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Do you have an interesting case or question you would like to share? Email us at nikkib@aabb.org

Introducing... Our Newest Standards

AABB Relationship Testing Standards 12th Ed – Effective Jan. 1, 2016

1.1.7 Obtaining official transcripts for laboratory directors, laboratory director designees, and laboratory supervisors.

The committee added this standard to ensure that individuals in the positions listed above provide their additional documents attesting to their qualifications.

Guidance was added: To get an official transcript, an individual needs to contact his/her university and request that it be sent to the facility. A small fee may be incurred.

4.7.1 The facility shall have policies, processes, and procedures to evaluate and respond to possible altered or fabricated documents.

The committee added this standard to ensure that all documents that appear to have been altered and that the laboratory deems critical to its function are evaluated.

Guidance was added: Facilities have occasionally seen final reports and other documents that are altered or fabricated (commonly called “forgeries”). With improving computer technology, the ability to “cut and paste” pieces of legitimate documents into a fabricated document is much easier. Facilities should have mechanisms in place to readily identify these altered or fabricated documents. The use of a logo on reports that is different from that used on letters, the use of a unique signature block, or the use of colors within the document may serve as deterrents to alterations or fabrications. The facility might consider retaining exact copies of letters and other communications, including documents that are sent in response to a subpoena, for authentication purposes.

5.2.3.6 The laboratory shall have policies, processes and procedures to identify non-chain of custody cases. Standard 4.7 applies.

In place of having standards for non-chain cases, the committee added a standard to require accredited labs to have policies, processes and procedures to identify and handle non-chain of custody cases.

**Available
Now!**

**12th Edition Standards
for Relationship
Testing Laboratories**

*The effective date January
1, 2016*

**Copies are available for
purchase. Visit the
AABB Marketplace at:**

<http://marketplace.aabb.org/ebuspprod/Marketplace/AllProducts/ProductDetail.aspx?productId=12878771>

Notes on changed standards in the 12th Edition:

2.1.1 - The committee elected to remove the clause restricting this standard to “performing critical tasks” believing the standard should have a broader application.

3.2 - The committee elected to expand the standard by adding the second sentence.

5.1.3.2 - The committee removed the clause “before release of test results, products or services” at the end of the last sentence after ...investigated for clarity.

5.2 - The committee added “for Chain of Custody Cases” and removed “of sample collection” after verification in the description of the standard.

5.2.3 - The committee added “and Documentation” to emphasize the need for documentation even though the standard requires record retention.

5.2.3.5 - The terms “visa, passport” were added at the request of the US Department of State. The addition along with immigration and citizenship testing matches what is required for individuals attempting to validate citizenship.

5.2.4.3 - The committee added “and type” for clarity and completeness.

5.2.4.6 - The clause in 11th edition, “If a blood sample is collected...” was removed as it was deemed inaccurate as it pertains to the entire body of the 12th edition.

5.2.4.8 - The committee added “and documentation of shipment receipt” for completeness.

5.3.7.1 - This standard was edited for clarity by removing “non-parentage” and replacing it with “other than parentage”. The replacement does not alter the intent of the standard.

5.3.11.2 - The committee removed “consistency” and replaced it with “accuracy and reproducibility” to more accurately reflect the language used in the field today. The words “precision” and “accuracy” in parentheses in the 11th edition were removed.

5.3.11.3 - The committee added this change was made to be consistent with the change to 5.3.11.2.

5.5.3.1 – The committee removed the word “If” for clarity.

6.1.2 - The committee added the ending to the last sentence to ensure that the manufacturer’s instructions or package inserts are not used as a facility standard operating procedure, but could appear as supporting documentation.

6.1.5 - The committee added the last sentence to provide clarity for users of these standards.

6.3.3 - The committee added “meet these RT Standards” and the reference to Reference Standard 6.3A for completeness.

6.4.4 - The committee added the pen symbol to ensure that all laboratories maintain documentation to show that they have submitted data to AABB as it pertains to the AABB Relationship Testing Annual Report.

6.2.1A - official transcripts added to the list of records to be maintained.

