TITLE 13. PUBLIC SAFETY
CHAPTER 15. DEPARTMENT OF PUBLIC SAFETY – RAPID DNA

The table of contents on page one contains links to the referenced page numbers in this Chapter. Refer to the notes at the end of a Section to learn about the history of a rule as it was published in the Arizona Administrative Register.

This Chapter contains rules that were filed to be codified in the Arizona Administrative Code between the dates of April 1, 2022 through June 30, 2022

This is a new Chapter. Refer to the Table of Contents for a list of codified Sections.

Questions about these rules? Contact:
Department: Arizona Department of Public Safety
Address: POB 6638, Mail Drop 1150
          Phoenix, AZ 85005-6638
Website: www.azdps.gov
Name: Scott Rex, Crime Laboratory Manager, Rapid DNA
Telephone: (602) 223-2339
Email: srex@azdps.gov

This is a new Chapter
PREFACE

Under Arizona law, the Department of State, Office of the Secretary of State (Office), Administrative Rules Division, accepts state agency rule notice and other legal filings and is the publisher of Arizona rules. The Office of the Secretary of State does not interpret or enforce rules in the Administrative Code. Questions about rules should be directed to the state agency responsible for the promulgation of the rule.

Scott Cancelosi, Director
ADMINISTRATIVE RULES DIVISION

RULES
The definition for a rule is provided for under A.R.S. § 41-1001. "Rule" means an agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedures or practice requirements of an agency."

THE ADMINISTRATIVE CODE
The Arizona Administrative Code is where the official rules of the state of Arizona are published. The Code is the official codification of rules that govern state agencies, boards, and commissions.

The Code is separated by subject into Titles. Titles are divided into Chapters. A Chapter includes state agency rules. Rules in Chapters are divided into Articles, then Sections. The "R" stands for "rule" with a sequential numbering and lettering outline separated into subsections.

Rules are codified quarterly in the Code. Supplement release dates are printed on the footers of each Chapter.

First Quarter: January 1 - March 31
Second Quarter: April 1 - June 30
Third Quarter: July 1 - September 30
Fourth Quarter: October 1 - December 31

For example, the first supplement for the first quarter of 2022 is cited as Supp. 22-1. Supplements are traditionally released three to four weeks after the end of the quarter because filings are accepted until the last day of the quarter.

Please note: The Office publishes by Chapter, not by individual rule Section. Therefore there might be only a few Sections codified in each Chapter released in a supplement. This is why the Office lists only updated codified Sections on the previous page.

RULE HISTORY
Refer to the HISTORICAL NOTE at the end of each Section for the effective date of a rule. The note also includes the Register volume and page number in which the notice was published (A.A.R.) and beginning in supplement 21-4, the date the notice was published in the Register.

AUTHENTICATION OF PDF CODE CHAPTERS
The Office began to authenticate Chapters of the Code in Supp. 18-1 to comply with A.R.S. § 41-1012(B) and A.R.S. § 5302(1), (2)(d) through (e), and (3)(d) through (e).

A certification verifies the authenticity of each Code Chapter posted as it is released by the Office of the Secretary of State. The authenticated pdf of the Code includes an integrity mark with a certificate ID. Users should check the validity of the signature, especially if the pdf has been downloaded. If the digital signature is invalid it means the document’s content has been compromised.

HOW TO USE THE CODE
Rules may be in effect before a supplement is released by the Office. Therefore, the user should refer to issues of the Arizona Administrative Register for recent updates to rule Sections.

ARIZONA REVISED STATUTE REFERENCES
The Arizona Revised Statutes (A.R.S.) are available online at the Legislature’s website, www.azleg.gov. An agency's authority note to make rules is often included at the beginning of a Chapter. Other Arizona statutes may be referenced in rule under the A.R.S. acronym.

SESSION LAW REFERENCES
Arizona Session Law references in a Chapter can be found at the Secretary of State’s website, www.azsos.gov under Services-> Legislative Filings.

