Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2036126	12/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Consultants In Medical Oncology & Hematology	Crozer Medical Plaza Ii Cancer Center, Glen Mills, PA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel 5 (TP #5) , the Laboratory Director (LD) and testing personnel (TP) failed to sign 7 of 7 API PT attestation statements for Hematology/Coagulation testing performed in 2021, 2022, and 2023. Findings Include: 1. On the day of the survey, 12/11/23 at 12:01pm, the following 6 of 7 API PT attestation statements reviewed were not signed by the LD and the Testing Personnel: - Hematology/Coagulation - 2021 Event # 3 - 2022 Event # 1 and Event #3 - 2023 Event #1, Event #2, and Event #3 3. The following 1 of 7 API PT attestations were not signed by the Laboratory Director: - Hematology /Coagulation - 2022 Event # 2 4. TP#5 confirmed the findings above on 12/11/2023 around 1:00 pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by:

	Based on review of the competency policy and interview with testing personnel (TP) #5, the laboratory failed to provide a competency procedure that includes the six componenets required for competency assessment for 8 of 10 TP who performed Hematology examinations from 2/16/2022 to the day of survey. Findings Include: 1. On the day of survey, 12/11/2023 at 09:38, the laboratory failed to provide a complete procedure that includes the required 6 components of competency assessment per CLIA from 2/16/2022 to 12/11/2023. 2. Review of competency assessment records revealed the laboratory failed to assess 8 of 10 TP (CMS 209 testing personnel #2, #3, 4, 5, #6, #7, #9, #10) who performed complete blood cell counts (CBC) with the 6 components required for competency assessment from 2/16/2022 to 12/11/2023. 3. TP #5 confirmed the findings above on 12/11/2023 around 9:30 am.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel #5 (TP #5), the laboratory failed to verify the accuracy for 1 of 5 PT specimens performed for blood cell identification for Event #3 in 2022. Findings Include: 1. On the day of survey, 12/11/2023 at 12:04 pm, review of 2022 API proficiency testing records revealed, the laboratory did not verify the accuracy for the following PT results for API Blood Cell Identifications: - 1 of 5 PT results were not graded by the proficiency testing agency (BCL-14). 2. TP #5 confirmed the finding above on 12/11/2023 aorund 2:00 pm.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, operator manuals, and interview with testing personnel #5 (TP #5), the laboratory failed to have a complete written and approved procedure manual for the XN-430 Sysmex Hematology analyze from 3/8 /2023 to the day of survey. Findings include: 1. On the day of the survey, 12/11/2023 around 11:41 am, review of the procedure manuals for hematology revealed the operators manual were used to perform testing on the following from 3/8/2023 to day of survey: - XN-430 Sysmex (hematology). 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements: - Step by step performance of the procedure including test calculations and interpretation of results. - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures. - Corrective

	action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - Limitations in the test methodology, including interfering substances. - 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. - Reference intervals (normal values). -The reportable range for test results for the test system as established or verified. 3. Review of the operator manual and the procedure manual revealed that the Laboratory Director failed to approve, sign and date the procedure for use of the XN-430 Sysmex. 3. TP #5 confirmed the findings on 12/11/2023 around 11:41 am.
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: Based on review of validation records, quality control records, patient reports and interview with testing personnel #5 (TP #5), the laboratory failed to verify the performance specifications for the Sysmex before reporting patient results from March 8, 2023 to May 8, 2023. Findings include: 1. On the day of survey, 12/11/2023 at 12:30 pm, review of the XN-430 Sysmex validation records revealed the validation was reviewed and approved by the Laboratory Director on May 8, 2023. 2. Review of the ACT-Diff maintenance records revealed the laboratory stopped performing maintenance on March 2023. 3. Review of the XN-430 Sysmex maintenance and QC records revealed the laboratory started performing QC on March 8, 2023. 4. During an interview with TP#5 it was revealed that the XN-430 Sysmex was used to report patients starting in March of 2023. 5. 676 patient results were reported between March 8, 2023 to May 8, 2023. 6. The above findings were confirmed by TP#5 on 12/11/23 at approximately 1:15 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with Testing Personnel 5 (CMS-209 testing personnel 5), the laboratory failed to perform maintenance for 1 of 1 microscopes for 2023. Findings include: 1. The Laboratory's procedure, "Microscope Maintenance," states: "All microscopes require annual service to include cleaning and maintenance and must be documented on the Microscope Service Record." 2. On the day of survey, 12/11/2023 at 11:25, review of the microscope service records revealed

	the microscope was last serviced on 2/18/2022. 3. The above findings were confirmed in interview with TP #5 on 12/11/2023 at approximately 11:25 am. *This is a repeated deficiency.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel #5 (TP #5) the laboratory failed to have an adequate system in place to ensure test results were accurately and reliably sent from the point of data entry to final report destination from 2/16/2022 to 12/11/2023. Findings include: 1. On the day of survey, 12/11 2023 at approximately 12:50 pm, the laboratory failed to provide records for the periodic checks performed to verify that transmitions of patient results were accurately transmitted between the LIS (LabDaq) and the EMR (Mossaic) from 2/16/2022 to 12 /11/2023. 2. The laboratory could not provide a procedure for performing periodic checks between the LIS and the EMR. 3. TP #5 confirmed the findings above on 12/11 /2023 at 12:50 pm.
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 review of delegation of duties records and interview with Testing Personnel #5 (TP #5), the Laboratory Director (LD) assigned a nondelegable duty to 3 of 3 designees in 2022 and 2023. Findings Include: 1. The laboratory provided a form, for both 2022 and 2023, that states "To All Lab Directors, Please sign below to delegate your authority to another person, i.e. medical technician or RN, to sign Procedure Manuals, Proficiency Testing, etc. in your abscence." 2. The approval of a procedure manual is a non-delegable duty of the Laboratory Director. 3. The above findings were confirmed in interview by TP #5 on 12/11/23 at approximately 11:41 am.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, delegation of duties, and interview with Testing Personnel #5 (TP #5), the laboratory director (LD) specified, in writing, delegable duties to unqualified personnel from 2/16/2022 to 12/11/2023. Findings include: 1. On the day of survey, 12/11/2023, the laboratory provided a form, for both 2022 and 2023, that states "To All Lab Directors, Please sign below to delegate your authority to another person, i.e. medical technician or RN, to sign Procedure Manuals, Proficiency Testing, etc. in your abscence." 2. Review of the document provided revealed the LD assigned the duities to Testing Personnel #2 (TP #2). 3. Per CMS-209, TP #2 does not qualify as a Technical Consultant or Technical Supervisor. 4. TP #2 has an associate degree in nursing. 5. Review of competency assessment records revealed that competency assessment was performed by unqualified personnel (TP #2 and TP #5). 6. TP #5 confirmed the findings above on 12/11/23 at approximately 12: 00 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of competency assessment (CA) records and interview with the Testing Personnel #5 (TP #5), the Technical Consultant (TC) failed to assess the six month competency of 7 of 8 Testing Personnel (TP) who performed XN-430 Sysmex Complete Blood Cell (CBC) counts in hematology from 5/8/2023 to 12/11/2023. Finding Include: 1. On the day of survey, 12/11/23 at 10:40 am, review of Testing Personnel compentencies revealed that the six month competency for a new instrument, the XN-430 Sysmex, was not performed on site for 7 of 8 Testing Personnel. 2. The laboratory performed 676 CBC with auto differential from 3/8/2023 to 5/8/2023. 3. TP #5 confirmed the findings above on 12/11/2023 around 2:00 pm.