Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2294971	09/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Diagnostic Pathology Associates	3987 E Paradise Falls Dr, Tucson, AZ	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of ambient temperature and humity records for review from 2/1/2024 through the date of the survey, review of the manufacturer's specifications for the Diesse Minicube, Vitros 5600, Vitek 2, Arkray HA-8180V and Sysmex XN-L530, and interview with the testing personnel (TP-2), the laboratory failed to monitor and document the ambient temperature of the room where patient testing is performed. Findings include: 1. The laboratory began performing patient testing on 2/1/2024 under the specialties of Microbiology, Hematology and Chemistry with a reported annual test volume of 18,017. 2. The laboratory utilizes the Diesse Minicube, Vitros 5600, Vitek 2, Arkray HA-8180V and Sysmex XN-L530 to perform patient testing. 3. The manufacturer's specifications for the Diesse Minicube analyzer reviewed during the survey listed an operating temperature range of 15-35 degrees Celsius and an operating relative humidity range of 20% - 80%. 4. The manufacturer's specifications for the Vitros 5600 analyzer reviewed during the survey listed an operating temperature range of 18-30 degrees Celsius and an operating relative humidity range of 40% - 80%. 5. The manufacturer's specifications for the Arkray Adams HA-8180V analyzer reviewed during the survey listed an operating temperature range of 10-30 degrees Celsius and an operating relative humidity range of 20% - 80%. 6. The

	manufacturer's specifications for the Sysmex XN-L530 analyzer reviewed during the survey listed an operating temperature range of 15-35 degrees Celsius and an operating relative humidity range of 30% - 85%. 7. The manufacturer's specifications for the Vitek 2 analyzer reviewed during the survey listed an operating temperature range of 15-30 degrees Celsius and an operating relative humidity range of 20% - 80%. 8. On the survey date of 9/11/25, no documentation was provided for review to indicate the laboratory monitored and documented the temperature and humidity of the room where the above analyzers were utilized on each day of patient testing from 2 /1/24 through the date of the survey. 9. The TP-1 interviewed on 9/11/25 at 12:15 PM confirmed the laboratory failed to monitor and document the ambient temperature and humidity as indicated above.
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 lack of performance specification documentation for the Diesse Minicube analyzer and interview with the testing personnel (TP-2), the laboratory failed to verify the manufacturer range and reportable range for the Minicube analyzer prior to reporting patient test results. Findings include: 1. The laboratory began using the Minicube analyzer to perform Erythrocyte Sedimentation Rate (ESR) testing on patients in January 2025. 2. The laboratory failed to demonstrate that it can obtain the manufacturer range and reportable range comparable to that established by the manufacturer for the Minicube analyzer prior to reporting patient test results. 3. The TP-2 interviewed on 9/11/25 at 11:30 AM confirmed the laboratory failed to verify the manufacturer range and reportable range for the Minicube analyzer prior to reporting patient test results. 4. The laboratory performs approximately 10 ESR tests on patients per month.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a lack of Quality Control (QC) documentation, lack of sterility documentation and interview with the testing personnel (TP-2), the laboratory failed to check each batch of media for its ability to support growth and, as appropriate,

	select or inhibit specific organisms or produce a biochemical response; and failed to check each batch of media for sterility. Findings include: 1. The laboratory began patient testing on 2/1/24 under the subspecialty of Bacteriology, with an annual reported test volume of 227. 2. The laboratory utilizes Blood Agar (TSA w/Sheep Blood) and Macconkey (MAC) media to grow and isolate bacteria. 3. A lack of QC and sterility documentation revealed the laboratory failed to check each batch of media for sterility and failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms prior to using the media for patient testing. 4. The TP-2 interviewed on 9/11/25 at 1:45 PM acknowledged the laboratory failed to check each batch of media for its ability to support and/or inhibit growth and failed to check each batch of media for sterility. 5. The number of patients affected could not be determined at the time of the survey.
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 review of Quality Assessment (QA) documentation, analytic test records, laboratory policies and procedures and interview with the testing personnel (TP-2), the laboratory's analytic QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified with quality control and temperature and humidity checks. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) and sterility records for testing performed in the specialty of Microbiology. See D5413 for findings. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of ambient temperature and humidity records on each day of patient testing. See D5413 for findings. 3. The TP-2 interviewed on 9/11/25 at 2:00 PM confirmed the laboratory's QA processes at the time of the survey were not effective at monitoring, identifying and correcting problems associated with the analytic laboratory systems as indicated above.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a lack of policy and procedure and interview with the testing personnel (TP-