EXEMPTIONS FROM THE APA
It is not uncommon for an agency to be exempt from the steps outlined in the rulemaking process as specified in the Arizona Administrative Procedures Act, also known as the APA (Arizona Revised Statutes, Title 41, Chapter 6, Articles 1 through 10). Other agencies may be given an exemption to certain provisions of the Act.

An agency’s exemption is written in law by the Arizona State Legislature or under a referendum or initiative passed into law by Arizona voters.

When an agency files an exempt rulemaking package with our Office it specifies the law exemption in what is called the preamble of rulemaking. The preamble is published in the Register online at www.azsos.gov/rules, click on the Administrative Register link.

Editor’s notes at the beginning of a Chapter provide information about rulemaking Sections made by exempt rulemaking. Exempt rulemaking notes are also included in the historical note at the end of a rulemaking Section.

The Office makes a distinction to certain exemptions because some rules are made without receiving input from stakeholders or the public. Other exemptions may require an agency to propose exempt rules at a public hearing.

PERSONAL USE/COMMERCIAL USE
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Rhonda Paschal, rules managing editor, assisted with the editing of this Chapter.
TITLE 13. PUBLIC SAFETY

CHAPTER 15. DEPARTMENT OF PUBLIC SAFETY – RAPID DNA

Authority: A.R.S. §§ 17-1713(A)(4) and 41-1772(A)

Supp. 22-2

CHAPTER TABLE OF CONTENTS

ARTICLE 1. LAW ENFORCEMENT RAPID DNA TESTING


Section R13-15-101. Definitions .................................................. 2
R13-15-102. Exemptions ......................................................... 2
R13-15-103. Instruments; Approvals, Standards, Authorizations .......................................................... 3
R13-15-104. Operator Certification ............................................. 3
R13-15-106. Testing Site Minimum Facilities Requirements ........... 4
R13-15-107. Partner Agency Sites ............................................. 4
R13-15-108. Audits ............................................................... 4
CHAPTER 15. DEPARTMENT OF PUBLIC SAFETY – RAPID DNA

