IN THE SUPREME COURT OF THE STATE OF ARIZONA

In the Matter of:	)	
	)	Administrative Order
EXEMPTION OF REQUIREMENTS	)	No. 2023 - 54
IN § 6-110 OF THE ARIZONA CODE	)	
OF JUDICIAL ADMINISTRATION	)	
FOR CERTAIN DIAGNOSTIC TESTS	)	
	)	

Section 6-110 of the Arizona Code of Judicial Administration (ACJA § 6-110) includes requirements concerning alcohol and drug testing that are not necessary when the diagnostic testing services include synthetic urine detection and procedures are in place for DNA-authentication. For example, visual observation of the collection of a urine specimen is not needed when confirmation that the specimen is from a particular person can be made through DNA-authentication. Contingent on obtaining an exemption from the requirements in ACJA § 6-110 deemed unnecessary, the Court entered into an agreement with Genotox Laboratories, LTD, (Genotox) to provide such diagnostic testing services on a pilot basis. The agreement includes a Statement of Work that details in Sections 1-4 the drug testing procedures and laboratory requirements deemed necessary for diagnostic testing performed under the agreement. Sections 1-4 of the Statement of Work are attached.

The Court would benefit from additional information gained through a pilot program before deciding whether to adopt amendments to ACJA § 6-110. The Administrative Director will approve participation in the pilot program.

Therefore, pursuant to Article VI, Section 3, of the Arizona Constitution

IT IS ORDERED that alcohol and drug testing completed in accordance with Sections 1-4 of the Statement of Work are exempted from the requirements in ACJA § 6-110(E), (F)(1), and (G) through June 30, 2024.

IT IS FURTHER ORDERED that the Committee on Probation will submit a report to the Arizona Judicial Council on the effectiveness of the pilot program no later than March 2024.

Dated this 22nd day of March, 2023.

ROBERT BRUTINEL
Chief Justice

SECTIONS 1-4 OF STATEMENT OF WORK
DRUG TESTING SUPPLIES, SUBSTANCE USE
MONITORING, & DRUG TESTING LABORATORY SERVICES

1.0 SCOPE AND PURPOSE:

1.1 The initial phase of the pilot project will provide Arizona probation departments and drug courts an opportunity to evaluate the efficacy of a comprehensive testing environment which is trauma informed. Genotox will offer urine testing laboratory services of over 100 controlled substances in a private trauma informed manner. The method cross checks a subject's DNA with a pre-acquired buccal swab accessing 16 single nucleotide polymorphisms ("SNPs") to verify a match with the sample provided. Genotox will offer patented evaluation for the SNPs test itself and for synthetic urine tampering products. If a metabolite is found to be positive, the sample is automatically confirmed using Liquid Chromatography Mass Spectrometry ("LCMS") inclusive of the contracted rate.

1.2 Genotox will provide bar-coded testing kits that include, a buccal swab and tube, a collections cup, two vacutainer tubes, a specimen bag and a self-addressed pre-paid mailer bag and subsequent kits for ongoing testing that do not contain buccal swabs.

1.3 The Court through its staff and officers will manage the collection of the completed samples and place the samples in a local drop-off site for the courier.

1.4 Genotox will provide testing of controlled substances, DNA and synthetic tampering products at their Austin, Texas laboratory certified and accredited by Clinical Laboratory Improvement Amendments and Commission on Office Laboratory Accreditation. Genotox will provide the testing results to the Court and participating probation departments.

2.0 PROGRAM REQUIREMENTS:

Genotox shall:

2.1 Furnish all labor, materials, and equipment necessary to perform the work required.

2.2 Have capabilities to test by a variety of methods including but not limited to urinalysis, toxicology, buccal cheek swab, or other methods that are certified and accredited by the Clinical Laboratory Improvement Amendments and Commission on Office Laboratory Accreditation.

2.3 Have the capability of conducting both initial and confirmatory testing including Liquid Chromatography Mass Spectrometry for urine specimens.

2.4 Standard drug testing panel (100+ substances) shall consist of the illegal and legal substances as approved by the Court. Confirmation testing shall be conducted as standard and included in the fee as detailed in this exhibit.