6.3A B1 - The committee added “with the exception of Amelogenin, other markers used for gender determination, and linked loci, as defined in Standard 5.5” for completeness.

6.3A B3 - The committee added “or involve relationship testing other than parentage” for completeness.

7.1 - The committee reworded this standard for clarity and completeness.

8.1.4 - The committee added “personnel directly involved in the testing” to be inclusive of testing personnel and not just executive management.

8.2 No changes, this standard was moved from section 9. The committee felt that Quality Monitoring flowed better in Chapter 8 Assessments: Internal and External.

Looking Back to the 11th Edition's Most Common Nonconformances

The AABB Relationship Testing Annual Report Summary

To obtain a FREE copy
JUST CLICK:

<http://www.aabb.org/sa/facilities/Pages/RTestAccrFac.aspx>

1.1.5 Ensure that operational policies, processes, and procedures are defined, documented, implemented, maintained, and improved.

This standard is often cited when the facility is not following their own procedures or the facility has processes for which there is no written procedure. It is important to have a policy and procedure for every process and to follow the procedures as written.

5.1.2.6 Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).

For the relationship testing laboratory checking that both the testing and the calculations are accurate is an important part of quality control. Therefore proficiency testing should reflect the types of cases the laboratory tests and calculates. Currently the CAP proficiency testing program provides a mechanism to compare allele calls and calculations to other laboratories. The CAP proficiency testing provides graded proficiency testing for standard trios and an ungraded paper challenge that covers various family studies (reconstruction cases). If a laboratory is performing family studies, the laboratory should participate in the paper challenge in order to be proficiency tested in this area. Documentation of review of the paper challenge results should be kept. Single parent calculations are not currently routinely evaluated by CAP. One mechanism of checking the single parent studies is to recalculate tested trios and compare the results. Typically, a lower combined paternity index is expected when a parent is missing. Hand calculating a single parent case to evaluate the laboratory's computer calculations would also be documentation of checking this single parent calculation.

5.5 Calculation methods shall be validated. The results from loci with a significant degree of linkage shall not be used independently in calculations.

While not completely settled in the scientific community, two sets of loci that appear linked are Penta E / FES-FPS and VWA / D12S391. If a laboratory is using linked loci for relationship testing, the laboratory should consider development of haplotype frequencies and/or develop reporting criteria. If haplotype tables are not available, reporting one of the likelihood ratios of the two loci is appropriate. For this approach, the higher likelihood ratio will be closer to the likelihood ratio obtained from haplotype tables in paternity calculations only. For family studies / reconstruction cases, if no

autosomal allele is shared then that likelihood ratio should be reported regardless of the calculation of the other locus. For example, if a calculation for linked loci is done for a full sibling versus unrelated relationship and no allele is shared between one or more loci, reporting 0.25 would be appropriate as a single likelihood ratio for that set of linked loci. Similarly if the inconsistency is interpreted as a mutation, a single mutation likelihood ratio (calculated following laboratory protocols) would be used for both loci. The recommendation is to report both loci; the calculated likelihood ratio for the locus designated by the laboratory's reporting policy would be entered and the likelihood ratio for the other locus would be reported as 1 or the likelihood ratio could be left blank. If one locus is interpreted as exclusionary, the exclusionary locus would be reported with a likelihood ratio of 0 or if both loci are exclusionary, both would be reported with a likelihood ratio of 0. If the laboratory is not reporting both linked loci, the reporting policy should state which of the loci will be reported and that both loci will have documented review to determine whether an exclusion or a potential mutation exists. If there is a potential mutation of the locus that is designated to not be included in the report, this locus should be included in the report and the other linked locus would either not be reported or would be reported with a likelihood ratio of 1 or left blank as described above.

