Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0996878	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cancer & Leukemia Center Division Of Mhp	44344 Dequindre Ste 260, Sterling Heights, MI	

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 record review and interview with the laboratory liaison, the Laboratory Director (LD) failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for 1 (NC19-Q3) of 7 events reviewed. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) proficiency testing documents revealed the laboratory director did not sign the attestation statement sheet for 1 (NC19-Q3) of 7 events. 2. During the interview on 11 /21/19 at 12:12 pm, the laboratory liaison acknowledged the LD did not sign the attestation statement sheet.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison, the laboratory failed to retain the hematology Cell-Dyn 1800 patient data logs, patient accession logs, problem log, and the monthly eyewash inspection log for 2 (11/21/18 to 11/21 /19) of 2 years. Findings include: 1. Record review of the hematology Cell-Dyn 1800

	monthly documentation logs revealed the following were not available on the day of the survey: a. problem logs for 2018 b. accession logs from 11/1/18 to 12/5/18 c. data logs from 10/01/18 to 12/06/18 2. Record review of the monthly "Eye Wash Station Inspection" log revealed a lack of documentation for 11/21/18 to 11/21/19. 3. During the interview on 11/21/19 at approximately 3:00 pm, the laboratory liaison confirmed the above documents were not available on the day of the survey.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Hematology as specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to ensure written competency policies were implemented. Refer to D5209. 2. The laboratory failed to verify the proficiency testing accuracy of the hematology differential. Refer to D5215. 3. The laboratory failed to follow written procedures to establish new quality control ranges, enter new ranges into the hematology instrument, and review quality control and Levy-Jennings charts. Refer to D5401. 4. The laboratory failed to perform and document the hematology Cell-Dyn 1800 maintenance as required. Refer to D5429. 5. The laboratory failed to perform the hematology complete blood cell count (CBC) quality control testing as protocol states for each day of patient testing. Refer to D5445.
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 record review and interview with the office liaison, the laboratory failed to assess a 6 month and annual competency assessment for 6 {Testing Personnel #1 (TP1), #2 (TP2), #3 (TP3), #4 (TP4), #5 (TP5), and #6 (TP6)} of 10 testing personnel reviewed. Findings include: 1. Record review of laboratory personnel competency records revealed the following assessments were not documented: a. annual assessment - TP1 due in 8/2019 b. annual assessment - TP2 due in 9/2019 c. 6 month assessment - TP3 due in 12/2018 d. annual assessment - TP4 due in 5/2019 e. annual assessment - TP5 due in 9/2019 f. annual assessment - TP6 due in 5/2019 2. During the interview on 11/21/19 at 11:32 am, the laboratory liaison confirmed no documentation was available for the above competency assessments.
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 record review and interview with the laboratory liaison, the laboratory failed to verify the accuracy of the hematology differential for 1 (event NC18-Q3) of 7 events. Findings include: 1. Record review for 1 (event NC18-Q3) of 7 proficiency testing events revealed the laboratory failed to submit results for the "Cell ID" or white blood cell (WBC) differential (Diff) resulting in a final grade of "0". 2. When requested on 11/21/19 at 12:12 pm, the laboratory liaison was not able to provide documentation showing the laboratory had self evaluated the proficiency testing WBC diff. 3. During the interview on 11/21/19 at 12:12 pm, the laboratory liaison acknowledged the laboratory did not self grade the "0" score against the proficiency testing programs final results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: . Based on procedure review and interview with the laboratory liaison, the laboratory failed to follow written procedures to establish new quality control ranges, enter new ranges into the hematology instrument, and review quality control and Levy-Jennings charts for 11 (October 2018 to September 2019) of 24 months reviewed. Findings include: 1. Procedure review revealed the Technical Consultant (TC) at the time of the deficiencies did not follow written procedures to: a. establish new quality control ranges for the implementation of lot #91050 b. enter the new quality control ranges for lot# 91050 into the Cell-Dyn 1800 hematology instrument c. review the monthly quality control records and Levy-Jennings' charts 2. On 11/21/19 at approximately 3: 45 pm when queried, the laboratory liaison was not able to provide the surveyor the documentation requested. 3. During the interview on 11/21/19 at approximately 3:45 pm, the laboratory liaison acknowledged the laboratory had no documentation for the above procedural tasks for 11 of the 24 months reviewed by the surveyor.
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 record review and interview with the laboratory liaison, the laboratory failed to perform and document the hematology Cell-Dyn 1800 maintenance as

