

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0955681	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Norman Indich Pediatrics	Street Address, City, State 603 West County Line Road, Lakewood, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Complete Blood Count test from January 2017 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 9/5/2018 at 3:00 pm the laboratory was not enrolled in PT testing.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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)</p>

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 and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for corrective action documentation from January 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 9/5/18 at 2:00 pm that the laboratory did not establish the above procedure.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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

a) Based on review of the Performance Specifications (PS) records and interview with the Testing Personnel (TP) the laboratory failed to perform Reportable Range on White Blood Count (WBC) test performed on the Abacus 3CP analyzer from January 2017 to the date of survey. The TP#2 listed on CMS form 209 confirmed on 9/5/2018 at 1:00 pm that the laboratory did not perform linearity on WBC. b) Based on surveyor review of the PS records and interview with the TP, the laboratory failed to verify Accuracy and Precision for Hematology tests performed on the Abacus 3CP analyzer from January 2017 to the date of survey. The finding includes: 1. Accuracy was not performed on WBC, Red Blood Cell Count (RBC), Platelets (PLT), Hemoglobin (HGB), Lymphocyte (LYM), Mid-range absolute count (MID), and Granulocyte (GRA). 2. Precision was not performed on WBC, RBC, PLT, HGB, LYM, MID, GRA. 3. The TP#2 listed on CMS form 209 confirmed on 9/5/2018 2:00 pm that accuracy and precision was not performed for the aforementioned analytes. c) Based on review of the Performance Specifications (PS) records and interview with the TP, the laboratory failed to verify pediatric Reference Interval (RI) for hematology tests performed on the Abacus 3CP analyzer from January 2017 to the date of survey. The TP#2 listed on CMS form 209 confirmed on 9/5/2018 that the laboratory did not perform pediatric RI verification.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for Hematology tests performed on the Abacus 3CP analyzer from January 2017 to the date of survey. The TP#2 on CMS form 209 confirmed on 9/5/2018 at 12:30 pm that the laboratory did not verify QC materials for Hematology tests performed on the Abacas 3 analyzer.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory. The findings include: 1. The LD failed to ensure that PS procedures performed on the Abacus 3CP analyzer were adequate. Cross refer to D 6013. 2. The LD failed to enroll in an approved PT program for Hematology. Cross refer to D 6015.

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 Testing Personnel (TP), the Laboratory Director (LD) failed to

ensure that PS procedures performed on the Abacus 3CP analyzer were adequate from January 2017 to the date of survey. The finding includes: 1. The LD did not review and sign Linearity studies. 2. The TP # 1 listed on CMS form 209 confirmed on 9/5 /2018 at 2:30 pm that the linearity studies were not reviewed.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an approved PT program for Hematology tests performed on the Abacus 3CP analyzer from January 2017 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 9/5/2018 at 3:30 pm the laboratory was not enrolled in PT.