	2), the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably-transmitted into the patient's EHR. Findings include: 1. Patient-specific data and the final test result information for patient testing is electronically transmitted into the patient's EHR. 2. No documentation was presented for review during the survey conducted on 9/11/25 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are electronically transmitted into the patient's EHR. 3. The TP-2 interviewed on 9/11/25 at 1:30 PM confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are electronically transmitted into the EHR. 4. The laboratory began patient testing on 2/1/24 under the specialties of Microbiology, Hematology and Chemistry with a reported annual test volume of 18,017.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of test verification documentation for HbA1C performed on the Arkray Adams HA-8180V analyzer, and interview with the testing personnel (TP-2), the technical consultant failed to ensure the verification of performance specification documentation was signed and approved by a qualified laboratory director or qualified technical consultant prior to the start of patient testing. 1. The laboratory began using the Arkray Adams HA-8180V analyzer to perform HbA1C testing for patient testing on 5/1/25. 2. The HbA1C test verification documentation reviewed during the survey on 9/11/25 lacked the signature and approval of the laboratory director or technical consultant. 3. The TP-2 interviewed on 9/11/25 at 11:30 AM confirmed the HbA1C performance specification documentation failed to include the approval and signature of the laboratory director or technical consultant prior to the start of patient testing 4. The laboratory's annual test volume under the subspecialty of Routine Chemistry is 12,940.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the six month and annual competency documentation from 2024 and 2025 for two of two testing personnel and interview with the testing personnel (TP-2), the technical consultant failed to perform the evaluation of competency for testing performed in the specialities of Hematology and Chemistry. Findings include: 1. The six month competency evaluation documention reviewed during the survey for two of two testing personnel from 2024 revealed that the technical consultant failed to evaluate the competency for moderate-complexity testing performed in the specialties

	of Hematology and Chemistry. 2. The annual competency evaluation documention reviewed during the survey for two of two testing personnel from 2025 revealed that the technical consultant failed to evaluate the competency for moderate-complexity testing performed in the specialties of Hematology and Chemistry. 3. The TP-2 interviewed on 9/11/25 at 11:30 AM confirmed the technical consultant failed to evaluate the 2024 and 2025 six month and annual competency evaluations for the testing personnel indicated above.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of written documentation listing the duties and responsibilities of laboratory personnel and interview with the testing personnel (TP-2), the laboratory director failed to specify in writing, the duties and responsibilities of the the laboratory director (LD), technical consultant (TC), technical supervisor (TS), general supervisor (GS), the clinical consultant (CC) and testing personnel (TP). Findings include: 1. No documentation was provided for review during the survey to indicate the laboratory director specified, in writing, the duties and responsibilities of the LD, TC, TS, GS, CC and TP. 2. The CMS-209, Laboratory Personnel Form presented for review on 9/11/25 listed one Laboratory Director, one Technical Consultant, one Technical Supervisor, one General Supervisor, one Clinical Consultant and two testing personnel. 3. The TP-2 interviewed on 9/11/25 at 1:15 PM confirmed the laboratory failed to provide documentation indicating the duties and responsibilities of the LD, TC, TS, GS, CC and TP. 4. The laboratory began performing patient testing in the specialties of Microbiology, Hematology, Chemistry on 2/1/24 with a reported annual test volume of 18,017.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of the six month and annual competency evaluation documentation from 2024 and 2025 for two of two testing personnel and interview with the testing personnel (TP-2), the technical supervisor failed to perform the evaluation of competency for testing performed in the subspecialty of Bacteriology. Findings include: 1. The six month competency evaluation documention reviewed during the survey for two of two testing personnel from 2024 revealed that the technical

	supervisor failed to evaluate the competency for high-complexity testing performed in the subspecialty of Bacteriology. 2. The annual competency evaluation documention reviewed during the survey for two of two testing personnel from 2025 revealed that the technical supervisor failed to evaluate the competency for high-complexity testing performed in the subspecialty of Bacteriology. 3. The TP-2 interviewed on 9/11/25 at 11:30 AM confirmed the technical supervisor failed to evaluate the 2024 and 2025 six month and annual competency evaluations for the testing personnel indicated above.