

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2097353	(X3) Date Survey Completed 11/21/2023
Name of Provider or Supplier Regional Cancer Care Associates At Palisades	Street Address, City, State 7650 River Road, 2nd Floor, Suite 200, North Bergen, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all attestation statements provided by the College of American Pathologists (CAP) for Hematology 2nd and 3rd events in calendar year 2023 were signed by TP and the Laboratory Director (LD) . The findings include: 1. The attestation statements were not signed by both the LD and TP for CAP events FH2-C-23 and FH2-B-23. 2. TP #1 as listed on the CMS-209 form confirmed on 11/21/23 at 11:00 am that the attestation statements for the aforementioned events were not signed by the LD and TP.</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,</p>

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 Testing Personnel (TP) the laboratory failed to have all applicable procedures for Hematology Tests performed on the Sysmex XN analyzer from 11/1/23 to the date of the survey. The findings include: 1. The laboratory did not have the following procedures in the Sysmex Standard Operating Procedures (SOP) Manual: a. 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. Preparation of solutions, calibrators, controls, reagents and other materials used in testing. c. Calibration and calibration verification procedures. d. Control Procedures e. Corrective actions to be taken when calibrations or controls fail. f. Description of the course of action to take if a test system becomes inoperable. g. Limitations in the test methodology, including interfering substances. h. The reportable range for test results for the test system as established or verified in 493.1253. i. Description of the course of action to take if a test system becomes inoperable. 2. The TP #1 as listed on the CMS-209 form confirmed on 11/21/23 at 12:00 pm that the PM did not have all applicable procedures for the Sysmex XN 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 Testing Personnel (TP), the laboratory failed to record discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer from 11/1/23 to the date of survey. The finding includes: 1. TP#1 as listed on the CMS-209 form stated the Beckman Coulter AcT Diff2 is no longer in use and the Sysmex XN analyzer is currently in use for Hematology testing. 2. The TP #1 as listed on the CMS-209 form confirmed on 11/21/23 at 10:45 am that discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer were not documented.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on lack of Maintenance Records (MR), review of the Sysmex XN Manual and interview with the Testing Personnel (TP) the laboratory failed to document maintenance performed on the Sysmex XN analyzer from 11/1/23 to the date of the survey. The TP #1 as listed on the CMS-209 form confirmed on 11/21/23 at 10:45 am that the laboratory failed to document maintenance performed.

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 for the Sysmex XN analyzer were adequate from 11/1/23 to the date of survey. The findings include: 1. The LD failed to approve and sign the PS before the Sysmex XN analyzer was put into use. 2. TP # 1 as listed on CMS-209 form confirmed on 11/21/23 at 12:00pm the LD failed to approve and sign the PS records for the Sysmex XN analyzer.

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 Testing Personnel (TP), 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 11/1/23 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 TP#1 as listed on the CMS-209 form confirmed on 11/21/23 at 11:00 AM that approved procedures for the Sysmex BCQM was not available for review.