Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0102852	01/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Iyengar Hematology Oncology Medical Ctr Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 surveyor review of Patient Work Records (WR), review of the Manufacture Operator Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for Hematology testing performed on the Medonics analyzer from May 2022 to the date of survey. The findings include: 1. Ten out of Ten WR revived had an SCH flag on the Platelet count (PLT). 2. The OM Section "6.3 Morphology Flags, 6.3.1 Flags on PLT Distribution Curve"states "3- If the number of particles between 18fl and 25fl are too high, the "SCH" flag will be triggered. Suspect abnormalities include: Presence of Schizocytes, Presence of Platelet aggregates: Verify the Platelet results on a stained blood smear". 3. There was no evidence that the laboratory "Verified the Platelet results on a stained blood smear". 4. The TP confirmed on 1/30/24 at 1:40 pm the laboratory failed to follow the OM.
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 the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify Minotrol-16 lot # MX445 before use for Complete Blood Count (CBC) tests from 2/8/22 to the date of survey. The TP confirmed 1/30/24 at 2:15 pm that QC material was not verified before putting in use.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyors observation of Qualitry Control (QC) material in use and interview with the Testin Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for controls from 2/8/22 the time of the survey. The finding includes: 1. Controls in use did not have an open or expiration dates documented as per MS. 2. The TP confirmed on 1/30/24 at 1:20 pm that MS were not followed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 2/8/22 the date of survey. The finding includes: 1. The laboratory failed to have a Quality Control Verification (QVC) procedure that stated how to verify new lots of controls before they were put in use. 2. The TP confirmed on 1/30/24 at 1:40 pm that the laboratory failed to have the aforementioned procedure.
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 for Complete Blood Count (CBC) tests performed on the Modonic analyzer were adequate from May 2022 to the date of survey. The findings include: 1. There was no raw adequate for the method comparison. 2. There was no source for the patient Reference Range. 3. The analyzer that the laboratory used in the method comparison was not defined. 4. The TP confirmed on 1/30/24 at 1:15 pm that PS records were not adequate.