2.5 Be capable of testing for synthetic, designer, and emerging drugs of abuse that the Court identifies as substances of interest. Tests for these substances must be validated and approved.

2.6 Utilize instrumented laboratory testing methodologies, including heterogeneous and homogenous immunoassay, enzyme-linked immunosorbent, and liquid chromatography tandem mass spectrometry. Confirmation testing shall be conducted through LCMS.

2.7 Post to Genotox' portal-Lavgen, the electronic test results of the probationer's specimen, including LCMS final results, SynScan results and DNA authentication of the drug panel within 72 hours of receipt of collection.

2.8 Drug Testing Procedure Requirements:

2.8.1 Genotox shall be responsible for supplying and shipping sufficient drug testing supplies to the identified project probation departments. Initial drug testing supplies ordered shall consist of one (1) DNA buccal swab test per person with the initial test kit, specifically barcoded for bulk shipping at a minimum of 5 per shipment along with instructions for usage when randomly directed to test. Costs shall include: the drug testing supplies, shipment of drug testing supplies to the participating probation department, return shipping and packaging materials, laboratory testing fees and LCMS confirmation for the initial and subsequent samples submitted for testing.

2.8.2 For the initial drug test as directed, the probation department staff, must observe the probationer submit the DNA buccal swab sample as well as verifying that the probationer referred for testing matches the name on their official government issued identification. This DNA sample shall be matched with all future drug tests by Genotox to ensure that it matches the identified probationer. The DNA sample shall be destroyed and eliminated from Genotox's databases, and those of any subcontractor, upon the probationer's termination from probation. Prior to eliminating DNA records from its database, Genotox must confirm with the probation department that probation has been terminated.

2.8.3 For subsequent tests, the probation department will collect urine samples from probationers using a urine test kit as provided by Genotox. The probation department will provide instructions to the probationer for collection and packaging of the specimen. The probation department will ship samples in packages of 5 or more by delivering them to the courier for overnight shipping to Genotox.. Genotox shall provide documentation of each specimen with test panel positive results with LCMS and SynScan results. Genotox shall perform diagnostic testing services including

synthetic urine detection and DNA-authentication of urine specimens on at least 25% of each probationer's specimens to ensure they belong to the probationer, and provide confirmation to the Court and the probation department.

2.8.4 Upon request from the probation department via email, Genotox shall provide a packet of discovery information including a notarized statement of testing, test description and General Laboratory Procedures, summary of events, copy of results, chain of custody forms and any confirmatory results obtained on the sample. The discovery packet shall be received by the probation department via email within seven (7) days of the date of the request from the probation department. Genotox will provide the original discovery packet with the notarized statement upon request from the probation department.

2.9 Laboratory Requirements:

2.9.1 Obtain and maintain accreditation in good standing by Clinical Laboratory Improvement Amendment and Commission on Office Laboratory Accreditation. Adhere to chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage and continuing until final disposition of specimens.

2.9.2 In the event Genotox loses its accreditation by Clinical Laboratory Improvement Amendment and Commission on Office Laboratory Accreditation, it must regain that accreditation within 30 days. Failure to do so may result in termination of the Contract. Genotox must also notify the Court within 72 hours of receipt of notice of loss of accreditation.

2.9.3 Require all urine specimens be tested with cutoff levels that meet and/or exceed regulatory accreditation by the Clinical Laboratory Improvement Amendment and Commission on Office Laboratory Accreditation.

2.9.4 Comply with applicable provisions of any state licensure requirements.

2.9.5 Comply with all applicable state and federal legal authority and related case law regarding privacy of drug testing results and release of such information.

2.9.6 Maintain all positive test specimens for at least fourteen (14) days from date of collection after confirmation testing has been completed.

2.9.7 Negative test specimens may be discarded immediately upon identifying the negative results from the test.

2.9.8 Provide the Court and the probation department with drug testing data as requested and any explanation of test results and laboratory policy and procedure.

2.9.9 Upon request, provide court testimony relevant to any issue involved with performance of its work under the Contract, including testing and verification of probationer's identity.