6.4.1 Promotional Materials – An AABB-accredited laboratory shall use AABB trademarks, including logos, or make claims about AABB accreditation only in reference to activities for which it is accredited by AABB

Standard 6.4 and its subparagraphs highlight a serious problem involving the misuse of AABB trademarks, logos and claims about activities that are not accredited by AABB (see the definition of "claims" in the glossary). AABB RT Standards provide for the testing of relationship cases using properly trained personnel, clear identification of the tested subjects, chain of custody, and appropriate testing and reporting. If the laboratory is offering testing that does not meet all AABB RT Standards, then the AABB trademark, logo or claims of accreditation cannot be made for this testing activity. This is also true of internet advertising. If an internet page contains advertisements for non AABB- accredited activity, then AABB cannot be mentioned on the page. (See standard 4.4.) This also includes final reports. For example, if there is no chain of custody (samples collected without following the AABB RT Standards), then the laboratory cannot claim that the "testing" meets the AABB RT Standards. The final report either meets the standards or it does not meet the standards; the laboratory cannot make claims that part of a test meets the standards. Another example is a third party administrator (TPA) advertising that all of the testing is performed in an AABB-accredited laboratory, and yet offers testing with collection procedures that do not follow AABB RT Standards. If a laboratory

performs testing for TPAs, under standard 4.2, the laboratory is required to have an agreement that clearly indicates what are the appropriate marketing materials and claims.

If an AABB accredited laboratory is offering testing that does not meet the AABB RT Standards for collections and thus are non-AABB accredited relationship tests, commonly referred to as “non-chain” or “self-collections”; the laboratory is still expected to follow all RT Standards for testing and the following guidelines for collections and reporting for these cases.

The collection of samples tested in this case was not witnessed by trained or laboratory personnel. Because there is no chain of custody associated with the case, there can be no assurance that the samples tested were collected from the individuals named on this report. This test should not be used as the basis for legally binding actions related to paternity or other relationships.

All records shall clearly indicate that the testing is for the purpose of non-chain of custody testing to distinguish this form of testing from activities covered in these RT Standards.

7.2 Nonconforming Proficiency Test Results – When nonconforming proficiency test results are obtained, the laboratory shall evaluate and take appropriate action in response to results with unacceptable grades or deviation from nongraded challenged with known answers or that have reached 80% consensus.

When there are discrepancies between the CAP paper challenge submitted by the facility and the answers published by CAP, a document review of the paper challenge addressing any discrepancies is required. If there is disagreement with the CAP published answers, this documentation should include notification to CAP of any identified issues.

If the paper challenge serves as the director competency, the competency requirements of standard 2.1.3.1 must also be addressed.

Upcoming Audioconference

Elementary Probability as Applied to Biological Relationship Determination

Monday, March 14, 2016

2:00 – 3:30 PM (ET) 7:00 – 8:30 PM (GMT)

Program # 164930

Director/Moderator: Nikki Bass-Jeffrey (CQIA)ASQ,
Accreditations Programs Coordinator, AABB

Speaker: Charles M. Kelly, Ph.D., Former Director, Fairfax Identity
Laboratories

Intended Audience: Parentage Laboratory Managers and
Technologists

Teaching Level: Basic/Intermediate

Objectives:

- To learn/review basic rules of probability, population and frequency.
- To apply the basic probability rules to derive mathematical expressions for genotype likelihoods.
- To calculate likelihood ratios for parentage given various scenarios of parental genotypes.
- To calculate a probability of parentage from the likelihood ratio/paternity index.
- To demonstrate the dependence of parentage probability on the weight of the non-genetic evidence in a legal proceeding.

Event Description: Participants will review basic probability principles using simple references to coin tosses and rolls of dice. Those principles will then be applied to biological inheritance and the calculation of parentage likelihood ratios. The effects of zygosity or the availability or unavailability of a parent on the final likelihoods will be made apparent.

[Register Now](#)



New from AABB

Relationship Testing Collector Training and Certificate



Are you
a DNA
collector?

Have you enrolled in AABB's relationship
testing collector training?

This self-paced online course teaches individuals the proper methods to collect, process, and submit high quality DNA samples. Successful individuals will earn a Certificate of Training from AABB and be included on the list of qualified collection professionals given to AABB Accredited Relationship Testing laboratories nationwide.

LEARN MORE AND ENROLL TODAY!

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For more information:

Phone: +1.301.215.6482 • Email: professionaldevelopment@aabb.org

Registration Fees*

December 23, 2015 – December 31, 2016: \$99

January 1, 2017 – June 30, 2017: \$59

July 1, 2017 – December 31, 2017: \$29

WANTED

Audio Conference Content

Would you like to repurpose your old talks or presentations?

