Advancing Transfusion and Cellular Therapies Worldwide

# Relationship Testing Accreditation Program

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**AABB**

# Introduction to AABB

An international, not-for-profit association representing individuals and institutions involved in the field of Relationship Testing

AABB is committed to improving quality through:

-Standards

-Accreditation

-Educational Programs

# AABB Sets Standards In the Following Areas

- Blood Banks and Transfusion Services
- Cellular Therapy Services
  - Hematopoietic Progenitor Cell Services (HPC)
  - Cord Blood
  - Somatic Cells
- Immunohematology Reference Laboratories
- Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens
- **Relationship Testing Facilities**
- Perioperative Autologous Blood Collection and Administration
- Patient Blood Management

# AABB Accredited RT Facilities

- Currently 44 accredited facilities
  - 33 Accredited testing laboratories
  - 11 accredited collection / verification facilities
  - 6 new applicants (as of July 2017)
- US, Canada, China, Dominican Republic and Philippines

# 13th Edition Standards for Relationship Testing

- In effect January 2018 – January 2020
- New standards specific to Rapid DNA testing
- Available at AABB.org ~ November 2017

# Define the Testing System

**Closed System:** An instrument and pre-assembled set of reagents that consist of cartridges, chips, or biochips whose purpose is to perform DNA extraction, or purification, amplification, and separation in a single unit without human intervention.

# Control for Sample Switches

**5.4.2 Closed Systems**
The laboratory shall have policies, processes and procedures for performing DNA testing using a closed system, including profile anomalies that may impact the result.

**5.4.2.1** Laboratories using closed systems shall confirm the placement of the sample in the specified location on the instrument through a visual check with a witness or electronic equivalent.

# Confirmation of Exclusions

**5.4.2.2** In cases where there is a finding of no relationship, the laboratory shall test a confirmatory sample:

**1)** If the sample is flagged for review by the closed system, or

**2)** If the closed system fails and the sample is manually manipulated.

**3)** Unless a human review is conducted and the flagged loci are found not to impact the results of the relationship findings.

# Positive and Negative Controls

**5.4.1** …The laboratory shall have a process that demonstrates reproducibility of test results.

...a human DNA control of known phenotype shall be tested with each analysis…

Negative control(s) shall be processed with samples from extraction through analysis… (5.4.1.1 #6)

For closed systems, reproducibility studies shall be a part of the acceptance process.

# Critical Supplies Acceptance

**4.5 Receipt, Inspection, and Testing of Incoming Critical Supplies and Samples**

Incoming reagents, samples, materials, equipment, and products shall be inspected and tested before reporting of results. The laboratory shall ensure that:

1) Each lot shall be tested.

2) Each shipment, regardless of lot, shall be tested.

3) Each lot within a shipment shall be tested.

**4.5.1** Criteria for acceptance and rejection of the inspection and testing shall be established.

# Process Validation

**5.3.14.1** Before the laboratory changes a process or procedure for an existing test method or adds a new process or procedure, it shall be validated.

**5.3.14.3** …the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory. If the laboratory establishes its own frequency database for the loci (or locus), the power of exclusion shall be determined and compared with published values, if available, as part of the validation process.

# Expert System Validation

**5.5.4.1** Validation of an Expert System shall include:

1) Evidence that the system correctly determines alleles and identifies artifacts that require human review by comparing at least 200 determinations made by the expert system with allele determinations made by a director or director designee.

2) Evidence that the system makes accurate allele determinations and identifies artifacts that require human review by comparing results from at least 200 electropherograms.

3) Demonstration that the expert system produces complete concordant results for at least 100 electropherograms that contain artifactual peaks or other anomalies requiring human review (eg, spikes, off-ladder alleles, contamination, size standard shifting).

# Expert System Validation

**5.5.4.1.1** For closed systems, the laboratory shall establish thresholds for allelic drop-in and dropout and establish procedures to ensure those thresholds are consistent with the validation studies.

**5.5.4.1.2** Validation studies shall be reviewed and accepted by the RT Standards Committee of the AABB before implementation.

# Calculation Software Validation

**3.5 Information Systems**

The laboratory shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these *RT Standards*. These processes shall include:

1) Risk analysis, training, validation, implementation, and evaluation of postimplementation performance.

2) Description of system maintenance and operation.

3) Documentation written in language that is understandable to the user.

4) A system for display and verification of added or amended data before final acceptance.

