Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0882114	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arp Diagnostics	1080 Caroline Drive Ste 200, Washington, MO	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of laboratory freezer, room temperature solutions, refrigerator, review of manufacturer's Site Planning Guide, and review of the verification of performance specifications for the Applied Biosystems Sciex 4000 for urine screening toxicology testing, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure reagents, solutions, and quality control (QC) were labeled to indicate preparation and expiration dates (Refer to D5415); the laboratory failed to ensure the laboratory's controls and calibrators were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to provide documentation of analytical sensitivity, analytical specificity, and reference intervals (normal values) for the analytes: 6-acetylmorphine, amphetamine, benzodiazepine, cocaine, methadone, opiates, oxycodone, and tramadol performed on a modified test system, Applied Biosystems Sciex API 4000 (Refer to D5423).
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 of the laboratory freezer, room temperature solutions, and interview with the laboratory director (LD), the laboratory failed to ensure reagents, solutions, and quality control (QC) were labeled to indicate preparation and expiration dates. Findings: 1. Observation of the freezer showed urine toxicology QC labeled "low 9/20" and "high 9/20" with no description of preparation or expiration date. 2. Observation of the freezer showed handwritten labeled bottles with no defined preparation or expiration dates for the following: nordiazepam 100 mg/ml 11/18 norfentanyl 100 mg/ml 11/18 fentanyl 10 mg/dl 11/18 alprazalom 2/25/18 clonazepam 11/18 fent D-S 11/19 UDT INT STD 10 ug 3/22/21 12 vials of neg urine & MCOH PCP 100 mg/ml 2/15/18 fentanyl 10 mg/ml 12/15/18 hydroxy-alprazolam 1000 mg/ml 6/1/18 diazepam 100 mg/ml 6/1/18 corisoprolol 100 mg/ml 5/2/18 clomazepam 100 mg/ml 2/15/18 chlordia 2/15/18 lorazepam 100 mg/dl 6/1/18 oxazepam 100 mg/ml 6/1 /18 norfentanyl 100 mg/ml 2/15/18 nordiazepam 100 mg/ml 6/1/18 topontad 100 mg /dl 2/15/17 omazepam diazepam 100 mg 11/18 temazepam 100 mg 2/15/19 lorazepam 100 mg 11/18 3. Observation of room temperature solutions and QC in use showed: mobile phase B, no preparation or expiration date Utak benzodiazepines plus lot #C3321, no preparation or expiration date DAU LC urine control lot #C2437, no preparation or expiration date PM100 urine control lot #C4550, no preparation or expiration date 4. Interview with the LD on May 5, 2021 at 10:45 AM confirmed, the laboratory failed to ensure reagents, solutions and QC were labeled to indicate the preparation and expiration dates.
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 of the laboratory freezer, laboratory refrigerator, and interview with the laboratory director (LD), the laboratory failed to ensure the laboratory's controls and calibrators were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory freezer showed Cerilliant chemistry calibrators and controls still in use: hydrocodone lot # FE09211501 exp. 9/20 hydrocodone lot #FE010161604 exp. 1/21 Norbuprenorphine lot #FE05041901 no open date and no exp. date buprenorphine lot #FE07101501 exp. 8/20 hydrocodone lot #FE07171507 exp. 8/20 codeine D6 lot #11241503 exp. 12/20 nordiazapam lot #FE11201801 no open date and no exp. date temazapam DT lot #Fe03011601 exp. 3 /21 benzoylegonine D3 lot #09091503 exp. 9/20 hydrocodone lot # FE09091505 exp. 9/20 hydorcodone lot #FE09091508 exp. 9/20 nordiazepam lot #FE11181503 exp. 11 /20 oxazepam lot #FE11181503 exp. 11/20 nordiazepam lot #05261603 exp. 6/20 6 acetylmorphine lot #0710501 exp. 8/20 tramadol lot #FE09231512 exp. 12/20 hydrocodone lot #FE09091505 exp. 9/20 buprenorpine lot #FE09211501 exp. 9/20 benzoylecgonine lot #FE01061604 exp. 1/21 cis-tramadol-hci lot #FE09231512 exp. 9 /20 lorazepam lot #FE10151502 exp. 10/20 oxazepam lot # FE05261603 exp. 6/20 benzoylecgonine lot #FE01061604 exp. 1/21 PCP-DS lot #FE10231501 exp. 11/20