Share your content as part of AABB's 2016 RT Audio Conference Series.

Please let us know if you have given a talk or presentation in the last 2-3 years on a topic that you think may be of interest to the relationship testing community. Topics of interest may include but are not limited to calculations, new technologies, expert systems, court room basics, forensics, DNA etc. If you decide to submit your content, you can choose to moderate the audio conference or we can assign a speaker for you.

For more information or to submit your content, contact Nikki Bass at nikkib@aabb.org

Articles

Do you have an interesting case or question you would like to share through this newsletter? Or is there a topic or issue you would like us to write about? Email us at nikkib@aabb.org

RTAPU or RTSPU Member

- ❖ Are you interested in ensuring that assessment/audit procedures are in consistent with AABB policies established by the AABB Accreditation Program Committee?
- ❖ Are you interested in working with U.S. Citizenship and Immigration Service and/or the Dept. of State as it relates to RT?

If these issues are of interest to you, the **Relationship Testing Accreditation Program Unit** would like to have you as a member.

- ❖ Are you currently an AABB Member?
- ❖ Would you like to be involved in creating and revising the Relationship Testing Standards?
- ❖ Would you like to be involved in creating and revising the Guidance for the Standards?

If these issues are of interest to you, the **Relationship Testing Standards Program Unit** would like to have you as a member. To get involved, please contact Nikki Bass at the AABB National Office at nikkib@aabb.org.

2015-2016 RTAPU Members

Robert Wenk, MD Chair

Marisol De Castro Reyes, MD
Zack Gaskin
Charles Kelly, PhD
James Fuller, PhD
George Maha, JD, PhD

2015-2016 RTSPU Members

Mary Mount, MT(ASCP)
Chair

Debra Davis, PhD
Susan Greenspoon, PhD
Donna Housley, PhD
Zahra Mehdizadeh Kashi, PhD
Robert Wenk, MD
Marilyn Pollack, PhD
Jane Pritchard, BS,
MT(ASCP), CLSp(MB)
Neils Morling, MD, DSc
Kaitlin Keating
Meghan Nemeth, JD

GREAT RESOURCES

- ✚ Access FREE Recording of the previously held (Nov. 17th) audio conference titled Changes from the 11th Edition to the 12th Edition of Standards at the following link:
<https://www.youtube.com/watch?v=oF7dYzXiB7g&feature=youtu.be>
- ✚ AABB has launched the 2nd Edition of the Collector Training certificate course for individuals who would like to be recognized as AABB-trained sample collectors for relationship testing purposes. Find more information at the following link:
<http://marketplace.aabb.org/EbusPPROD/Default.aspx?TabID=55&productId=12970612&>
- ✚ Standards for Relationship Testing Laboratories for 12th Edition is now available. You can purchase a copy at:
<http://marketplace.aabb.org/EbusPPROD/Marketplace/Standards.aspx#filter=&searchTerm=&searchItemNameTerm=&searchDescriptionTerm=&productClass=>

Misleading Claims of Accreditation and Logo Misuse

With the explosion of advertising on the internet, there has been increasing misuse of AABB's trademarked logos and misleading claims of AABB accreditation. We are renewing our efforts to stop such practices and are actively searching out these organizations so that we can address this problem on a more global scale. These efforts benefit accredited laboratories by preserving the strong value of AABB accreditation and by ensuring that customer attention is focused on laboratories that actually are accredited. Our facilities work hard to achieve and maintain accreditation and deserve the maximum benefit of that accreditation. Increased vigilance will also benefit laboratories' customers by ensuring that they get the accredited-laboratory test that they have paid for. You can aid these efforts by bringing to our attention instances of logo misuse or misleading statements regarding accreditation. Please advise AABB's Accreditation Department (accreditation@aabb.org) by providing the offending Web site and briefly describing the issue. It would be particularly helpful if you copy and email the actual link from your browser's address bar, as some offending organizations maintain multiple Web sites. The AABB Trademark Usage Guideline can found on the AABB Web at the following link:

<http://www.aabb.org/membership/governance/Pages/default.aspx>

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