ARTICLE 1. LAW ENFORCEMENT RAPID DNA TESTING

In this Article, unless the context otherwise requires:
1. “Accredited laboratory” means a laboratory that currently meets ISO 17025 accreditation standards and holds accreditation through a nationally or internationally accrediting organization.
2. “Allele” means one of two or more versions of a gene.
3. “Chromosome” means the structure found in the nucleus of a cell that carries genetic information.
4. “CJIS” means “Criminal Justice Information Services”, a division of the Federal Bureau of Investigations which sets law enforcement standards for data security and encryption.
5. “Crime scene sample” means a sample collected from a crime scene believed to contain DNA of value to advance the investigation.
6. “Database” means a repository for convicted offender and arrestee samples to be used in a search against an unknown DNA sample in accordance with A.R.S. § 13-1610.
7. “Department” means the Arizona Department of Public Safety.
8. “Developmental validation” means a method, as outlined in the Quality Assurance Standards, of determining that a Rapid DNA instrument meets generally accepted scientific standards for Rapid DNA analysis. This validation is performed and/or coordinated by the manufacturer of the instrument and must be made publicly available.
9. “Director” means the Director of the Arizona Department of Public Safety.
10. “DNA” means deoxyribonucleic acid, which is the hereditary material in humans and other organisms.
11. “DNA profile” means a set of numbers from a series of genetic markers obtained from an individual’s DNA.
12. “Gene” means a unit of heredity which is transferred from a parent to an offspring that determines some characteristic of the offspring.
13. “Heredity” is the passing on of genetic characteristics from one generation to another.
14. “Internal validation” means a method performed by an accredited laboratory, as outlined in the Quality Assurance Standards, of determining that a Rapid DNA instrument meets generally accepted scientific standards for Rapid DNA analysis as used in the Rapid DNA testing program for the agency.
15. “Known reference sample” means a sample of DNA taken directly from an individual.
16. “Ladder” means a representation of the most common alleles present within a locus. The alleles present provide a reference to size the alleles present in the sample being analyzed.
17. “Locus” means the position of a gene on a chromosome.
18. “Negative control” means a quality control measure which is a sample used on the Rapid DNA instrument to detect DNA contamination in the reagents and consumables.
19. “Nucleus” means the center structure of a cell that contains genetic information.
20. “Performance check” means a series of analyses run on a Rapid DNA instrument at a Rapid DNA testing site to determine that the instrument can be put into service for Rapid DNA testing of crime scene and known reference samples.
21. “Positive control” means a known DNA sample processed on the Rapid DNA instrument that provides the expected DNA profile for that sample.
23. “Rapid DNA” means an automated process of developing a DNA profile from a crime scene samples or known reference samples within a compressed period of time, typically under two hours.
24. “Rapid DNA Consultant” means an individual who is a forensic scientist with training and experience in DNA analysis and interpretation; who has successfully completed an agency’s Rapid DNA Operator training program; who can perform interpretations on crime scene samples or known reference samples when requested by a Rapid DNA Operator; and who may teach training classes for new Rapid DNA Operators.
25. “Rapid DNA Coordinator” means an employee of the Arizona Department of Public Safety who meets the requirements of a Rapid DNA Consultant and who oversees the operations of the Department’s Law Enforcement Rapid DNA Program.
26. “Rapid DNA instrument” means a scientific instrument used to conduct Rapid DNA analysis.
27. “Rapid DNA Operator” means an individual who has successfully completed an agency’s Rapid DNA Operator training program and can operate the Rapid DNA instrument specific to their training.
28. “Rapid DNA partner agency site” means a Rapid DNA site that has met all of the requirements for a Rapid DNA testing site and that, additionally, has partnered with the Department to access their Rapid DNA database and receive support from the Rapid DNA Coordinator.
29. “Rapid DNA testing site” means a location at a law enforcement agency in the State of Arizona that meets the specific requirements to support and maintain a Rapid DNA law enforcement program and has been approved to do so by the Department.
30. “Raw data” is data from a Rapid DNA instrument prior to any adjustments that might be made by a software program utilized by the instrument.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).

R13-15-102. Exemptions
Rapid DNA applications that are not being performed as part of a law enforcement program to develop investigative leads from crime scenes and known reference sample and testing sites that are not associated with an accredited laboratory through a legally binding agreement and do not use personnel for testing associated with a law enforcement agency are exempt from this Chapter. These exempt applications include the following:
1. Unidentified human remains testing by medical examiner/coroner offices,
2. Victim identification in mass disaster scenarios,
3. Missing persons cases not associated with a law enforcement crime scene investigation,
4. Applications within accredited laboratories; or
5. Rapid DNA booking stations.

Historical Note
R13-15-103. Instruments; Approvals, Standards, Authorizations

A. The Director may approve instruments used to perform Rapid DNA analysis as part of a law enforcement program after receiving a report from an accredited laboratory that successfully tested a typical model of the instrument for compliance with the standards in subsection (B).

B. The instrument shall meet the following standards of performance:
   1. The instrument shall have a publicly-available developmental validation completed by the manufacturer which follows the requirements of the QAS and includes, where applicable:
      a. Characterization of the genetic marker,
      b. Species specificity,
      c. Sensitivity studies,
      d. Stability studies,
      e. Reproducibility,
      f. Case-type sample,
      g. Population studies,
      h. Mixture studies,
      i. Precision and accuracy studies; and
      j. PCR-based studies.
   2. The instrument shall have an internal validation completed by the submitting accredited laboratory which follows the requirements of the QAS and includes, where applicable:
      a. Known and mock evidence samples,
      b. Precision and accuracy studies,
      c. Sensitivity and stochastic studies,
      d. Mixture studies; and
      e. Contamination assessments.
   3. The instrument shall allow the accredited laboratory performing the internal validation the ability to access, view and interpret raw data from the instrument in order to ensure the integrity of the analysis.