2.9.10 Genotox's urine drug testing facility must have a designated certifying scientist who reviews all pertinent data and quality control results to attest to the validity of the laboratory's test reports. Genotox may designate more than one person as a certifying scientist. The certifying scientist(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

2.9.11 Genotox shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, accessioning, aliquoting, chain-of-custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

2.9.12 A run for the LC/MS will contain no more than ninety-six (96) specimens and controls. The run must contain a minimum of five urine quality control specimens: one certified standard the cutoff concentration, one certified negative urine specimen, and at least two certified positive urine specimens at concentrations above the cutoff, and one hydrolysis control that must be within 40% of the certified value. The linearity and precision of the method must be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen must also be documented. The calibrators must be quantitatively measured within 20% of the target value when the calibrators are certified. The concentration of all quality control specimens must assay within + or - 20% of their certified value. The calculated concentration of the negative quality control specimens must not exceed the established limit of detection of the instrument for the drug being tested. All but one positive quality control sample must be within the acceptable range and meet all chromatographic criteria with all ion ratios within the range established by the certified quality controls before reporting any sample results in that run. The

chromatography of an internal standard from the negative specimen must meet the retention time and ion ratio requirements.

2.9.13 Failure to meet a passing or acceptable level of performance on a test shall be cause for suspension of screening until remedial action is taken, and another performance test has been completed in which a passing or acceptable level of performance and no false positive confirmations are achieved.

2.9.14 The Court shall be notified within 24 hours of any failed performance test.

2.10 At Genotox's expense, attend workshops or training as requested by the Court. Provide training at no additional cost to Court and probation department personnel as requested by the Court. Training may incorporate information regarding the testing of urine specimens, chain of custody at the laboratory, threshold limits of positive specimens, confirmatory testing and methods of specimen falsification, use of Genotox' website or portal, current drug trends in the State of Arizona, and emerging drug testing strategies.

2.11 Designate one (1) point of contact at the staff level for purposes of communication regarding probation cases and update as needed.

2.12 Genotox content or forms (to include informational flyers, brochures, working documents, information on a website, etc.) provided to probationers must be submitted to the Court in advance and approved by the Court prior to distribution. Genotox shall not in any manner make representations on behalf of the Court or probation departments.

2.13 Provide the Court any drug testing data as requested.

2.14 Have written procedures for testing of urine specimens.

2.15 Have an automated records management system with redundant systems capable of fully integrating data. Technical staffing and capacities to manage and store historical records with a scope of up to 1,000,000 test results.

2.16 Allow for probationers to use debit card and credit card in cases of self-payment for services.

2.17 Retain adequate accounting and case reconciliation records for review by the Court.

2.18 Direct Service Standards:

2.18.1 Inform the probationer of drug testing collection instructions/rules, which includes but is not limited to confidentiality, offender rights, and expected behavior; obtain their written consent for Release of Information. Maintain documentation in the probationer's case file;

2.18.2 Report drug testing laboratory results via portal access to the Court and probation departments; and

2.18.3 Document and report all non-compliance incidents to the probation department. Examples of non-compliance incidents include: specimen adulteration, urine specimen not matching offender's DNA on file, or offender's substitute of urine sample.

3.0 CONTRACTOR QUALIFICATION REQUIREMENTS:

3.1 Genotox shall hold and maintain during the performance of this contract, a current, applicable CLIA and COLA certification that is in good standing, for each facility from which services shall be provided.

3.2 Genotox shall protect information and records protected by federal confidentiality rules (e.g., 42 CFR Part 2 and HIPAA Rules at 45 CFR Parts 160, 162, and 164) and state confidentiality rules (e.g., A.R.S. §§ 12-2291 et seq.), and ensure that Genotox and its employees and subcontractors comply with said rules and employ all administrative and physical safeguards as may be required by law to protect confidential information. The Genotox shall be responsible for ensuring the execution of any business associate agreements, qualified service organization agreements, and nondisclosure/confidentiality agreements that may be required under federal and state confidentiality rules.

4.0 CONTRACTOR REPORTING REQUIREMENTS:

4.1 Genotox must provide secure access for Court staff and the probation department to obtain program metrics and probationer case records at any time and maintain indefinite storage for the duration of this contract.

4.2 Genotox shall provide additional data and information to the Court and probation department, as requested.