	required for 4 (April, June, July, and August) of 24 monthly logs reviewed. Findings include: 1. Record review of the "Cell-Dyn 1800 Maintenance Log" revealed the following tasks for the weekly and monthly maintenance as follows: a. weekly - "Aspiration Probe Exterior" b. monthly - "Clean Aperture Plate (Count time +/- 0.2s), Lyse Inlet Tubing Rinse, Print Data Log, Print QC Logs & Graphs (Director Review), and Perform Quality Assurance Review." 2. Record review of the "Cell-Dyn 1800 Maintenance Log" revealed for 4 of 24 months the following weekly and monthly tasks not completed: a. weekly 1. April 2019 - 1 of 4 weeks not completed 2. June 2019 - 3 of 4 weeks not completed 3. July 2019 - 1 of 4 weeks not completed 4. August 2019 - 4 of 4 weeks not competed b. monthly 1. no monthly maintenance documented for April, June, July, and August in 2019 3. During the interview on 11/21 /19 at 1:45 pm, the office liaison confirmed the above maintenance tasks were not performed and documented.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with the laboratory liaison, the laboratory failed to perform the hematology complete blood cell count (CBC) quality control testing as protocol states for each day of patient testing for 1) 13 (4/24 /2019 to 10/16/2019) of 100 days of testing reviewed for lot # 9105 and 2) for 2 (9587 and 1536) of 12 patient charts reviewed. Findings include: 1. The "Quality Control Policy" found in the "Policy & Procedure Manual" states that 3 levels of controls must be run each day of patient testing and that 2 out of the 3 levels makes for an acceptable run. 2. Record review of the daily CBC quality printouts for lot # 9105 revealed the laboratory ran patient specimens when the laboratory did not have at least 2 of the 3 levels of controls within control ranges as follows: a. white blood cell (WBC) 1. 2 of 3 controls out of range for June 25, 2019 (low and normal) 2. 3 of 3 controls out of range for June 26-June 28 and July 1-3, 5, and 8 (low, normal, and high) b. % lymphocytes 1. 2 of 3 controls out of range for July 1 and July 3 (normal and high) c. % granulocytes 1. 2 of 3 controls out of range for July 1 and July 3 ((normal and high) d. lymphocytes 1. 2 of 3 controls out of range for July 27-28 and July 1-3, 5, and 8 (normal and high) e. red blood cell (RBC) 1. 2 of 3 controls out of range for October 7-10 (normal and high) f. hematocrit (HCT) 1. 2 of 3 controls out of range for October 7 and 8 (normal and high) 3. Record review for 2 (9587 and 1536) of 12 patient charts reviewed revealed the following: a. 9587 run on 10/11/18 - no documentation of controls run b. 1536 run on 10/10/19 - 2 of 3 controls out of range 4. During the interview on 11/21/19 at approximately 3:30 pm, the office liaison confirmed patient samples had been run when the controls were not within acceptable ranges and no corrective action was documented.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison, the Laboratory Director (LD) failed to ensure all proficiency testing final reports were reviewed by the appropriate staff to evaluate the laboratory's performance for 1 (NC19-Q2) of 7 testing events reviewed. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) testing records revealed a lack of documentation of review by appropriate staff and the LD for 1 (NC19-Q2) of 7 events. 2. During the interview on 11/21/19 at 12:12 pm, the laboratory liaison acknowledged there was no documentation of a review by the appropriate staff for the above proficiency testing event.