

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0102852	<b>(X3) Date Survey Completed</b> 02/08/2022
<b>Name of Provider or Supplier</b> Iyengar Hematology Oncology Medical Ctr Pa	<b>Street Address, City, State</b> 27 East 29th Street, Bayonne, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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) and interview with the Technical Consultant (TC), the laboratory failed to follow their procedure for "Policy for Repeat CBC" from 10/20/20 to 12/14/20. The finding include: 1. The "Policy for Repeat CBC" states "Repeat CBC is an asterisk appears". 2. One out of three patient results had an analyte flagged with and asterisk. 3. There was no documented evidence that the patient sample was rerun. 2. The TC confirmed on 2/8/22 at 11:21 am the "Policy for Repeat CBC" was not being followed.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Instructions (MI), Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to follow the MI for "What Flags Mean" from 8/10/21 to 10/06/21. The finding</p>

includes: 1. COULTER 4C Plus Cell Control Low Lot # 068300 Flagged "\*" for White Blood Cell Count (WBC) and Differential 10 out of 35 days from 8/10/21 to 10/06/21. 2. The MI stated "If \* on WBC and Differential # only, 35 fL count interference check failed. Possible interference with WBC count.", "1. Thoroughly mix and rerun the sample. 2. If the voteout repeats, zap apertures" 3. There was no documented evidence that the aforementioned procedure was performed. 4. The TC confirmed on 2/8/22 at 10:00 am the laboratory did not follow the MI.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Calibration (CAL) records, Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Act 2 analyzer from January 2020 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory performed Cal once in the calendar years 2021 and 2020. 2. The TC confirmed on 2/8/22 at 10:32 am that the laboratory failed to perform and document Cal once every six months.

**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 Technical Consultant (TC), the laboratory failed to verify that the assayed QC

materials were within the acceptable ranges before they were put into use for tests performed on the Beckman Coulter AcT from 5/29/19 to the date of survey. The TC confirmed on 2/8/22 at 11:10 am that the laboratory did not verify QC material.

**D5783**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records and interview with Technical Consultant (TC) the laboratory failed to take corrective action when one out of two levels of controls were out of range for Complete Blood Count (CBC) tests performed on COULTERACT diff Analyzer from on 11/24/21. The findings include:  
1. COULTER 4C Plus Cell Controls level 1 and 2 was out of range for Red Cell Distribution Width, Hemoglobin, Mean corpuscular hemoglobin concentration, mean corpuscular hemoglobin, White Blood Cell Count, on 11/24/21. 2. 15 patients were run and reported. 3. The TC confirmed on 2/8/22 at 11:00 am that no corrective action was taken for out of range QC.

**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 surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure that the QC program was maintained for laboratory services provided from 5/26/19 to the date of the survey. The findings include: 1. There was no evidence of quarterly QC review by the LD. 2. There was no documented corrective action when QC analytes were flagged and rerun. 3. The TC confirmed on 2/8/22 the LD did not ensure the QC plan was maintained. .

**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 lack of a Quality Assurance (QA) plan and interview with the Technical Consultant (TC), the Laboratory Director failed to establish a QA plan from 5/29/2019 to the date of the survey. The TC confirmed on 2/8/22 at 11:30 am that a QA plan had not been established.