Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2254947	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Anatomical Pathology Associates-Cp Lab	417 N Monte Vista, Ada, OK	

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	The initial survey was performed on 06/13,14/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant, and laboratory manager during an exit conference performed at the conclusion of the survey.
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 observation and interview with the technical consultant and laboratory manager, the laboratory failed to label containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 06/13/2023 at 10:25 am, the technical consultant and laboratory manager stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 06/13/2023 at 10:26 am identified three unlabeled Copeland jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the technical consultant and laboratory manager. Both stated on 06/13/2023 at 10:25 am, the Copeland jars contained staining materials to stain peripheral blood smears and had not been labeled with the identify, expiration date, and lot number.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant and laboratory manager, the laboratory failed to ensure that expired staining materials were not available for use for one of two boxes of Epredia Three Step Stain set. Findings include: (1) On 06/13/2023 at 10:25 am, the technical consultant and laboratory manager stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 06/13/2023 at 10:26 am identified one box of Epredia Three Step Stain set, lot #114828 with an expiration date of 01/2023 available for use; (3) The stain set was reviewed with the technical consultant and laboratory manager. Both stated on 03/16/2023 at 10:28 am, the expired stain was available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to utilize the demonstrated reportable range for three of three new test methods introduced into the laboratory. Findings include: ALCOR MINII SED ANALYZER (1) On 06/13/2023 at 09:55 am, the technical consultant and laboratory manager stated the laboratory began using the miniiSED analyzer to perform automated patient ESR (Erythrocyte Sedimentation Rate) testing on 05/24/2022; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated a reportable range of 3-72 mm/hr; (3) Interview with the technical consultant and laboratory manager on 06/13/2023 at 02: 30 pm confirmed the laboratory was using the manufacturer's reportable range of 0-130 mm/hr instead of the reportable range that had been demonstrated. SYSMEX XN-550 (1) On 06/13/2023 at 10:00 am, the technical consultant and laboratory manager stated the laboratory began using the Sysmex XN-550 analyzer to perform CBC (Complete Blood Count) testing on 05/24/2022; (2) A review of the performance specification records identified the following for the reportable ranges for one of six analytes reviewed: (a) Hematocrit - The laboratory had demonstrated a reportable range of 0-68.3. (3) Interview with the technical consultant and laboratory manager on 06/13/2023 at 10:55 am, confirmed the laboratory was using the manufacturer's reportable range of 0.2-74.5 for Hematocrit instead of the reportable range that had been demonstrated. ORTHO VITROS 5600 (1) On 06/13/2023 at 10:10 am, the technical consultant and laboratory manager stated the laboratory began using the Ortho Vitros 5600 analyzer to perform routine chemistry testing which included the analytes ALT (Alanine Aminotransferase), Vitamin B12, Sodium, Total Bilirubin, and BUN on 05/24/2022. (2) A review of the performance specifications records identified

	the laboratory had demonstrated the following reportable ranges for three of five analytes reviewed: (a) ALT - 8-736.4 (b) Total Bilirubin - 0.86-17.05 (c) BUN - 3.5-115.3 (3) Interview with the technical consultant and laboratory manager on 06/13 /2023 at 01:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) ALT - 4-750 (b) Total Bilirubin - 0.1-27 (c) BUN - 2-120
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 a review of records, manufacturer's instructions, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing weekly maintenance procedures for one of four analyzers reviewed from June 2022 through the current date. Findings include: (1) On 06/13/2023 at 10:33 am, the technical consultant and laboratory manager stated the laboratory began performing the following using the Cepheid Gene Xpert IV analyzer: (a) MRSA (Methicillin Resistant Staphylococcus aureus) testing on 05/31/2022; (b) Clostridium difficile testing on 06/07/2022; (c) Chlamydia trachomatis and Neisseria gonorrhoeae testing on 12/28/2022. (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Power Down the GeneXpert Xpress Instrument (b) Power Down the GeneXpert Xpress Hub (c) Clean Instrument Fan Filter (3) A review of maintenance logs from June 2022 through the current date identified no documentation the weekly maintenance had been performed between: (a) 06/28/2022 and 07/08/2022 (b) 03/22/2023 and 04/03/2023 (c) 05/15/2023 and 05/30/2023 (4) The records were reviewed with the technical consultant who stated on 06/14/2023 at 12:48 pm, the maintenance had not been documented as performed as shown above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for one of three function checks performed during the review period of March 2022 through the current date. Finding include: (1) On 06/13/2023 at 09:50 am, the technical consultant and laboratory

	manager stated the following: (a) Urine sediment examinations were performed in the laboratory beginning 05/24/2022; (b) The specimens were processed in the McKesson Unico 602 centrifuge at a speed of 2000 rpm (revolutions per minute) for 5 minutes; (2) A review of the policy titled, "Centrifuge Function Check Protocol" required the centrifuge speed and time be checked twice a year; (3) A review of centrifuge records from March 2022 through the current date identified the centrifuge timer had not been checked at the time urines were processed for one of three checks performed as follows: (a) 09/28/2022 - The timer had been checked at ten minutes. (4) The records were reviewed with the technical consultant who stated on 06/13/2023 at 12:05 pm, the laboratory had not followed their policy.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and laboratory manager, the laboratory failed to follow the manufacturer's quality control specifications for ESR (Erythrocyte Sedimentation Rate) control materials for two of two lot numbers reviewed. Findings include: (1) On 06/13/2023 at 09:55 am, the technical consultant and laboratory manager stated the following: (a) The laboratory began using the miniiSED analyzer to perform automated patient ESR (Erythrocyte Sedimentation Rate) testing on 05/24/2022; (b) Two levels (Level 1 and Level 2) of Alcor Scientific Seditrol QC (quality control) materials were performed each day of patient testing. (2) A review of the manufacturer's instructions for the control materials stated "It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as a guide": (3) A review of QC records for the current lot numbers of control materials (Level 1 control lot #C141 and Level 2 control lot #C241), put into use on 12/12/2022, identified the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert; (4) The findings were reviewed with the technical consultant who stated on 03/16/2023 at 02:15 pm, the laboratory did not follow the manufacturer's instructions and had utilized the package insert means and limits instead of establishing their own.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on a review of records, MedTox Scan Drugs of Abuse test system package insert, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 03/16/2023 at 10:20 am, the technical consultant and laboratory manager stated Urine Drug Screen testing was performed using the Profile V Medtox Scan Drugs of Abuse test system; (2) A review of the Profile V Medtox Scan Drugs of Abuse test package insert stated, "The Profile-V MedTox Scan Drugs of Abuse test system provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC /MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained." (3) A review of one patient report with Urine Drug Screen test results reported on 05/18/2023 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the technical consultant who stated on 06/14/2023 at 10:45 am, the patient report did not include the disclaimer.