	hydromorphone lot #FE04101502 exp. 6/20 noroxycodone hci lot #FE07161507 exp. 8/20 chloridiazepoxide lot #FE07241502-11 exp. 8/20 hydromorphone H-004 lot #FE04101502 exp. 6/20 hydromorphone H-003 lot #FE09091505 exp. 9/20 meperidine lot # FE01191502 exp. 2/20 nordiazepam lot # FE11181503-111 exp. 11 /20 carisoprodol lot #FE07151505 exp. 8/20 benzoylecgonine lot #FE01061604 exp. 1 /21 EDDP perchlorate lot #FN06121503 exp. 8/20 +mdma lot #FE01121502 exp. 2 /20 benzoylecgonine lot #FE05291403 exp. 8/19 +mdea lot #FE06021504 exp. 6/20 morphine lot #FE03191402 exp. 3/19 oxymrphone lot #FE12181403 exp. 3/20 meprobamate lot #FE01051504 exp. 2/20 clonazepam lot #FE07211504 exp. 8/20 clonazepam lot #FE04161402 exp. 5/19 methadone lot #FE06221502 exp. 7/20 alpha-hydroxyalprazolam lot #FN11191504 exp. 11/20 oxazepam lot #FE05261603 exp. 6 /20 lorazepam lot #FE10151502 exp. 10/20 methamphetamine lot #FE02201501 exp. 4/20 codeine lot #FE11021502 exp. 12/20 amphetamine lot#FE06011503 exp. 6/20 MDA lot #FE03111501 exp. 4/20 diazepam lot #FE01261603 exp. 2/21 fentanyl-DS lot #FE08141402 exp. 10/19 phentermine lot #FE09231511 exp. 9/20 delta 9-THC lot #03091602 exp. 3/21 amphetamine D5 lot #FE111111592 exp. 12/20 cocaine-D3 lot #FE02101602 exp. 3/21 PCP-DS lot #FE10231501 exp. 11/20 methamphetamine-D5 lot#FE09091502 exp. 9/20 2. Observation of the freezer reagents showed that the identity of reagents were not legible but still in use for the following: lot #FE04101502 exp. 6/20 lot #FE09091505 exp. 9/20 lot #FE11021502 exp. 12/20 lot #FE0716507 exp. 8/20 lot #FE08141515 exp. 11/20 lot #FN06121503 exp. 8/20 lot #FE12181403 exp. 3/20 3. Observation of the laboratory refrigerator showed: E1-Anti-TPO lot #01193240 exp. 1/14/2020 E1-Anti-Thyroglobulin lot #01193241 exp. 1/14 /2020 4. Review of urine toxicology patient results showed 23,000 toxicology analytes reported in 2020. 5. Interview on May 5, 2021 at 11:00 AM with the LD confirmed the laboratory failed to ensure the laboratory's controls and calibrators were not used when they had exceeded their expiration date.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's Site Planning Guide, review of the verification of performance specifications for the Applied Biosystems Sciex 4000 for screening toxicology testing, and interview with the laboratory director (LD), the laboratory failed to provide documentation of analytical sensitivity, analytical specificity, and reference intervals (normal values) for six of six analytes performed on a modified test system, Applied Biosystems Sciex API 4000. Findings: 1. Review of the Applied Biosystems Sciex API 4000 Site Planning Guide states that the Applied Biosystems Sciex API 4000 test system is "For Research Use Only. Not for use in Diagnostic Procedures." 2. Review of the laboratory's verification of performance specifications

	for the Applied Biosystems Sciex 4000 for screening toxicology testing showed the laboratory failed to verify analytical specificity, analytical sensitivity, and reference intervals (normal values) for the analytes: 6-acetylmorphine, amphetamine, benzodiazepine, cocaine, methadone, opiates, oxycodone, and tramadol. 3. Interview with the LD on May 5, 2021 at 10:00 AM confirmed, the laboratory failed to provide documentation of analytical sensitivity, analytical specificity, and reference intervals (normal values) for the analytes: 6-acetylmorphine, amphetamine, benzodiazepine, cocaine, methadone, opiates, oxycodone, and tramadol performed on modified test system Applied Biosystems Sciex API 4000.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT), review of antinuclear antibody (ANA) quality control (QC), review of patient reports, and review of procedures, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6091); the laboratory director failed to ensure the QC program was maintained and failed to identify failures in quality as the occur (Refer to D6093); the laboratory director failed to ensure tests results include the correct date patient testing was performed (Refer to D6098); and the laboratory director failed to provide an approved written procedure for urine screening toxicology testing on the Applied Biosystems Sciex API 4000 test system (Refer to D6106).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the 2019 and 2020 immunology proficiency testing (PT) records, 2019 and 2020 chemistry miscellaneous PT records, and interview with the laboratory director (LD), the LDfailed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the immunology PT records for the first, second, and third PT testing events of 2019 showed the laboratory obtained a not graded result for antinuclear antibody (ANA) test. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 2. Review of the chemistry miscellaneous PT records for the first and second PT testing events of 2019 showed the laboratory obtained a not graded result for methadone. The laboratory could not provide documentation to show appropriate staff

