Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0964576	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
J2 Laboratories Inc	3640 N 1st Ave Ste 130, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of test requisition documentation and interview with the laboratory director (LD) on 6/02/26 at 2:17 PM, (A) the laboratory failed to have a written or electronic request for urine drug confirmation testing performed on the Agilent Infinity 1290/6490 LC/MS/MS test system for 2 out of 3 patients whose samples were tested in 2025; and (B) the laboratory failed to have a written or electronic request for patient testing from an authorized individual for 1 out of 1 patient tests performed in 2026. Findings include: 1. The laboratory performs urine and oral fluid drug confirmation testing in the subspecialty of toxicology, with a reported annual test volume of 76,707. The laboratory began patient testing on 2/01/25 and utilizes the Agilent Infinity 1290/6490 LC/MS/MS test system. A1. No written or electronic test requisition for urine drug confirmation testing was presented for review for two out of three patients (Patient #1 and Patient #3) from testing that occurred in 2025. A2. The LD interviewed on 6/02/26 at 2:17 PM confirmed that the laboratory failed to provide evidence of test requisitions for Patient # 1 and Patient #3, as referenced above. B1. The test requisition for oral fluid drug confirmation testing presented for review for one of one patient (Patient #2) revealed the test was ordered by an individual (Registered Nurse/RN) who is not authorized to order tests under Arizona State Law. B2. The LD interviewed on 6/02/26 at 3:15 PM acknowledged the test requisition for Patient #2 indicated the confirmation testing was ordered by a Registered Nurse.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the laboratory director (LD) on 6/02/26 at 3:33 PM, the laboratory failed to establish policies and procedures during the time frame of 2/01/25 through 6/02/26 for specimen preservation and specimen acceptability and rejection. Findings include: 1. The laboratory began patient testing on 2/01/25 on the Agilent 1290/6490 LC/MS/MS analyzer in the subspecialty of toxicology, and reports an annual test volume of 76,707. 2. The policy and procedure manual reviewed on 6/02/26 failed to include evidence of established policies and procedures for specimen acceptability, specimen rejection and specimen preservation (stability). 3. The LD interviewed on 6/02/26 at 3:33 PM confirmed the laboratory failed to present evidence of established policies and procedures for specimen acceptability, specimen rejection and specimen preservation (stability).
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the laboratory director (LD) on 6/02/26 at 2:40 PM, the laboratory failed to establish calibration and calibration verification procedures for the Agilent 1290/6490 Infinity LC/MS/MS test system during the time frame of 2/01/25 through 6/02/26. Findings include: 1. The laboratory began urine and oral fluid drug confirmation testing on the Agilent 1290/6490 Infinity LC/MS/MS test system on 2/01/25 in the subspecialty of toxicology with a reported annual test volume of 76,707. 2. No evidence was presented for review to indicate the laboratory determined calibration and calibration verification procedures for testing performed on the Agilent 1290/6490 Infinity LC /MS/MS test system from 2/01/25 through 6/02/26. 3. The LD interviewed on 6/02/26 at 2:40 PM confirmed the laboratory failed to provide evidence of documented calibration and calibration verification procedures for urine and oral fluid drug confirmation testing performed on the Agilent 1290/6490 Infinity LC/MS/MS test system.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of patient test reports for urine drug confirmation testing and interview with the laboratory director on 6/02/26 at 3:15 PM, the laboratory failed to include the confirmation test result on 1 out of 1 test reports reviewed during the survey. Findings include: 1. The laboratory performs urine and oral fluid drug confirmation testing in the subspecialty of toxicology, with a reported annual test volume of 76,707. The laboratory began patient testing on 2/01/25 and utilizes the Agilent Infinity 1290/6490 LC/MS/MS test system. 2. One out of one test reports (Patient #2) failed to include the confirmation test results for Fentanyl testing. 3. The LD interviewed on 6/02/26 at 3:15 PM acknowledged that confirmation test result for Fentanyl testing performed on 4/24/26 for the patient indicated above was not included on the final test report.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the technical supervisor (TS) on 6/02/26 at 1:35 PM, the technical supervisor failed to evaluate and document the performance of one out of one testing personnel, at least semiannually during the first year the individual tested patient specimens during 2025. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel (TP-1) who began patient testing in February 2025. 2. The TS-1 interviewed on 6/02/26 at 1:35 PM confirmed the technical supervisor failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. The laboratory began patient testing on 2/01/25 in the subspecialty of toxicology, with a reported annual test volume of 76,707.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2026 and interview with the technical supervisor (TS) on 6/02/26 at 1:35 PM, the technical supervisor (TS) failed to evaluate and document the performance of one out of one individuals

	responsible for high complexity testing at least annually during 2026. Findings include: 1. No documentation of an annual competency evaluation from 2026 was presented for review for one out of one testing personnel (TP-1). 2. The TS-1 interviewed on 6/02/26 at 1:35 PM confirmed the TS failed to evaluate and document the performance of the testing personnel indicated above at least annually during 2026. 3. The laboratory began patient testing on 2/01/25 in the subspecialty of toxicology, with a reported annual test volume of 76,707.