (LS), the laboratory failed to record discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer from 11/1/21 to the date of survey. The finding includes: 1. The LS stated the Beckman Coulter AcT Diff 2 is no longer in use and the Sysmex XN 540 analyzer is currently in use for Hematology testing. 2. The LS on 1/31/24 at 11:45 am that discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer were not documented.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Lab Supervisor(GS), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Sysmex XN-540 analyzer were adequate from 11 /1/21 to 1/31/24. The finding includes: 1. The LD failed to provide a source for reference intervals/range (normal values) for the laboratory's patient population. 2. The LD failed to establish a reportable range for the Sysmex XN540 analyzer. 3. There was no documented evidence the LD reviewed and approved the PS for the Sysmex XN 540 analyzer before it was put into use for patient testing. 4. The LS confirmed on 1/31/24 at 11:20 am that the LD failed to ensure the PS were adequate before put into use for patient testing.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Assessment (QA) plan, review of the Procedure Manual (PM) and interview with Lab Supervisor (LS), the Laboratory Director (LD) failed to ensure the QA program was maintained to assure the quality of laboratory services provided from 11/1/23 to the date of the survey. The findings include; 1. The LD failed to have procedures for Electronic Medical Record (EMR)

	review for the Sysmex XN 540 analyzer. 2. The PM states " Lab personnel will conduct audits of 5-10 chart/month, to verify manually entered results are present in the correct chart." The LS stated this procedure is no longer being performed due to results being interfaced in the EMR. 3. The LS confirmed on 1/31/24 at 11:00 am that the LD failed to ensure the QA program was maintained.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM) and interview with the Lab Supervisor (LS), the Laboratory Director (LD) failed to ensure that approved procedures for the use of the Sysmex BeyondCare Quality Monitor (BCQM) for Hematology testing was available to all TP from 11/1/21 to the date of survey. The findings include: 1. The laboratory could not provide approved procedures for the use of the Sysmex BCQM for Hematology testing that was approved and signed by the current LD. 2. The LS confirmed on 1/31/24 at 12:00 pm that the LD failed to have approved procedures for the Sysmex BCQM available for review.