Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0718860	04/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Blood & Cancer Center Inc	3695a Boardman-Canfield Rd, Canfield, OH	

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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to achieve College of American Pathologists (CAP) proficiency testing (PT) scores of at least 80% (percent) for iron in one out of three testing events in 2024 and total bilirubin (tbil) in one out of three testing events in 2025 in the specialty of Chemistry resulting in unsatisfactory analyte performance. Findings Include: 1. Review of the laboratory's 2024 and 2025 CAP Chemistry PT documentation, provided on the date of the inspection, found iron was scored 40% for the first testing event of 2024 and tbil was scored 40% for the second testing event of 2025. 2. Further review of the laboratory's 2024 and 2025 CAP PT documentation of the unsatisfactory iron and tbil results revealed the unacceptable PT challenges were re-run and within acceptable limits. 3. TP#1 confirmed, on 4/15/2026 at 2:15 PM, the unacceptable iron and tbil PT scores. 4. This deficient practice had the potential to affect 1,912 patient iron tests performed between the third testing event of 2023 and the second testing event of 2024 (09/2023-05/2024) and 6,294 patient tbil tests performed between the first and third testing events of 2025 (03/2025-09/2025).
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. In addition,

	retain the following: This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to retain analytic system activity records, including patient test records for the Architect Ci4100 Chemistry analyzer test system for the past two years with the implementation of the new instrument in January 2024. This deficient practice affected 536,102 out of 577,340 patient chemistry test results between 01/04/2024 through 04/15/2026. Findings Include: 1. Review of all of the laboratory's policies and procedures and the "Procedure for Architect Ci4100", approved via signature and date by the Laboratory Director on 09/12/2019, did not find any mention of archive and retention requirements for the Architect Ci4100 analytic system activity. 2. Review of the laboratory's volume of patient test records revealed the laboratory completed a total of 577,340 patient chemistry test results on the Architect Ci4100 instrument between 01/04/2024 through 04/15/2026. 3. The Inspector requested the laboratory's approved record retention policy and procedure and their 2024, 2025 and 2026 Architect Ci4100 instrument patient records from TP#1. TP#1 confirmed the laboratory did not establish a record retention policy and procedure, did not routinely print patient instrument results and the Architect Ci4100 software system only retains up to 50,000 analyte results then overwrites them by first in first out. TP#1 further confirmed they were unable to access or retrieve any of the 536,102 patient results from the instrument prior to March 5, 2026 and was unable to provide at least the prior two years of patient instrument results. The interview occurred on 04/30/2026 via a telephone conversation at 10:01 AM.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to retain analytic system activity records for the Architect Ci4100 Chemistry analyzer test system for the past two years, to include the test system performance specification raw data conducted in January 2024 with the implementation of the new instrument since the last CLIA inspection on 11/08/2023. This deficient practice had the potential to affect 536,102 out of 577,340 patient chemistry test results between 01/04/2024 through 04/15/2026. Findings Include: 1. Review of all of the laboratory's policies and procedures and the "Procedure for Architect Ci4100", approved via signature and date by the Laboratory Director on 09/12/2019, did not find any mention of archive and retention requirements for the Architect Ci4100 analytic system activity. 2. Review of laboratory volume test records revealed the laboratory completed a total of 577,340 patient chemistry test results on the Architect Ci4100 instrument between 01/04/2024 through 04/15/2026. 3. The Inspector requested the laboratory's 2024 performance specification raw data from the newly installed Architect Ci4100 conducted prior to patient test implementation on 01/04/2024 from TP#1. TP#1 was unable to locate the printed documentation in the laboratory records, from the installation vendor nor the instrument archived data prior to March 5, 2026. TP#1 further confirmed the

