aaBB Accreditation

Relationship Testing News

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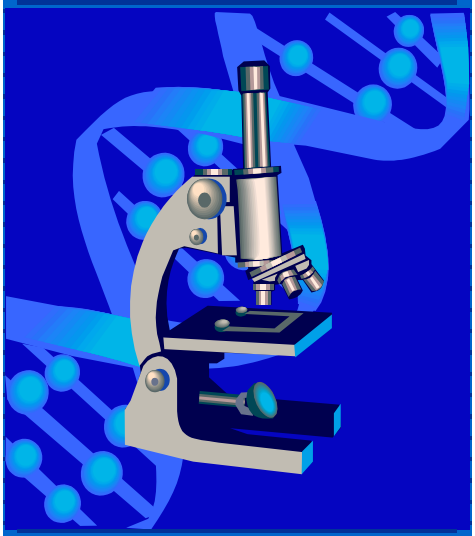

In This Issue

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

Nonconformances in Accreditation Assessments

At the AABB Annual Meeting in October 2008 we presented a discussion of assessment subjects and nonconformances to standards cited in assessments during the preceding year. During the period discussed, two major changes occurred. First, the Eighth Edition of the AABB Standards for Relationship Testing came into effect, superseding the Seventh Edition. Second, the AABB hired a Staff Lead Assessor to focus on the relationship testing laboratories. The AABB hired the Staff Assessor for several reasons. One reason is to increase the uniformity of the assessments and another is to alleviate a concern by some laboratories that a potential competitor could assess their laboratory.

Since the inception of the Eighth Edition of the Standards, I have been asked to emphasize several things: assessment of the management aspect of the Standards, the supplier qualification Standard and observing objective evidence of conformance to Standards. Additionally, we are assessing over a slightly longer period: 1.5-2 days as compared to 1-1.5 days. Because of these new emphases, the average number of nonconformances cited in assessments has increased from the Seventh to the Eighth Edition.

The time period discussed at the 2008 Annual Meeting Presentation was from October 2007 through July 2008. During that time, there were a total of 81 nonconformances cited, 14 during the 2.5 months that the Seventh Edition was still in force and 67 in 7 months that the Eight Edition was in force. At the Annual Meeting, I presented the statistic that this amounted to a rate that was about 1.7 times more nonconformances per month in the Eighth Edition than in the Seventh Edition. A better measure is probably the number of nonconformances cited per assessment, which is actually nearer 4 times more in the Eighth Edition than in the Seventh Edition.

The largest number of nonconformances were to *1.0 Organization* (11), *3.0 Equipment* (12), *5.0 Process Control* (27), and *6.0 Document Control* (14). The nonconformances cited are below. In the list, nonconformances to a parent Standard (i.e., 5.0) that are cited based on objective evidence of nonconformances to daughter Standards (i.e., 5.2.3 and 5.2.4.4 were objective evidence given for the nonconformance cited to Standard 5.0) are indicated by "(subs)," and

new or changed standards are underlined (i.e., 5.4.2.2 #7). The nonconformances listed are to the Eighth Edition except as indicated by a subscript 7 (i.e., 1_7). Nonconformances to the Seventh and Eighth Eds. are indicated by subscript 7/8 (i.e., $3_{7/8}$).

1.0	ORGANIZATION (subs)	1
1.1	Executive Management	1
1.1.5	Ensuring policies, processes and procedures are defined, documented, implemented, maintained, and improved	2
1.2	Laboratory Director Qualifications and Responsibilities	1
1.2.1	Laboratory director shall be a part of executive management	1
1.4	Staffing Changes:30 days	$3_{7/8}$
1.5	Emergency Preparedness	2
2.1	Human Resources (subs)	1
2.1.1	Qualification	1_7
2.1.2	Training	1_7
2.1.3	Competence	1
2.1.4	Continuing Education	1
3.0	Equipment (subs)	1
3.1	Selection of Equipment	1
3.4	Control of Critical Equipment	4
3.5	Computer Systems	1+1 subs
3.5.1 1)	Validation of system software, hardware, databases, user-defined table, electronic data transfer, and/or electronic data receipt. (Computer System Records)	1
3.5.1 3)	Numerical designation of system versions, if applicable, with inclusive dates of use. (Computer System Records)	1
3.5.2	The laboratory shall have an alternative system that ensures continuous operation in the event that computer-assisted functions are unavailable. The alternative system shall be tested at least annually.	1
3.5.3	Personnel responsible for management of computer systems shall be responsible for compliance with the specified requirements that affect their use.	1_7
4.1	Supplier Qualification	1
5.0	Process Control (subs)	3
5.1.1	Change Control	1
5.1.2	Proficiency Testing Program	$2_{7/8}$
5.1.2.3	When a formal graded external proficiency testing program is available, the laboratory shall participate three times a year for each genetic system analyzed in the laboratory.	2

