Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315529	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Pa Of West Tennessee, The	264 Coatsland Dr, Jackson, TN	

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
D0000	During a recertification survey conducted on 3/18/2026, the laboratory was found out of compliance with the following conditions: 493.1215 Condition: Hematology. 493. 1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and staff interview, the testing personnel and laboratory director/previous technical consultant failed to sign the PT attestation statement for Hematology 2024 Event Three (one of eleven PT events reviewed from 2024 and 2025). The findings include: 1. Review of the laboratory's CAP PT records revealed that the testing personnel and laboratory director failed to sign the PT attestation statement for Hematology 2024 Event Three (FH16-C). 2. The current technical consultant confirmed the survey findings during an interview on 03/18/26 at 4:30 p.m.
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 a review of the laboratory's Proficiency Testing (PT) policy, a review of the laboratory's proficiency testing records, laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) quality control (QC) records, a review of instrument validation records, a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), a review of laboratory records, and staff interview, the laboratory failed to follow the PT policy for review of PT performance evaluation reports and failed to follow the policy for performing corrective action for unacceptable and unsatisfactory PT scores for three of eleven events reviewed from 2024 and 2025 (Refer to D5291), failed to follow the QC corrective action for CBC w/Diff (Refer to D5401), failed to ensure performance verification studies were adequate (Refer to D5421), and failed to ensure quality assessment policies and procedures were followed (Refer to D5791).
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Proficiency Testing (PT) policy, a review of the laboratory's proficiency testing records, and staff interview, the laboratory failed to follow the PT policy for review of PT performance evaluation reports and failed to follow the policy for performing corrective action for unacceptable and unsatisfactory PT scores for three of eleven events reviewed from 2024 and 2025. The findings include: 1. A review of the laboratory's proficiency testing policy revealed the following: PT results are reviewed by the lab director upon receipt from the PT program. If a score below 100% is received, an investigation is conducted to determine why the samples fell outside the acceptable range. The investigation and corrective actions that caused the failure will be documented and signed by the lab director, lab supervisor, and involved personnel. "Technical problems must be considered when investigating unsatisfactory scores. QC values around the time of the PT sample testing can be a good indicator of a testing system failure. These records must be reviewed. QC results that require excessive repeats, shifts for trends could indicate a failing testing system and should be scrutinized." Patient results reported during the period the PT was unsatisfactory will be reviewed to identify any patient effect during the period. 2. A review of the laboratory's proficiency testing records revealed the following: For 2024 FH16-B Hematology: The laboratory failed to participate in PT due to not changing PT modules when instrumentation changed. The self-evaluation for FH16-B showed scores that were not acceptable according to the laboratory's calculated acceptable ranges. Corrective action was not documented for the unacceptable scores for sample FH16-10 for White Blood Cell count, Neutrophil absolute count, erythrocyte count, hemoglobin, or hematocrit. For 2024 FH16 - C Hematology: The performance evaluation and corrective action had not been reviewed by the laboratory director. The Cell Identification was scored as 60%, the white blood cell count and hemoglobin were scored as 0%. The documented corrective action did not include a review with affected testing personnel, a review by the laboratory

