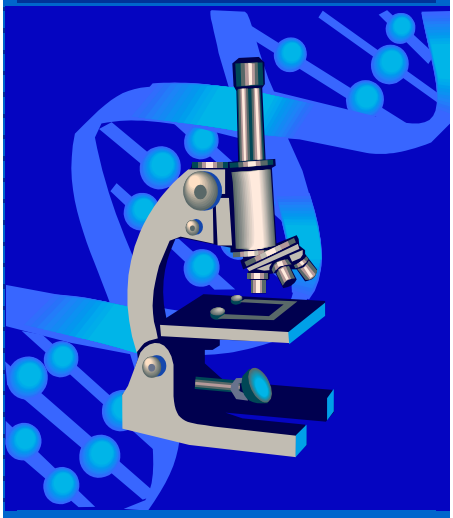
aaBB Accreditation

Relationship Testing News

February 2010 Volume 5, Number 1



In This Issue

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

New Standard 4.2.3

Careful examination of the recently published 9th Edition of Standards for Relationship Testing Laboratories will reveal several new Standards and a few discontinued ones. The focus of this article is the new Standard 4.2.3, which addresses the role of third party administrators ("brokers") in the accredited lab testing process. Many labs make use of third party administrators for specimen collection in accredited tests. This practice is permissible as long as the relevant Standards are satisfied. However, certain issues seem to be commonly encountered in assessments of labs that use broker services.

Standard 4.2.3 states: "There shall be written agreements between laboratories and third party administrators that define the following:" Five elements are then spelled out, each with its own Guidance. The APU feels that it is very important for all accredited labs to understand the scope and intent of this new Standard, as it impacts both the quality and perception of the AABB's accredited lab work product.

First and foremost***, the lab must define, in a written contract, the responsibility and accountability for collection, testing and reporting of the test results***. These are the first three elements of the five discussed in this Standard. Often, the brokers collect the specimens, the lab performs the testing and issues the report back to the third party administrator, who then forwards that original report directly to their client. Labs with a broker agreement following this model typically satisfy the Standards for these three elements.

The last two elements of the Standard are more frequently misunderstood. ***The lab using a third party administrator must ensure, through their written agreement, that no inappropriate marketing claims are being made.*** This expands upon the 8th Edition Standard 4.4, in which it was implied but not overtly stated that the lab must monitor the advertising materials and claims of a broker providing a stream of specimens to the accredited lab.

NOW AVAILABLE

9th Edition Standards for Relationship Testing Laboratories

****with attached ****

9th Edition of Guidance for Standards for Relationship Testing Laboratories

TO ORDER A COPY

JUST CLICK:
https://portal.aabb.org/apps/marketplace/category.aspx?cat=Standards%20and%20Quality&subcat=Standards

Also, the name and contact information and accession or case number of the testing lab must be present on the report. This allows for feedback to AABB in the event of problems with the testing.

The lab must ensure in its policies and agreements that its third party administrator(s) understand and agree to follow these five elements of the Standard. Some examples of common misconceptions are given below.

-A broker with a Web presence who sends specimens to an accredited lab ***cannot claim that their firm is AABB accredited***. Labs are accredited; brokers typically are not. Brokers may perform specimen collection, provided that the broker's activities do not put the lab's overall procedures in violation of the Standards.

-The broker may safely make the statement that their specimens are sent to an AABB accredited lab.

-***The broker may not use the AABB logo on their Web page***, or use any other tactic that might be misleading to the clients. Again, specimen collection agencies are not AABB accredited. If they choose not to divulge the name of the lab they use for their testing, they are not permitted to "borrow" the claim of accreditation from the fact that they forward the specimens to an accredited facility.

On a related note, a lab selling accredited tests as well as "curiosity tests" directly to the consumer must be very careful in the design of its website. The AABB logo must not appear on a web page describing the unaccredited activity of self-collected (non-chain) testing.