5.1.5.1	Reagents shall meet defined criteria.	$3_{7/8}$
5.1.6	Identification and Traceability	1
5.2.3	The person collecting the sample and/or verifying the process, shall confirm that the following conditions exist:	1
5.2.3 1)	The identification of the tested person is accurate and the stated relationship is recorded.	1
5.2.3 3)	The sample was collected from the intended person.	1
5.2.3 4)	The label is accurate.	1
5.2.4.4	Printed name, signature, and contact information of the person collecting the sample and/or witnessing the sample collection.	1
5.2.4.5	Printed name, signature, and contact information of the person verifying collection process, if different from the person collecting the sample.	1
5.2.4.6	If blood is collected, transfusion in the preceding 3 months, or any allogeneic hematopoietic progenitor cell transplantation.	1
5.3 1)	Testing: Multiple independent genetic systems as the basis for its findings.	1_7
5.3.1.1	With other relationship testing, the laboratory shall establish reporting policies for the indices obtained (avuncular index, sibling index, etc.).	1_7
5.3.3.1	For homozygotes, only the observed phenotype shall be listed.	1
5.3.4	Minimum performance thresholds shall be defined and monitored.	1_7
5.3.5.3	For added loci, validation using at least 20 biological test samples	1
5.4.2.2 7)	The laboratory shall have policies and procedures to evaluate contamination and preferential amplification for each sample.	2
5.5.1	All calculations shall be reviewed by a laboratory supervisor and/or laboratory director.	1
6.0	The laboratory shall have a process for document control that includes the following elements: (subs)	1
6.1.1	A master list of documents, including policies, processes, procedures, labels, and forms related to the requirements of these RT Standards.	2
6.1.4	Annual review of each policy, process, and procedure by the laboratory director.	1

Did you know ?

1) Additional questions or uncertainties regarding any standard can be submitted to the Relationship Testing Accreditation Program Unit for review as a topic for the newsletter and/or educational topic at the National AABB Meeting. Forward topic suggestions to nikkib@aabb.org

2) Questions encountered during an onsite assessment can be addressed immediately by calling 301.215.6492.

6.1.5	Use of only current and valid documents available at all locations where activities are performed.	1
6.1.6	Identification and appropriate archival of obsolete documents.	1
6.3A	Requirements for Testing Reports (subs)	
6.3A A) 4)	Racial/ethnic background used by the laboratory for calculations.	1
6.3A A) 5)	The original signature of the laboratory director or director designee.	1
6.3A B. 1)	Report the phenotypes of tested individuals for all genetics systems that meet the laboratory's minimum performance thresholds	1
6.3A B. 3)	IF: A statement of non-relationship is rendered. THEN: The basis for the finding shall be included in the statement of non-relationship	1
6.3A B. 3) d)	IF: There is a failure to exclude…THEN: The report shall include the following information: A statement that the calculations compare the tested individuals to a defined population.	1
6.3A B. 3) e)	IF: There is a failure to exclude…THEN: The report shall include the following information: A statement that the calculations compare the tested individual to either an unrelated or related individual.	2
7.1	Upon discovery, nonconforming materials, samples, and services shall be evaluated and their disposition determined.	1 7
7.2.1	Nonconforming results in a graded proficiency testing program shall be investigated in accordance with **Standard 9.1** and a corrective action plan shall be developed and implemented.	1
7.2.1.1	If the laboratory fails more than one overall conclusion regarding alleged relationships within a 2-year period, the corrective action plan shall include communicating this nonconformance to the AABB.	1
8.0	The laboratory shall have a process to ensure that external and internal assessments are scheduled and conducted annually.	1
8.1	Management of Assessment Results (subs)	1
8.1.2	Corrective and/or preventive action shall be implemented to address deviations and nonconformances from internal/external assessments.	1