	director, a review of quality control, or a review of patient testing reported during the period. For 2024 CM-B Clinical Microscopy: The PT evaluation report had not been reviewed by the laboratory director. Unacceptable results were obtained for sample number USP-05 (urine microscopy) with no documented corrective action. The urine microscopy sample CMP-14 was ungraded, with no evaluation of the results to assess the laboratory's performance. 3. The current technical consultant confirmed the survey findings during an interview on 03/18/26 at 4:30 p.m. Word Key: QC=Quality Control
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) quality control (QC) records, and staff interview, the laboratory failed to follow the procedure for performing QC corrective action for one of three master lot numbers selected for review from 2024 and 2025. The findings include: 1. Laboratory observation on 03/18/26 at 8:15 a.m. revealed the Beckman Coulter DxH 500 (serial number BH020022) used for patient testing for CBC w/Diff. 2. A review of the laboratory's Beckman Coulter DxH procedure manual revealed the following steps for resolving out-of-range quality control: "Before rerunning the control: 1 Ensure that the material is properly mixed according to the instructions for use. 2 Ensure that the identification information is entered correctly. If using a bar-code scanner, ensure the bar-code labels are clean and positioned correctly. 3 Ensure that the setup information (assigned values and expected ranges) matches either the Table of Expected Results for the control or your laboratory's established values. If they do not, change the control information to match. 4 Ensure there are no errors during the cycle. 5 Rerun the control. If the control fails again, try running a new tube of that same control level (or another level of control, if desired). 6 If the control recovery failure continues, contact your Beckman Coulter Representative." 3. A review of the laboratory's CBC w/Diff quality control records for master lot 25169 (352516911 (low level), lot 362516912 (normal level), and lot 372516913 (high level)) used from 02/06/25 to 03/21/25 revealed the following: For the normal level: On 02/27/25, the laboratory performed the normal control 4 times, but did not achieve acceptable QC performance. Documented corrective action was "2 levels w/i range." Affected analytes were the erythrocyte count (RBC), white blood cell count (WBC) and WBC differential. On 03/04/25, the laboratory ran the normal level 5 times before obtaining acceptable QC performance. Affected analytes were the RBC, hemoglobin, and hematocrit. On 03/05/25, the laboratory ran the normal level 14 times before obtaining acceptable QC performance. Affected analytes were the WBC, RBC, hematocrit, hemoglobin, and WBC differential. On 03/07/25, the laboratory ran the normal level 5 times before obtaining acceptable QC performance. Affected analytes were the RBC, hemoglobin, hematocrit, and WBC differential. On 03/10/25, the laboratory ran the normal level 9 times before obtaining acceptable QC results. Affected analytes were the RBC and WBC differential. On 03/14/25, the laboratory ran the normal level 19 times. Acceptable performance was not achieved on that date. Documented corrective action was "2 levels w/i range." The affected analytes were

	RBC, hemoglobin, hematocrit, platelet, and WBC differential. For the high level: On 02/28/25, the laboratory ran the high level 7 times before obtaining acceptable QC results. Affected analytes were the WBC, RBC, hemoglobin, hematocrit and WBC diff. On 03/07/25, the laboratory ran the high level 5 times before obtaining acceptable QC results. Affected analytes were the RBC and hematocrit. 4. Testing person two stated during an interview on 03/18/26 at 4:30 p.m. that the previous lab lead had instructed them to keep repeating the QC until it came in range. This confirmed the survey findings. Word Key: w/i = within
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory observation, review of instrumentation validation records, a lack of documentation, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interview, the laboratory failed to evaluate the reportable range data for the Beckman Coulter DxH 500 CBC w/Diff instrument prior to the instrument being placed into use in July 2024, with approximately 16,500 patient CBC w/Diff analytes reported annually. The findings include: 1. Laboratory observation on 03/18/26 at 8:15 a.m. revealed the Beckman Coulter DxH 500 (Serial # BH 020022) used for patient testing for CBC w /Diff (new since the last survey date). 2. A review of the instrument validation records, signed by the laboratory director/previous technical consultant, on 07/12/24, revealed the following statement: "Instrument Validation has been completed per Beckman Coulter Inc. procedures." "The instrument is fit for use." On the survey date, there was no documentation that the raw data for the linearity study had been evaluated to determine if the study passed or failed. 3. A review of the Form CMS-116 revealed the laboratory performed approximately 16,500 CBC w/Diff analytes annually. 4. The current technical consultant confirmed the survey findings during an interview on 03/18/26 at 4:30 p.m.
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. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, review of laboratory records, and a staff interview, the laboratory failed to follow the policy for reviewing the DxH 500 Complete Blood Count with automated White Blood Cell differential (CBC /Diff) maintenance records from January 2025 to July 2025, failed to review temperature

