Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0665438	04/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Akron Children's Hospital Pathology And Lab Med	One Perkins Square, Laboratory Office 5th Floor, Akron, 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) 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 interviews with the Administrative Director (AD), General Supervisor (GS) #4 and GS#11, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte partial pressure of oxygen (pO2) for the second PT event in 2023 in the specialty of Chemistry. This deficient practice had the potential to affect 10,227 out of 10,227 patient pO2 test results from the second PT event on 09/17/2023 to the first PT event in 2024. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policy", approved by the Laboratory Director via signature and date on 04/28/2023 and provided on the date of the inspection, found the following statements: "Unacceptable results are evaluated for PT and APT by laboratory director or delegate with appropriate corrective action taken. Evaluation must be started within 30 days of receipt of survey results to determine the impact on patient test results and correct identified problems." "Prepare Samples/Test Survey 1. Prepare the specimen according to the package instructions. Pay special attention to all timelines..." 2. Review of the laboratory's 2023 College of American Pathologists (CAP) Chemistry PT documentation from the second testing event on 09/17/2023, provided on the date of the inspection, revealed the pO2 test results were scored at 20% which was an unsatisfactory analyte testing score. 3. Further review of the laboratory's 2023 CAP PT investigation and corrective action documentation of the unsatisfactory pO2 results in the second testing event revealed the the CAP PT instructions were not followed and the PT challenges were not at room temperature

	for at least four hours prior to testing. 4. The AD, GS#4 and GS#11 confirmed the unsatisfactory pO2 PT scores in the second testing event in 2023. The interview occurred on 04/15/2024 at 3:40 PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interviews with Clinical Consultant (CC) #2 and General Supervisor (GS) #37, the laboratory failed to establish and conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity tissue biopsy gross testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 25,776 out of 25,776 tissue biopsy blocks grossed between 04/15/2022 through 04/15/2024. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policies" policy and procedure, approved by the Laboratory Director on 04/28/2023 and provided on the date of the inspection, found "Alternative Performance Assessment/Testing (APT)" instructions for TAV activities as follows: "It is the responsibility of the laboratory director in conjunction with the department delegates to define an APT system when no approved PT material is available. Criteria for acceptable performance should be defined. APT must be performed at least twice annually for each analyte. Results should be reviewed by the department delegate/s and corrective action documented as indicated by results. Corrective actions should include: - Process of investigation - Conclusion as to cause of the unacceptable result - Corrective action taken - Plan to prevent reoccurrence - Evidence of successful correction The laboratory must maintain a list of tests requiring APT and records of review and evaluation of assessments by laboratory director or delegate A minimum of two (2) specimens should be tested Appropriate APT examples are:... - Split sample analysis with another laboratory - Split specimens independently tested by two (2) different technologists... - Clinical validation by chart review An electronic or paper copy should be maintained for all APT for two (2) calendar years... QM: Proficiency Testing Policy Approved and current. Effective starting 5/23/2023. 129798.245 (version 19.1) QM: Proficiency Testing Policy" 2. The Inspector requested the laboratory's 2022, 2023 and 2024 documentation of blind TAV for the tissue gross test procedures performed from CC#2 and GS#37. CC#2 and GS#37 confirmed the laboratory did not follow the laboratory's policy and procedure for blind TAV activities at least twice annually for the high complexity tissue biopsy gross testing procedures performed and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/16/2024 at 2:25 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation, record review and interviews with Clinical Consultant (CC) #2, General Supervisor (GS) #37 and Histology Processor (HP) #4, the laboratory failed to label each of the secondary containers of reagents, solutions and stains with the lot numbers (pertinent information required for proper use) and expiration dates of their contents which were utilized for the processing of high complexity tissue biopsy gross testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 25,776 out of 25,776 tissue biopsy blocks grossed between 04/15/2022 through 04/15/2024. Findings Include: 1. Direct observation of the Histopathology slide staining station and tissue processor on 04/16/2024 at 2:02 PM found each of the secondary containers of reagents, solutions and stains labeled only with their contents and without any indication of the lot numbers and expiration dates. 2. Further direct observation of the Histopathology grossing area did not find any stock reagents, solutions and stains that were expired based on the manufacturer's expiration dates. 3. Review of the laboratory's "Safety Signs and Labels" policy and procedure, approved by the Laboratory Director via signature and date on 07/08/2022 and provided for the inspection, found the following labeling instructions for secondary containers of reagents, solutions and stains: "4. Labeling: A. All reagents, calibrator, controls, and solutions must be labeled with the following elements as applicable and appropriate: 1. Content and quantity, concentration or titer 2. Storage requirements, special instructions 3. Date prepared or reconstituted by laboratory 4. Expiration date 5. Lot number as applicable B. The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log." 4. The Inspector requested the laboratory's 2022, 2023 and 2024 reagent logs from CC#2, GS#37 and HP#4. CC#2, GS#37 and HP#4 confirmed the laboratory did not establish a reagent log, per their own policy and procedure, as evidence showing, that within the past two years, the laboratory did not utilize any reagent, solution and stain beyond its expiration date, the laboratory did not label all secondary containers of reagents, solutions and stains as required by their own policy and procedure and CLIA regulation and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/16/2024 at 2:02 PM.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interviews with the Administrative Director (AD), General Supervisor (GS) #4 and GS#11, the Laboratory Director failed to ensure that all testing personnel (TP) had demonstrated that they could perform arterial blood gas (ABG) testing procedures reliably to provide and report accurate results prior to