8.1.3	Follow-up action shall verify the implementation and effectiveness of corrective and preventative action.	1
8.1.4	The results of internal and external assessments and associated corrective and preventive action shall be reviewed by executive management.	1
9.1.2	Investigation of the root cause of nonconformance.	1
9.1.3	Investigation of the root cause of customer complaints.	1_7
10.2	The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the Quality of results.	1

As labs that have already been assessed are aware, AABB has been putting more emphasis on the management standards than in previous assessments and has been looking for objective evidence that the laboratory is in conformance with the Standards. These factors have led to greater numbers of nonconformances cited at each assessment. This has led to a citation rate about 4 times higher than in the previous year; running at an average of more than 8 nonconformances per lab.

Standard 5.5 Calculations and the independence of loci

This standard states that results from loci with a significant degree of linkage shall not be used independently in calculations. If loci are on different chromosomes, are separated by more than 50 centimorgans, or have been shown in the literature to segregate independently, the lab can assume that they are independent for the purpose of calculation. However, if loci are closely spaced on the same chromosome and have not been demonstrated to be independent, then the results from those loci may not be used independently in calculations. Generally, the loci in commercial kits have been demonstrated to be independent of one another (e.g., D5S818 and CSF1PO on chromosome 5). However this may not apply when two different kits are used, or when the laboratory develops their own multiplexes. In those cases, some loci may be closely spaced on the same chromosome (e.g., Penta E and FESFPS on chromosome 15). Laboratories must not use the results from closely spaced loci independently until they have documented their independence. In the case of loci that are linked, the lab could either not use the results of one locus for calculations or could use a calculation method that takes into account the linkage, if the recombination frequency is known. If the lab is using a method taking into account the linkage, that method must be validated.

The AABB Relationship Testing Annual Report Summary

To obtain a FREE copy

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http://www.aabb.org/Content/Accreditation/Parentage_Testing_Accreditation_Program/ptprog.htm

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****CONTENT FROM 2002- 2008 SESSIONS ARE STILL AVAILABLE**

AABB ANNUAL MEETING & TXPO 2009

New Orleans October 24-27

Session: **Relationship Testing SIG I: New Directions in Forensic Medicine**
Held: **Saturday, Oct. 24, 2009**
10:30 am – 12:00 pm

Director: Mary Mount, MT(ASCP)
Moderator: Michael Baird, PhD
Faculty: Steven Hofstadler, PhD; Katie Horsman-Hall, PhD; Robert Bever, PhD

Event Description:
This program will highlight recent advances in forensics including the use of laser micro dissection to separate sample mixtures, the use of mitochodrial DNA and chromosome short tandem repeats (Y STRs) in the testing of sample mixture, the application of Ninhydrin staining on clothing to detect secondary transfer and the use of ionization mass spec to analyze short tandem repeat (STR) and single nucleotide polymorphism (SNP) data simultaneously.
Event Level: Intermediate

Objectives:

- Explain current topics of interest in human identification.
- Identify the latest technologies that show promise in solving difficult forensic problems.
- Review new technologies being developed that have the potential to change the way forensic science is currently being done.
- Discuss problems that occur in forensic case work and approaches being used to overcome the problems.

Session: Relationship Testing SIG II:
Held: Saturday, Oct. 24, 2009
2:00 pm – 5:30 pm

Director/Moderator: Mary Mount, MT(ASCP)
Faculty: George C. Maha, JD, PhD, MT(ASCP); George Riley, PhD; Michael Baird, PhD
Intended Audience: Physicians, Scientists, Technologists, Nurses, Managers/Supervisors

Event Description:
This session covers administrative actions affecting Relationship Testing Laboratories. It will include a discussion of the upcoming (effective Jan 2010) 9th edition of the Standards for Relationship Testing Laboratories. It will also include a review of a paper challenge from the CAP Relationship Testing proficiency program including the proper method to use to calculate the Relationship Index. Finally, it will discuss the assessment process, give some examples of the nonconformances cited and how these nonconformances could be addressed.
Event Level: Basic

Objectives:

- Review the changes in the 9th edition of the Standards for Relationship Testing Laboratories.
- Review a paper challenge from a recent CAP PAR/PARF proficiency survey.
- Discuss the assessment process and give examples of some non-conformances and what the corrective action might be to address the nonconformance.