-If the broker reformats the report provided to them by the lab, ***the accredited lab remains responsible for ensuring that the Standards are met***. The testing lab's name, contact information and accession or case number must be revealed on the report.

The intent of the new Standard 4.2.3 is to prevent the lab from pointing the blame at the third party administrator for not following the Standards and ethical business practices. Refer to the AABB Relationship Testing Code of Conduct, in addition to the 9th Edition Guidance, for further detail. This issue is going to be more closely monitored on this cycle of assessments to determine whether additional measures are required to ensure compliance among the labs.

The AABB Relationship Testing Annual Report Summary

To obtain a FREE copy

JUST CLICK:

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

Linked Loci / FESFPS and Penta E

The Loci FESFPS and Penta E map close together, approximately 6 Mbp apart. This creates a presumption they are linked. Standard 5.5 requires that the results from loci with a significant degree of linkage not be used independently in calculations. Currently more than one laboratory is working on determining linkage and the recombination rate. For linked loci, laboratories should not use the results for both loci independently in calculations. Laboratories may choose to: use one or the other by default, use the least conservative or use the most conservative in their calculations. All of those are valid and defensible methods of calculation. Ideally laboratories will develop haplotype tables in order to use these in their calculations. Also laboratories should keep in mind that vWA is possibly linked to D12S391, one of the ENFSI recommended loci.

Problem with samples from SA

One of our accredited labs has noticed a problem with some but not all of the sample collection kits they receive from South America, particularly Peru and Ecuador. The kits are being returned to the lab using Federal Express. Some of the kits arrive at the lab with yellowed paperwork and brittle swabs. The lab has had to contact the US Embassy and request new samples from the beneficiary in most instances. Please contact Nikki Bass-Jeffrey at NIKKIB@aabb.org if you are experiencing the same issues.

Topics for the AABB Annual Meeting Relationship Testing Sessions

At the upcoming AABB Annual Meeting in Baltimore, Relationship Testing Program Unit has 2 sessions scheduled for Saturday, October 9, 2010. The morning session (10:30 AM – noon) is devoted to Forensics and the afternoon session (2:00 PM– 5:30 PM) features Relationship Testing topics. We are asking for your suggestions for topics and speakers for these sessions. Please contact Nikki Bass-Jeffrey at nikkib@aabb.org by **3/15/2010**.

ANNUAL MEETING RECAP

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

Thank you, Dr. Susan Greenspoon of the Virginia Department of Forensic Science for finding the speakers for this session.

Visualization of Touch DNA was presented by **Katie M. Horsman-Hall** from the Virginia Department of Forensic Science. The source of the touch DNA are fingerprints found on money, doorknobs, cans, clothing, etc. This study was conducted to determine if the substrates used to visualize fingerprints on clothing interfered with DNA yield and profiles. The study concluded that the substrate, Ninhydrin, was useful in determining the location of touch DNA and it did not have an effect on DNA yield but it was only useful on light colored clothing. A combination of the substrates 5-MTN and Genipin were useful to indicate the location of touch DNA on both light and dark colored clothing. More work is needed to determine if extraction methods affect DNA recovery and allele success with dual-mode stains.

Physical Separation and STR Analysis of Forensic Mixtures using Laser Microdissection and Fluorescent In Situ Hybridization was presented by **Dr. Robert Beaver** from Bode Technology. The objectives of the research are to develop and implement laser microdissection (LM) as a tool to resolve cellular evidence mixtures, to develop protocols incorporating LM techniques to optimize low copy sample processing and to identify and separate male and female cells of similar morphology based on Fluorescent In Situ Hybridization (FISH) probe signals. It is difficult to find single source genetic profiles from sexual assault and touch cellular mixtures remain to be a challenge in forensics. LM is a method of isolating and collecting

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THE AABB LIVE LEARNING CENTER

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http://www.softconference.com/aabb/

****CONTENT FROM 2002- 2009 SESSIONS ARE STILL AVAILABLE**

cells from biological samples and mixtures. It allows for performance of single source genomic interpretation on samples from multi-cellular tissues or mixtures. It has been used primarily in cancer and genetic diagnostics. Two LM techniques were discussed. LM uses a laser to cut the target cells and transfers the cells to a collection tube using laser energy or adhesion. Laser Capture Microdissection (LCM) uses a low energy laser to melt a thermoplastic film onto the target cell. The film and attached cells are lifted from the slide. Each technique provides a method of component separation to obtain single source DNA profiles from mixed samples.