C. The accredited laboratory shall provide the following to the Department for approval of the Rapid DNA instrument:
   1. A copy of the developmental validation,
   2. A summary of the internal validation,
   3. All data from the internal validation; and
   4. Any additional supporting documentation or calculations needed to support the internal validation.

D. The Department, upon specific findings that a device is unreliable, inaccurate, or otherwise unable to meet the requirements of a validation, shall publish a disapproval of use of the instrument.

E. The following instrument is approved by the Director.

<table>
<thead>
<tr>
<th>Instrument Device/Model</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>RapidHIT ID</td>
<td>Thermofisher</td>
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</tbody>
</table>

F. Only Rapid DNA Operators are authorized to operate approved Rapid DNA instruments for use at law enforcement agencies.

G. The Director may publish a temporary approval of a Rapid DNA instrument that has been successfully tested for compliance with the standards in subsection (B) for use prior to and pending the instrument being added to subsection (E). The temporary approval shall expire three years after its effective date.

**Historical Note**

New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).

R13-15-104. Operator Certification

A. In order to be certified as a Rapid DNA Operator to operate a Rapid DNA instrument as part of a law enforcement program, an employee of a law enforcement agency shall successfully complete training that meets the following criteria:
   1. A training program approved by the Director.
   2. The training program shall include at a minimum the following:
      a. Information on basic biology, specifically including what DNA is and its purpose,
      b. Information on basic DNA analysis,
      c. Identification of appropriate sample types for analysis on Rapid DNA instrumentation,
      d. Proper collection and preservation of samples for analysis on Rapid DNA instrumentation,
      e. Information on clean techniques to process samples and minimize contamination,
      f. Information on DNA databases,
      g. Evaluation and interpretation of DNA results,
      h. Basic knowledge of the operation of a Rapid DNA instrument,
      i. Information on court testimony regarding Rapid DNA analysis,
      j. Taking a sample from collection to identification of an investigative lead using the Rapid DNA instrument and where applicable any associated database,
      k. A written examination covering the objectives in subsections (A)(2)(a) through (i); and
      l. A practical examination to demonstrate competence in subsection (A)(2)(j).
   3. Certification as a Rapid DNA Operator is contingent upon successful completion of the approved training program as measured by the written and practical examinations associated with the program. The written examination shall be passed with a minimum score of 90% and the prospective operator shall demonstrate the ability to successfully operate the Rapid DNA instrument in a practical-use test.
   4. Maintaining certification as a Rapid DNA Operator is contingent on completing one of the following on an annual basis:
      a. Submission to the Department of evidence of successful operation of the Rapid DNA instrument during the annual period; or
      b. Submission to the Department of evidence of successful completion of a proficiency test that demonstrated operation of the instrument and receiving the expected result as shown by the test record completed by the operator on the Rapid DNA instrument during the annual period.

B. The Department may suspend or revoke the certification of a Rapid DNA Operator for any of the following reasons:
   1. Any falsified test results or false statements to the Department, other law enforcement agency or criminal justice entity.
   2. Failure of an operator to maintain quality control over sample preparation, reagents, or instrumentation during analysis of samples.
   3. Failure of the operator to provide evidence of successful operation of the instrument on an annual basis pursuant to subsection (A)(4)(a) or (b).
   4. Failure to operate the Rapid DNA instrument according to approved procedures or methods.
CHAPTER 15. DEPARTMENT OF PUBLIC SAFETY – RAPID DNA

5. Undertaking actions that compromise the integrity of the results or of the Rapid DNA testing program.

C. The provisions of A.R.S. Title 41, Chapter 6, Article 10 are applicable to denials, revocations, suspensions and administrative appeals.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).