	evaluated the not graded results to identify any problems that may require corrective action. 3. Review of the immunology PT records for the first, second, and third PT testing events of 2020 showed the laboratory obtained a not graded result for ANA test. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 4. Review of chemistry miscellaneous PT records for the first and second PT testing events of 2020 showed the laboratory obtained a not graded result for methadone. The laboratory could not provide documentation to show appropriate staff evaluated the not graded results to identify any problems that may require corrective action. 5. Interview with the LD on May 5, 2021 at 10:00 AM confirmed, the LD failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of patient reports, 2020 and 2021 BioTek analyzer quality control (QC) records, and interview with the laboratory director (LD), the LD failed to ensure the QC program was maintained and failed to identify failures in quality as they occur. Findings: 1. Review of antinuclear antibodies (ANA) patient report showed anti-single stranded DNA (ssDNA), anti-double stranded DNA (dsDNA), Smith Antigen (Sm), Ribonucleoprotein antibodies (RNP/Sm), SSA antibodies (SSA), SSB antibodies (SSB), Chromatin, antiscleroderma 70 (Scl-70) and Centromere are resulted. 2. Review of ANA QC performed on the BioTek analyzer showed: On March 5, 2021 dsDNA positive QC was 629, acceptable range 194-496. QC was not within acceptable limits according to the EL-ANA manufacturer's data sheet. On March 5, 2021, 19 ANA patients results were reported. On March 30, 2021 dsDNA positive control was 514, acceptable range 194-496 and ssDNA was 893, acceptable range 270-880. QC was not within acceptable limits according to the EL-ANA manufacturer's data sheet. On March 30, 2021, 49 ANA patients results were reported. On April 29, 2021 dsDNA positive QC was 513, acceptable range 194-496 and ssDNA was 890, acceptable range 270-880. QC was not within acceptable limits according to the EL-ANA manufacturer's data sheet. On April 29, 2021, 38 ANA patients results were reported. 3. Interview with the LD on May 5, 2021 at 11:15 AM confirmed the LD failed to identify failures in ANA QC.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of four of four patient reports and interview with the laboratory director (LD), the LD failed to ensure tests reports include the correct date patient

	testing was performed. Findings: 1. Review of a screening urine toxicology patient report showed on 10/15/19, the patient specimen was collected and on 11/05/19 at 14: 46 the patient specimen was tested. Interview with the LD on May 5, 2021 at 11:00 AM stated the patient specimen was tested on 11/6/19. 2. Review of a screening urine toxicology patient report showed on 2/19/21, the patient specimen was collected and on 3/8/21 at 14:29 the patient specimen was tested. Interview with the LD on May 5, 2021 at 11:00 AM stated the patient specimen was tested on 3/18/21. 3. Review of a confirmation urine toxicology patient report showed on 2/19/21, the patient specimen was collected and on 3/08/21 at 14:29 the patient specimen was tested. Interview with the LD on May 5, 2021 at 11:00 AM stated the patient specimen was tested on 3/19 /21. 4. Review of a screening urine toxicology patient report showed on 3/11/21, the patient specimen was collected and on 3/19/21 at 15:11 the patient specimen was tested. Interview with the LD on May 5, 2021 at 11:00 AM stated the patient specimen was tested on 3/23/21. 5. Interview with the LD on May 5, 2021 at 11:00 AM confirmed the patient reports did not include the correct date patient testing was performed.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the laboratory director (LD), the LD failed to provide an approved written procedure for urine screening toxicology testing on the Applied Biosystems Sciex API 4000 test system. Findings: 1. Review of the laboratory procedures showed no procedure for urine screening toxicology testing on the Applied Biosystems Sciex API 4000 test system. 2. Interview with the LD on May 5, 2021 at 10:30 AM confirmed the LD could not provide an approved written procedure for urine screening toxicology testing on the Applied Biosystems Sciex API 4000 test system.