	records from May 2024 to May 2025, and failed to review CBC w/Diff quality control (QC) for one of the three dates / master lot numbers selected for review from 2024 and 2025. The findings include: 1. A review of the laboratory policy titled "Quality Assurance Policy" revealed: "The laboratory has an ongoing QA program that is designed to monitor , evaluate and improve the quality of laboratory performance and ensure the reliability of testing data." "The lab will identify and resolve any problems that may affect performance and thereby patient care." "The following QA monitors will be actively evaluated to maintain an established standard of laboratory performance and compliance. Data from each monitored area will be collected, recorded and evaluated. When required, appropriate corrective action will be implemented and documented. Monitoring will be continued to assure that the action taken is appropriate and results in correction of the identified problems." Areas included for monitoring were instrument maintenance, temperature monitoring, and quality control. 2. A review of the monthly maintenance records for the Beckman Coulter DxH 500 revealed no documented review of the maintenance records from January 2025 to July 2025. 3. A review of the laboratory's environmental records revealed no documented review or corrective actions from May 2024 to May 2025. Humidity readings were outside the laboratory's range in January 2025 for the following dates: 01/08, 01/09, 01/14, 01/15, 01/16, 01/20, 01/21, 01/22,01/23, 01/27; in February 2025 for the following dates: 02/18, 02/20, 02/21, and 02/24; and in March 2025 on 03/03. 4. A review of the laboratory's CBC w/Diff quality control records for master lot 25169 (lot 352516911 (low level), lot 362516912 (normal level), and lot 372516913(high level) used from 02/06/25 to 03/21/25 revealed no documented review by the laboratory director. For the normal level: On 02/27/25, the laboratory performed the normal control 4 times without obtaining acceptable QC performance. Documented corrective action was "2 levels w/i range." On 03/05/25, the laboratory performed the normal level 14 times before obtaining acceptable QC performance. On 03/10/25, the laboratory performed the normal level 9 times before obtaining acceptable QC results. On 03/14/25, the laboratory performed the normal level 19 times. Acceptable performance was not obtained on that date. Documented corrective action was "2 levels w/i range." For the high level: On 02/28/25, the laboratory performed the high level seven times before obtaining acceptable QC results. On 03/07/25, the laboratory performed the high level five times before obtaining acceptable QC results. 5. During an interview on 03/18/26 at 4:30 p.m., the current technical consultant confirmed the laboratory failed to follow the Quality Assurance policy when it did not conduct review of laboratory records and perform corrective actions. Word Key: w/i=within
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on laboratory observation, lack of documentation, a review of the CASPER 0155 report, a review of the laboratory's proficiency testing records, a review of the laboratory's proficiency testing policy, a review of the laboratory's procedure manual, a review of laboratory records and staff interviews, the laboratory director failed to ensure verification procedures for the DxH 500 CBC w/Diff instrument were adequate (Refer to D6013), failed to ensure the laboratory was properly enroll in proficiency

	testing when test methods changed (Refer to D6015), failed to ensure the proficiency testing quality assessment policy was followed (Refer to D6018), failed to ensure the laboratory's PT corrective action policy was followed (refer to D6019), and failed to ensure the quality control and quality assessment programs were maintained in 2024 and 2025 (Refer to D6020).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, and staff interview, the laboratory director failed to ensure the reportable range study for the Beckman Coulter DxH 500 Complete Blood Count with automated White Blooc Cell Differential (CBC w/Diff) instrument had been evaluated (Refer to D5421).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in the correct PT module when instrumentation changed in 2024. The findings include: 1. Laboratory observation on 03/18/26 at 8:15 a.m. revealed the Beckman Coulter DxH 500 (serial number # BH 020022) used for patient testing for CBC w/Diff (new since the last survey date). 2. A review of the CASPER 0155 report revealed no scores for 2024 Event Two. 3. A review of the laboratory's CAP proficiency testing records revealed the following: Survey sample set FH2-B was received on 04/30/24. The stated due date was 05/21/24. On 05/20/24, documentation revealed that the laboratory contacted CAP regarding the survey sample set. On 05/23/24, the new survey set (FH16-B) was received. Documentation stated on 07/02/24 stated that the lab did not get enrolled in time to be able to access results. 4. Testing person two stated during an interview on 03/18/26 at 10:00 a.m. that the correct PT set was not ordered when the laboratory changed instruments. This confirmed the survey findings.
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 a review of the laboratory proficiency testing policy, proficiency testing records and staff interview, the laboratory director failed to ensure PT evaluation reports were reviewed in 2024. (Refer to D5291)
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing policy, proficiency testing records and staff interview, the laboratory director failed to ensure PT corrective actions were performed according to policy in 2024. (Refer to D5291)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, a review of laboratory records, and staff interviews, the laboratory director failed to ensure the quality control and quality assessment programs were maintained in 2024 and 2025 (Refer to D5401 and D5791).