A. Rapid DNA testing sites shall be associated with an accredited laboratory through a legally binding agreement and use personnel for testing associated with a law enforcement agency to develop investigative leads from a crime scene and known reference samples.

B. Rapid DNA testing conducted at law enforcement sites shall follow the procedures or protocols outlined in the training program for that agency, site, and Rapid DNA instrument.

C. Rapid DNA Operators shall follow on-screen prompts on the Rapid DNA instrument when performing Rapid DNA testing.

D. The amount of sample used in Rapid DNA testing for a case shall not compromise the ability of the associated accredited laboratory to complete conventional DNA testing on that sample.

1. If Rapid DNA testing would consume too much of the sample to allow conventional DNA testing within the associated accredited laboratory, Rapid DNA testing shall not be conducted on that sample.

2. Consultation with the associated accredited laboratory may be necessary to determine whether the amount of sample is sufficient to complete both Rapid DNA and conventional DNA testing.

E. Rapid DNA testing shall be conducted only on sample types approved for the specific Rapid DNA instrument being used as demonstrated by the internal validation for the instrument and as outlined in the training program for the instrument.

F. Each instrument run shall be documented on a run log which shall include at a minimum the following:

1. Instrument and site information,

2. Date and time of sample run,

3. Date and time of sample collection,

4. Lot numbers of reagents,

5. Case number,

6. Agency,

7. Operator,

8. Type of sample,

9. Type of case; and

10. Results of analysis.

a. If profile developed.

b. If investigative lead developed.

G. Run logs shall be maintained for a minimum of two years at each Rapid DNA testing site and be made immediately available for review by the Department when requested.

H. Supplemental reports documenting the Rapid DNA test shall be included with each case file.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).

A. All Rapid DNA testing sites shall have the following:

1. A minimum of six square feet of counter space to perform sample preparation and sample analysis,

2. A minimum of 100 square feet of space to house the Rapid DNA instrument, a computer with monitor, and a printer,

3. Appropriate temperature, lighting and humidity to maintain the integrity of samples, the Rapid DNA instrument, and reagents as specified by the manufacturer of the instrument and reagents.

4. Restrictions on personnel access to reduce potential contamination of samples,

5. Uninterrupted power supply or other backup power source to prevent damage to the instrument and to prevent failures of Rapid DNA tests due to power loss,

6. Floors and countertops able to withstand frequent decontamination with bleach solutions, and

7. A temperature-monitored refrigerator for storage of reagents, where applicable.

B. Testing sites cannot be used for any other purpose besides preparation of samples for Rapid DNA analysis and running of samples on the instrument.

C. Floors, countertops and equipment shall be decontaminated on a regular basis at minimum of every two weeks to maintain cleanliness and minimize any foreign DNA. A cleaning log should be maintained at each testing site and be made available for review by the Department when requested.

D. Equipment calibration and maintenance shall be tracked in a log that is maintained at each Rapid DNA testing site. At a minimum the log shall contain information on the date and nature of the calibration or maintenance and include any associated paperwork from the person performing the calibration or maintenance. This log shall be made available for review by the Department when requested.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).

A. A partner agency site shall meet all the standards in R13-15-105 and R13-15-106.

B. Additional standards include the following:

1. The partner agency site shall comply with any additional internal program requirements of the Department which includes a memorandum of understanding (MOU) between the agencies.

2. Run logs shall be provided to the Department on a calendar quarterly basis.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).


B. If the audit of the Rapid DNA testing site determines that the site is not in compliance with the standards in subsection (A), the testing site shall be suspended and cease operations until the associated accredited laboratory and the Department determines the site is once again in compliance.

C. Documentation of audits shall be maintained at both the testing site and at the associated accredited laboratory for a minimum of five years.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 998 (May 13, 2022), effective July 3, 2022 (Supp. 22-2).