	laboratory did not routinely print instrument results and the Architect Ci4100 software system only retains up to 50,000 analyte results then overwrites them by first in first out. TP#1 was unable to provide the requested documentation within 15 days from the date of the inspection. The interview occurred on 04/30/2026 via a telephone conversation at 10:01 AM.
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 an interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow written policies and procedures to assess the competency of three out of three of the Technical Consultants (TC) based on the responsibilities of the position for moderate complexity routine chemistry, endocrinology and hematology testing procedures performed. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 03/31/2026 and provided on the date of the inspection, revealed three out of three qualified and listed individuals to function as TC's for the moderate complexity chemistry, endocrinology and hematology testing procedures performed. 2. Review of all of the laboratory's policies and procedures provided on the date of the inspection revealed no policy and procedure to conduct TC competency assessments based on the CLIA responsibilities of the position. 3. Review of the laboratory's 2024, 2025 and 2026 competency assessment documentation did not find any competency assessment documentation based on the TC responsibilities for TC#1, TC#2 or TC#3. 4. The Inspector requested the laboratory's approved competency assessment policy and procedure based on the responsibilities of the TC and the 2024, 2025 and 2026 TC competency assessment documentation from TP#1. TP#1 confirmed the laboratory did not establish a policy and procedure to assess the TC's based on the responsibilities of the position and did not conduct competency assessments on TC#1, TC#2 and TC#3 in 2024, 2025 and 2026. TP#1 was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/15/2026 at 1:40 PM. 5. Review of laboratory test records revealed 835,020 patient test results reported between 11/08/2023 and 04/15/2026.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to document corrective actions taken when the complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed outside of established operating parameters on the Coulter DxH600 hematology analyzer in the specialty of Hematology. This deficient practice had the potential to affect 216,450 out of 216,450 patient hematology test results between 11/08/2023 and 04/15/2026. Findings Include: 1. Review of the laboratory's "Complete Blood Count Procedure" policy and procedure, approved by the Laboratory Director on 09/12/2019 and provided on the date of the inspection, did not find any instructions to document errors and incidents when any system, calibration or quality control (QC) errors were not acceptable, along with the actions taken to correct the problem(s). 2. Review of the laboratory's 2024, 2025 and 2026 CBC QC records identified errors with no corrective action documentation as follows: Date QC level Error 12/20/24 level 2 excessive debris 12/31/24 level 3 excessive debris 01/10/25 level 3 WBC, NE and LY-high 12/29/25 level 1 RBC, HGB-high, NE-low 12/29/25 level 2 excessive debris 01 /19/26 level 2 RBC-high 01/20/26 level 2 Cellular interference 02/23/26 level 3 System Event:D WBC; white blood cell count NE; neutrophil count LY; lymphocyte count RBC; red blood cell count HGB; hemoglobin D; system error 3. The Inspector requested the laboratory's approved corrective action policy and procedure and their 2024, 2025 and 2026 corrective action documentation for the Coulter DxH600 hematology analyzer from TP#1. TP#1 confirmed the laboratory did not establish a corrective action policy and procedure, did not document errors or incidents when any system errors, calibration or quality control results were not acceptable, along with the corrective action measures taken and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/15/2026 at 2:30 PM.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure the laboratory's unacceptable College of American Pathologists (CAP) proficiency testing (PT) performance for iron in one out of three testing events in 2024 and total bilirubin (tbil) in one out of three testing events in 2025 were evaluated with corrective action. Findings Include: 1. Review of the laboratory's 2024 and 2025 CAP Chemistry PT documentation, provided on the date of the inspection, found iron was scored 40% for the first testing event of 2024 and tbil was scored 40% for the second testing event of 2025. 2. Further review of the laboratory's 2024 and 2025 CAP PT documentation of the unsatisfactory iron and tbil results revealed the unacceptable PT challenges were re-run and within acceptable limits with no evaluation and corrective action documented. 3. TP#1 confirmed, on 4 /15/2026 at 2:15 PM, the unacceptable iron and tbil PT scores lacked documented evaluation and corrective action. 4. This deficient practice had the potential to affect 1,912 patient iron tests performed between the third testing event of 2023 and the second testing event of 2024 (09/2023-05/2024) and 6,294 patient tbil tests performed between the first and third testing events of 2025 (03/2025-09/2025).

D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure procedures were established to document and review the acceptable levels of analytical performance of maintenance, quality control (QC), calibration, calibration verification, and patient quality assessments (QA) tracer activities for three subspecialties/specialities (routine chemistry, endocrinology and hematology) utilized for patient testing. This had the potential to affect 835,020 out of 835,020 patients test results between 11/08/2023 to 04/15/2026. Findings Include: 1. Review of the laboratory's CMS-116, approved via signature and date by the Laboratory Director on 03/31/2026 and provided on the date of the inspection revealed the laboratory performed routine chemistry, endocrinology and hematology testing on patient specimens. 2. Review of all of the laboratory's policies and procedures did not find any mention of instructions to document, via signature and date, the review of the laboratory's maintenance, QC, calibration, calibration verification and patient QA tracer activities as evidence the laboratory's criteria of acceptability had been met. 3. Review of the laboratory's 2024, 2025 and 2026 maintenance, QC, calibration, calibration verification and patient QA tracer records did not find evidence, via signature and date, that any review was conducted. 4. The Inspector requested the laboratory's approved policy and procedure indicating instructions for record review and their 2024, 2025 and 2026 documented evidence of maintenance, QC, calibration, calibration verification and patient QA tracer record review from TP#1. TP#1 stated all documentation is reviewed before filing into their respective 3-ringed binders and confirmed there was no signature and date as evidence. The interview occurred on 04/15/2026 at 3:00 PM. 5. Review of the laboratory's test records revealed 835,020 patient test results reported between 11/08 /2023 and 04/15/2026.