	performing patient testing on the newly installed ABL90 ABG analyzer in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 2,066 out of 2,066 patient ABG tests performed from implementation of the analyzer (s) on 11/03/2023 through 04/15/2024. Findings Include: 1. Review of the laboratory's "Laboratory Services Training/Competency Program" policy and procedure, approved by the Laboratory Director on 07/03/2022 and provided on the date of the inspection, found the following instructions: "Prior to the start of patient/client testing and prior to reporting results for any new test method or instrumentation, each testing employee must have documented demonstrated skill (i.e., checklist, direct observation, etc.) for proper test performance. Training should include all phases of testing: pre-analytics, analytic and post-analytic." 2. Review of the laboratory's 2023 and 2024 competency assessment documentation did not find any demonstration of competence documentation for any TP prior to independent patient ABG testing on the ABL90 test system. 3. The Inspector requested the laboratory's 2023 and 2024 initial demonstration of competence documentation for all ABG TP. The AD, GS#4 and GS#11 confirmed that the laboratory did not conduct and document initial demonstration of competence for any TP performing ABG testing procedures on the ABL90 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/16/2024 at 10:42 AM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interviews with the Administrative Director (AD) and General Supervisor (GS) #9, the Laboratory Director failed to ensure that all testing personnel (TP) had demonstrated they could perform all testing operations reliably to provide and report accurate results on the newly installed Cellavision instrumentation for white blood cell (WBC) differential (diff) testing procedures prior to performing patient testing in the specialty of Hematology. This deficient practice had the potential to affect 3,692 out of 3,692 patient WBC diff tests performed from implementation in 12/2023 through 02/15/2024. Findings Include: 1. Review of the laboratory's "Laboratory Services Training/Competency Program" policy and procedure, approved by the Laboratory Director on 07/03/2022 and provided on the date of the inspection, found the following instructions: "Prior to the start of patient/client testing and prior to reporting results for any new test method or instrumentation, each testing employee must have documented demonstrated skill (i.e., checklist, direct observation, etc.) for proper test performance. Training should include all phases of testing: pre-analytics, analytic and post-analytic." 2. Review of the laboratory's competency assessment documentation for 2023 and 2024 did not find any demonstration of competence documentation for any TP prior to independent patient WBC diff testing and reporting utilizing the Cellavision instrumentation. 3. The Inspector requested the laboratory's 2023 and 2024 initial demonstration of competence documentation for all WBC diff TP. The AD and GS#9 confirmed that the laboratory did not conduct and document initial demonstration of competence for any TP performing WBC diff testing procedures utilizing the Cellavision instrumentation and were unable to provide the

	requested documentation on the date of the inspection. The interviews occurred on 04 /16/2024 at 11:37 AM and 12:56 PM.