Session: HLA 101 - *ASHI/AABB Joint Program*
Held: Sunday, Oct. 25, 2009
8:30 am – 12:00 pm

Director/Moderator: Geoffrey Land, PhD, HCLD
Faculty: Carol Pancoska, PhD, D(ABHI); Deborah Crowe, PhD, D(ABHI)
Intended Audience: Physicians, Scientists, Technologists, Nurses, Managers/Supervisors, CEOs/CFOs, Perfusionists

Event Description:
Traditionally, human histocompatibility testing (HLA) has been relegated to the narrow fields of bone marrow and solid organ transplantation. Consequently, basic information in the field has not been available to the wider laboratory medicine community. With the current interest in platelet typing and antibodies, HLA antibodies and severe respiratory problems, and the relationship of certain HLA genotypes to resistance or susceptibility to infectious diseases, there is a need for making general information on the HLA-system and its testing available to a much wider audience. This program will focus on presenting general principles of human histocompatibility testing in two parts: 1) the basic theory of the HLA system and typing, and 2) HLA antibody testing with current testing strategies. The lectures combined with case studies emphasize the use of HLA typing and antibody testing in transplantation and in transfusion medicine. There will be plenty of opportunity for questions.
Event Level: Basic

Objectives:

- Define the basic structure and function of the human major histocompatibility complex.
- Determine HLA nomenclature and its relationship with HLA-specific genetic information and the cell surface molecules or antigens it codes for.
- Explain current testing procedures for HLA typing and antibody characterization.
- Provide guidelines on the application of HLA testing in the selection of platelet donors and in other transfusion-related clinical problems.

GREAT RESOURCES

ANNOUNCEMENT!!!

- Accreditation Program Granted Accreditation by the International Society for Quality in Healthcare

AABB is happy to announce that the Accreditation Program has been granted accreditation by the International Society for Quality in Health Care (ISQua). AABB joins the Joint Commission International and The Accreditation Council of Canada as the only ISQua accredited programs in North America. ISQua is known as the "accreditor of accrediting bodies" around the globe.

AABB staff spent a year preparing the detailed self evaluation report required for submission prior to the arrival of the survey team. In December 2008, surveyors from Canada, New Zealand and India conducted an intensive on-site inspection at AABB, evaluating every department within the organization and how each supports the AABB Accreditation and Quality Department.

The survey included a week-long peer review at the AABB National Office in Bethesda, as well as interviews with representatives of a local facility that had undergone an AABB Assessment in the previous year. The surveyors also spoke via teleconference with personnel at several AABB accredited facilities and with a cross section of assessors throughout the country.

ISQua, the International Society for Quality in Healthcare, is a non-profit independent organization with members in more than 70 countries. ISQua works to provide services to guide health professionals, providers, researchers, agencies, policy makers and consumers to achieve excellence in health care delivery to all people and to continuously improve the quality and safety of care.

- The Relationship Testing Standards Committee has completed the 9th Edition of Standards for Relationship Testing Laboratories that will become effective January 1, 2010. It will be available at the 2009 AABB Annual Meeting in New Orleans along with the Guidance Document attached as a compact disk.

- The AABB Career Link is a good way to bring together great job opportunities and great candidates. To find out more information visit the following link: http://www.aabb.org/Content/Professional_Development/CareerLink/careerlink.htm

- You can obtain a list of Accredited Relationship Testing Laboratories at the following link: http://www.aabb.org/Content/Accreditation/Parentage_Testing_Accreditation_Program/AABB_Accredited_Parentage_Testing_Laboratories/aboutptlabs.htm

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 (accrediation@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 site under About the AABB/Governance and Policies.

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John McMannis, PhD

WANTED

RTAPU or RTSPU Member

Are you currently an assessor? Would you like to be involved in planning for sessions at the AABB Annual Meeting? Would you like to review corrective action plans for process non-conformances? Would you like to be involved in the newsletter? 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 review the requests for variance from the 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.

Please contact Pam Lubel at the AABB National Office at plubel@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