

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0140891	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Westchester Cancer Care Rllp	Street Address, City, State 175 Memorial Highway, Suite 1-7, New Rochelle, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory competency records and an interview with the laboratory director and the testing person, the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing. Findings Include: It was confirmed by the laboratory director on August 22, at approximately 11:30 am, that the laboratory director acting as the technical consultant failed to have documentation of semi-annual competency for the new testing person who performs hematology 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) 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</p>

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 a review of the laboratory procedure manual and an interview with the laboratory director and testing person, the laboratory failed to have a complete procedure manual. Finding Include: The laboratory director confirmed in an interview on August 22, 2019, at approximately 11:15 AM, the laboratory failed to have a procedure for the lot to lot verification for new lots of control material.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of maintenance records for the Cell Dyn 1700 and confirmed in an interview with the laboratory director and testing person at approximately 11:00 am, the laboratory failed to retain all copies of the instrument start-up from October 5, 2017, to the date of this survey. Approximately 980 patients test were performed and results released. This is a repeat deficiency from the survey of October 5, 2017.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, QC records and an interview with the laboratory director and testing person, the laboratory director failed to ensure that the QC program was maintained for hematology testing. Refer to: D5411 This is a repeat deficiency from the survey of October 5, 2017.

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 a review of QA procedures, and an interview with the laboratory director and testing person, the director failed to ensure that the laboratory's QA program for hematology was maintained for all phases of laboratory testing. Refer to: D5209 and D5403

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with the director and testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual competency for the new testing person during the first year of patient testing in 2018. Refer to D5209.