

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1078232	(X3) Date Survey Completed 02/20/2025
Name of Provider or Supplier Princeton Medicine Physicians	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on the lack of daily quality control work records (QCWR) and surveyor interview with the Testing Personnel # 1 (TP #1) provided on the CMS-209, the laboratory failed to maintain daily QCWR print-outs from the analyzer for complete blood cell (CBC) and automated differential (AUTODIFF) tests performed on the Sysmex XN 530 analyzer from 1/31/24 to 2/20/25. The finding includes: 1. The TP #1 stated, "we are not saving the daily quality control print-outs since we print the monthly Levey-Jennings reports." 2. The TP #1 confirmed on 2/20/25 at 10:45 am that the laboratory did not maintain the daily QCWR's from the Sysmex XN 530.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), patient work records (PWR) and test reports (TR) and interview with the Testing Personnel #1 (TP #1)</p>

provided on the CMS-209, the laboratory failed to follow the procedure to verify flagged complete blood cell (CBC) and automated differential (AUTODIFF) results from 1/31/24 to 2/25/25. The findings include: 1. The PM states "If there are flags, the printed report will be repeated and then presented to the lab director or ordering physician for review and approval. If a flag persists after repeat testing, the physician may determine that a result is not to be used for diagnostic purposes, and testing personnel with not include it in the patient's EMR. All CBC results will be initialed by the provider." 2. Seven out of seven flagged CBC and AUTODIFF PWR and TR reviewed had no verification by repeat testing performed and/or documented: a. Sample No. 1040524749, 4/5/24, R flag on AUTODIFF b. Sample No. 1061224955, 6/12/24, R flags on white blood cell (WBC), platelet (PLT) and AUTODIFF c. Sample No. 1061224954, 6/12/24, R flags on WBC, PLT and AUTODIFF d. Sample No. 1090624505, 9/9/24, R flags on WBC and AUTODIFF e. Sample No. 1112124915, 11/22/24, R flags on WBC and AUTODIFF f. Sample No. 1112224918, 11/22/24, R flags on WBC and AUTODIFF g. Sample No. 1011325903, 1/13/25, R flags on WBC and AUTODIFF 3. The TP #1 confirmed on 2/20/25 at 12:30 pm that the laboratory failed to follow the PM and repeat flagged patient results.

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 Procedure Manual (PM) and interview with the Testing Personnel #1 (TP #1) provided on the CMS-209, the laboratory failed to have all applicable procedures for Hematology Tests performed on the Sysmex XN 530 analyzer from 1/31/24 to 2/20/25. The findings include: 1. The laboratory failed to have the correct established reportable ranges for white blood cell (WBC) and hemoglobin (HGB) test results for the Sysmex XN 530 analyzer. a. The manufacturer's WBC minimum reportable range value is 0.04 uL but the PM has 0.4 uL. b. The laboratory established a maximum HGB reportable range of 24.6 dL but the PM used 26 dL which is beyond the established range. 2. The laboratory failed to provide the source of the reference intervals in use for the Sysmex XN 530 analyzer in the PM. 3. The laboratory failed to have a flagging guide procedure for the Sysmex

XN 530 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 table 6.4 was not provided in the PM. 4. The laboratory failed to have procedures for using the Sysmex Beyondcare Quality Montior for Hematology tests. 5. The laboratory failed to provide panic/critical values in the PM. 6. The TP #1 confirmed on 2/20/25 at 10:30 am that the PM did not have all applicable procedures for the Sysmex XN 530 analyzer.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of Performance Specification (PS) records, the Sysmex XN 530 Operator's Manual (OM), the Procedure Manual (PM) and Patient Work Records (PWR) and interview with Testing Personnel #1 (TP #1) provided on the CMS-209, the laboratory failed to ensure that all PS records were adequate for the Complete Blood Cell (CBC) testing on the Sysmex XN 530 analyzer from 1/31/24 to 2/20/25. The findings include: 1. The laboratory failed to correctly establish their reportable ranges by comparing their linearity and Sysmex's reportable ranges and using the strictest values on the PWR's. 2. The laboratory failed to place the correct established reportable ranges into use to ensure that patient results outside the ranges would not be reported. a. The manufacturer's white blood cell (WBC) minimum reportable range value is 0.04 uL but the PWR's have 0.4.uL. b. The laboratory established a maximum HGB reportable range of 24.6 dL but the PWR's have 26 dL which is beyond the established range. 3. The TP #1 confirmed on 2/20/25 at 11:30 am that the laboratory failed to ensure that correct established reportable ranges were placed into use on the PWR's.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and thermometers and interview with the Testing Personnel #1 (TP #1) provided on the CMS-209, the laboratory failed to provide a written procedure for and documentation of calibration for all thermometers used in the laboratory from 1/31/24 to 2/20/25. The findings

include: 1. The laboratory could not provide a written procedure for the calibration or replacement of all thermometers used including the MarketLab thermohygrometer, S/N 192148869, used for room temperature and humidity in the laboratory. 2. The laboratory could not provide documentation of current calibration for the MarketLab thermohygrometer, S/N 192148869, due 01 May 2021. 3. The TP #1 confirmed on 2/20/25 at 10:15 am that they could not provide a written procedure for performing calibration or replacement of the thermometers nor provide documentation of current calibration for the thermohygrometer.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on lack of an Accession Log (AL) and interview with Testing Personnel #1 (TP #1) provided on the CMS-209, the laboratory failed to maintain an AL for Hematology tests from 1/31/24 to 2/20/25. The findings include: 1. The laboratory failed to maintain an AL through either written or electronic medical record (EMR) documentation. 2. The TP #1 confirmed on 2/20/25 at 12:00 pm that the laboratory did not maintain an AL for Hematology testing through written or EMR documentation.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Work Test Records (WTR), Test Reports (TR) generated from the electronic medical record (EMR) for Complete Blood Cell (CBC) and automated differential (AUTODIFF) testing and interview with the Laboratory Director (LD) and Testing Personnel #1 (TP #1) provided on the CMS-209, the laboratory failed to know the source of the Reference Interval's (RI) on the WTR and TR from 1/31/24 to 2/20/25. The findings include: 1. The WTR's and TR's do have the same RI's provided for the CBC and AUTODIFF. 2. The LD and TP #1 confirmed on 2/20/25 at 12:15 pm that the laboratory did not know the source of the RI's provided on the WTR and TR.