Ibis Forensics Technology Overview: Using Automated High Performance Mass Spectrometry to Characterize Human DNA Forensics Markers was presented by **Steven Hofstadler**, VP of Research in the Ibis Biosciences Division of Abbott Laboratories. The objectives of the research are to use Mass Spectrometry on amplified nucleic acids and to apply the approach to CODIS STRs and mtDNA. The Ibis approach for CODIS 13 STRs may help resolve repeats containing SNPs not resolved by electrophoresis, loci appearing to be homozygous that may actually be heterozygous and heterozygotes that appear to be the same length.

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

At the AABB Annual Meeting, the 9th Edition of the Standards for Relationship Testing laboratories was unveiled. This Edition will be in effect for two years starting on January 1, 2010. The differences between the current and previous Editions were highlighted in a presentation at the Relationship Testing SIG. A crosswalk between the Editions is found at the back of the Standards book and traces the standards in each Edition. The Guidance for Standards for Relationship Testing Laboratories 9th Edition is now on a disc and is included with the purchase of the Standards book. The Relationship Testing Standards Committee will begin work on the 10th Edition of Standards later this year. If there are any current standards that you would like the group to review or new standards you would like to see implemented, please send your suggestions to nikkib@aabb.org.

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 24/7 by calling 301.215.6492.**

At the AABB Annual Meeting in October 2009 we presented a discussion of assessment subjects and nonconformances to standards cited in assessments during the preceding year. The time period discussed at the 2009 Annual Meeting Presentation was from August 2008 through August 2009. During that time, there were a total of 125 nonconformances cited and 140 non-conformances noted (either cited as a nonconformance or cited as objective evidence in a nonconformance to a parent standard). An average of 6.7 nonconformances was cited per assessment.

The largest numbers of nonconformances were to *1.0 Organization* (11), *2.0 Resources* (18), *3.0 Equipment* (18), *5.0 Process Control* (56), and *6.0 Documents and Records* (17). 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).

It should be noted that the majority of the nonconformances to Standard 4.4, which requires that a laboratory have a process to ensure that promotional materials conform to all AABB requirements, were due to issues regarding the use of claims of accreditation and the AABB Accredited logo in conjunction with tests that are not accredited (i.e., "home," "non-legal" or self collected tests).

The laboratory's process must ensure that promotional materials, including print and web sites, conform to the RT Code of Ethics Appendix 4.1.6.B paragraphs VII and VIII, in which labs pledge to adhere to the following:

RT Code of Ethics Appendix 4.1.6.B
VII. Indicate accreditation status clearly in a way that does not imply AABB accreditation for activities which are not accredited. Thus it is important that the promotional materials do not associate logo or accreditation claims with unaccredited testing. On web pages, the web page footers can be an issue.

RT Code of Ethics Appendix 4.1.6.B
VIII. Use of the AABB Accreditation logo and AABB accredited statements on reports that contain **only** results of accredited activities or a mix of accredited and unaccredited activities only when the unaccredited activities are **clearly and unambiguously** identified.

It follows that the laboratory must not put accreditation claims or the logo on unaccredited testreports, such as "home" test reports.

The report letterhead paper can be an issue if the same letterhead is used for both accredited and unaccredited tests (e.g., report letterhead).

The process must also ensure that promotional materials conform to the AABB Brand Usage Guidelines http://www.aabb.org/Documents/About_AABB/Governance/logoguideline.pdf

Specific Nonconformances
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) are indicated by "(subs)".