5) Description of how modifications to the system are authorized and recorded.

6) Validation of calculation software including all formulae used by the laboratory to generate test reports.

## Appendix 3: Formulas for Paternity Index and RMNE Values for Simple Codominant Systems

Myrna Traver, MD

The following formulas apply only to systems controlled by a single locus, with no null alleles, and with negligible mutation rates. A, B, C, and D represent alleles; a and b are allele frequencies.

| # | M | C | AF | X | Y | PI | RMNE* |
|---|---|---|---|---|---|---|---|
| 1 | BD | AB | AC | 0.25 | 0.5a | 1 / 2a | a(2-a) |
| 2 | BC | AB | AC | 0.25 | 0.5a | 1 / 2a | a(2-a) |
| 3 | BC | AB | AB | 0.25 | 0.5a | 1 / 2a | a(2-a) |
| 4 | BC | AB | A | 0.5 | 0.5a | 1 / a | a(2-a) |
| 5 | B | AB | AC | 0.5 | a | 1 / 2a | a(2-a) |
| 6 | B | AB | AB | 0.5 | a | 1 / 2a | a(2-a) |
| 7 | B | AB | A | 1 | a | 1 / a | a(2-a) |
| 8 | AB | AB | AC | 0.25 | 0.5(a+b) | 1 / [2(a+b)] | (a+b)(2-a-b) |
| 9 | AB | AB | AB | 0.5 | 0.5(a+b) | 1 / (a+b) | (a+b)(2-a-b) |
| 10 | AB | AB | A | 0.5 | 0.5(a+b) | 1 / (a+b) | (a+b)(2-a-b) |
| 11 | AB | A | AC | 0.25 | 0.5a | 1 / 2a | a(2-a) |
| 12 | AB | A | AB | 0.25 | 0.5a | 1 / 2a | a(2-a) |
| 13 | AB | A | A | 0.5 | 0.5a | 1 / a | a(2-a) |
| 14 | A | A | AB | 0.5 | a | 1 / 2a | a(2-a) |
| 15 | A | A | A | 1 | a | 1 / a | a(2-a) |
| 16 | | AB | AC | 0.5b | 2ab | 1 / 4a | (a+b)(2-a-b) |
| 17 | | AB | AB | 0.5(a+b)2ab | | (a+b) / 4ab | (a+b)(2-a-b) |
| 18 | | AB | A | b | 2ab | 1 / 2a | (a+b)(2-a-b) |
| 19 | | A | AC | 0.5a | $a^2$ | 1 / 2a | a(2-a) |
| 20 | | A | A | a | $a^2$ | 1 / a | a(2-a) |

* PE = ( 1 – RMNE)

# Requirements for initial accreditation

**5.1.2.1** A laboratory seeking initial accreditation shall participate in either one of the following:

1) A proficiency testing program for 2 years with successful results.

2) An exchange of at least 12 blinded cases representative of the casework the laboratory proposes to perform with an accredited relationship testing laboratory and demonstrate concordant results.

# Requirements for Accreditation

**1.2 Laboratory Director Qualifications and Responsibilities**

The laboratory shall have a director who has a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science.

The laboratory director shall have at least 2 years of training or experience in relationship testing in an AABB accredited laboratory (or equivalent) or under the guidance of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience.

**1.2.1** The laboratory director shall be a part of executive management.

**1.2.1.1** The laboratory director shall have responsibility and authority for all policies, processes, and procedures.

# Requirements for accreditation

- Be in operation for a minimum of 6 months in the desired activity before applying.
- Access to the online standards portal can be obtained in the Marketplace at AABB.org
- Ensure that there is a policy, procedure, or process for EACH element in the standards.

# **Accreditation Process** - Application

- Contact AABB to begin application process
- Pay dues
- Assigned to a technical specialist – one consistent contact person to work with throughout the accreditation process.

# Accreditation Process

- Phase 1
  - Self-assessment to the AABB standards
  - Document Review by AABB technical staff
  - Document Review by AABB Relationship Testing Accreditation Committee

# Accreditation Process

- Phase 2
  - on-site assessment phase, 1-2 days, one assessor.
  - Quality review of assessment
  - Issue Accreditation Certificate
  - Once accredited, a facility goes through the accreditation process (on-site assessment) every two years.

# For more information

accreditation@aabb.org

1.301.215.6492

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# THANK YOU

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