Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0973254	11/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	1550 Watertower Place Suite 500, East Lansing, 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
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 observation, record review, and interview with Testing Personnel (TP) #1, TP2, and the Office Manager (OM), the laboratory failed to establish written procedures to perform testing on the new Beckman Coulter DxH 520 hematology instrument for 14 (11/4/2020 to 11/18/2020) of 14 days of operation. Findings include: 1. An observation made by the surveyor on 11/18/2020 at 9:18 am during a tour of the laboratory revealed a Beckman Coulter DxH 520 hematology instrument in the laboratory. 2. A review of the laboratory's procedures revealed a lack of procedures to perform the hematology testing for 14 (11/4/2020 to 11/18/2020) of 14 days of operation for the Beckman Coulter DxH 520 instrument. 3. An interview on 11 /18/2020 at approximately 4:00 pm with TP1, TP2, and the OM confirmed the laboratory did not establish procedures to perform hematology testing on the new instrument prior to putting into use.
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 record review and interview with Testing Personnel (TP) #1, TP2, and the Office Manager (OM), the laboratory failed to perform the hematology calibration procedures as stated in the operator's manual for 2 (10/4/2019 and 10/16/2020) of 5 calibrations reviewed. Findings include: 1. A review of the operator's manual for the Beckman Coulter AcT diff 2 calibration procedure revealed the laboratory is to perform a reproducibility and carryover test prior to performing the calibration. 2. A record review of the calibration documents for 2 of 5 calibrations performed revealed a lack of documentation for the reproducibility and carryover testing as follows: a. 10 /4/2019 b. 10/16/2020 3. On 11/18/2020 at 11:27 am when requested, TP1 was not able to provide the surveyor with the documentation to show the reproducibility and carryover processes were completed prior to the calibration of the hematology instrument. 4. During the interview on 11/4/2020 at 11:27 am, TP1 confirmed the documentation of the reproducibility and carryover were not available.
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 record review and interview with Testing Personnel (TP) #1, TP2, and the Office Manager (OM), the laboratory failed to ensure control procedures were followed according to laboratory-established requirements for 31 testing days out of 2 years reviewed. Findings include: 1. A review of the laboratory's established "Quality Control " procedure revealed in a section titled "QC procedure using COULTER 4C PLUS Cell Control" step 12 states "Do not report patient test results until control values are acceptable." 2. A review of the laboratory's quality control records for the Beckman Coulter AcT Diff 2 hematology analyzer revealed for 31 days of 2 years reviewed the following days had only two of the three levels of controls within acceptable ranges: a. low control out of range 1. 1/10/2019 - 13 patients run 2. 2/14 /2019 - 10 patients run 3. 5/7/2019 - 9 patients run 4. 5/16/2019 - 17 patients run 5. 5 /21/2019 - 7 patients run 6. 5/23/2019 - 10 patients run 7. 6/5/2019 - 14 patients run 8. 6/11/2019 - 10 patients run 9. 6/26/2019 - 11 patients run 10. 1/15/2020 - 5 patients run 11. 2/21/2020 - 1 patient run 12. 3/31/2020 - 9 patients run 13. 4/16/2020 - 11 patients run 14. 7/13/2020 - 15 patients run 15. 7/14/2020 - 10 patients run 16. 8/12 /2020 - 10 patients run 17. 8/17/2020 - 11 patients run 18. 9/2/2020 - 8 patients run b. normal control out of range 1. 1/24/2019 - 6 patients run 2. 1/30/2019 - 7 patients run

	3. 1/31/2019 - 13 patients run 4. 6/7/2019 - 1 patient run 5. 9/23/2019 - 10 patients run 6. 10/8/2019 - 11 patients run 7. 12/18/2019 - 8 patients run 8. 1/2/2020 - 17 patients run 9. 1/27/2020 - 12 patients run 10. 3/23/2020 - 20 patients run c. high control out of range 1. 8/13/2019 - 7 patients run 2. 11/18/2019 - 15 patients run 3. 3/10/2020 - 7 patients run 3. An interview on 11/18/2020 at approximately 4:00 pm with TP1, TP2 and the OM confirmed all three levels of controls are required to be in range before reporting patient results.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, TP2, and the Office Manager (OM), the laboratory failed to provide reference intervals on test reports for 8 (#8 - #15) of 15 patient charts audited. Findings include; 1. On 11/18 /2020 at approximately 9:15 am, the OM stated that the facility started working with another healthcare entity in 1/1/2020. 2. A record review of patient charts chosen from the daily logs and patient complete blood cell count (CBC) test results entered into the electronic medical record (EMR) system showed for 8 of the 15 charts audited, the test reports did not have a reference range listed on the final report as follows: a. Patient #8 - no Mean Platelet Volume (MPV) b. Patient #9 - no MPV c. Patient #10 - no Red Blood Cell Count (RBC), Hemoglobin (Hgb), and MPV d. Patient #11 - no MPV e. Patient #12 - no RBC, Hgb, and MPV f. Patient #13 - no RBC, Hgb, and MPV g. Patient #14 - no RBC, Hgb, and MPV h. Patient #15 - no RBC, Hgb, and MPV 3. During an interview on 11/18/2020 at approximately 4:00 pm, TP1, TP2, and the OM confirmed the final CBC report in the EMR since the joining with the new healthcare entity did not contain all the analyte reference ranges.
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 record review and interview with Testing Personnel (TP) #1, TP2, and the Office Manager (OM), the Technical Consultant (TC) failed to evaluate the competency of testing personnel performing the hematology testing for 8 (TP1, TP2, TP3, TP4, TP5, TP6, TP7, and TP8) of 8 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of testing personnel competency assessments revealed testing personnel competencies were assessed by a "reviewer" TP1 and a TP no longer listed on the CMS-209 for the following: a. TP1 assessed by employee no longer listed on the CMS-209 with an assessment date of 2/27/2019. b. TP2 assessed by TP1, assessment dates of 3/16/2020 and 9/10/2020. c. TP3 assessed by TP1, assessment dates of 2/28/2019 and 4/6/2020. d. TP4 assessed by TP1, assessment dates of 2/27/2019 and 5/9/2020. e. TP5 assessed by TP1, assessment

	dates of 2/28/2020 and 8/19/2020. f. TP6 assessed by TP1, assessment dates of 5/14 /2019 and 5/7/2020. g. TP7 assessed by TP1, assessment dates of 8/16/2019, 3/20 /2020, and 5/7/2020. h. TP8 assessed by TP1, assessment dates of 2/27/2019 and 5/8 /2020. 2. A record review revealed the laboratory did not have a policy and procedure to show the technical consultant/supervisor is responsible for assessing the competency of the testing personnel. 3. An interview on 11/18/2020 at approximately 4:00 pm, TP1, TP2, and the OM confirmed TP1 and an employee no longer listed on the CMS-209 assessing the TP competencies was not qualified as a TC and not listed on the CMS-209 form as a TC.