1.0	ORGANIZATION (subs)	1
1.1.4	Conducting scheduled management reviews	1
1.2	Laboratory Director Qualifications and Responsibilities	2
1.2.2	Laboratory Director Designee Qualifications	1
1.3	Laboratory Supervisor Qualifications and Responsibilities	1
1.4	Staffing Changes: AABB Notification within 30 days - 2	2
1.5	Emergency Preparedness	3
2.1	Human Resources (subs)	1
2.1.1	Qualification	1
2.1.2	Training	2
2.1.3	Competence	7
2.1.4	Continuing Education	7
2.1.5	Personnel Records	1
3.0	Equipment	2
3.4	Control of Critical Equipment Process with schedule	7
3.4 #1	Equipment calibration	2
3.4 #3	Validity of results when equipment out of calibration	1
3.5	Computer Systems -	1+ 1 subs
3.5.1 #1	Computer System Records shall be maintained: Validation of system software, hardware, databases, user-defined table, electronic data transfer, and/or electronic data receipt	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.	2
3.5.3	Personnel responsible for management of computer systems shall be responsible for compliance with the specified requirements that affect their use.	1
3.5.4	There shall be processes and procedures to support the management of computer systems.	1
4.0	Supplier and Customer Issues The laboratory shall have policies, processes, and procedures to evaluate suppliers	1
4.1	Supplier Qualification The laboratory shall evaluate and participate in the selection of suppliers prior to acceptance of an agreement.	1
4.4	Promotional Materials The laboratory shall have a process to ensure that promotional materials conform to all AABB requirements.	5
5.0	Process Control (subs)	1
5.1.1	General Elements (subs)	1
5.1.2.3	When a formal graded external proficiency testing program is available for one or more of the genetic systems used to report test results, the laboratory shall participate three times a year for each genetic system analyzed in the laboratory.	5
5.1.2.4	When graded external PT is not (or is no longer) available for **any** of the genetic systems used to report test results, the laboratory shall test monthly 1) known samples from when PT was available, 2) a standard undisputed trio, *or* 3) participate in sample exchange 3x/year	1
5.1.2.5	When graded external PT is not (or is no longer) available for **some** of the genetic systems used to report test results, the laboratory shall test monthly 1) known samples from when PT was available, 2) a standard undisputed trio, *or* 3) participate in sample exchange 3x/year	1

5.1.3	**Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected. Results shall be reviewed and corrective and preventive action taken, where appropriate.	2
5.1.5.1	**Reagents** Reagents shall meet defined criteria.	7
5.1.5.1.1	The reactivity and/or specificity of all critical reagents and/or controls shall be evaluated and deemed acceptable before use in recording test results.	1
5.1.6	Identification and Traceability	2
5.1.7.1	**Final Inspection** The lab shall have a process to ensure that testing services and reports are acceptable before distribution	1
5.1.9.2	The laboratory shall release an identifiable sample of an individual only for purposes relevant to the actual testing	1
5.2.2	All collections of samples shall be performed or witnessed by a competent person with no interest in the test outcome.	1
5.2.3	Verification of Sample Collection The person collecting the sample and/or verifying the process, shall confirm that the following conditions exist:	1
5.2.3	Verification of Sample Collection 3) The sample was collected from the intended person.	1
5.2.3.2	The accuracy of the affixed label shall be verified in writing by the person whose sample is collected	2
5.2.3.4	Test participants shall not package or transfer samples.	1
5.2.4.4	Printed name, signature, and contact information of the person collecting the sample and/or witnessing the sample collection shall be acquired and maintained.	1
5.2.4.6	If blood is collected, a history of transfusion in the preceding 3 months, or any history of allogeneic hematopoietic progenitor cell transplantation shall be acquired and maintained.	1

5.3	**Testing** The laboratory shall use a group of tests identified in these RT Standards that include:	1
5.3 #1	Multiple independent genetic systems as the basis for its findings.	5
5.3 #1 b)	When the null hypothesis is that the tested alleged parent is the biological parent and the alternative hypothesis is that an untested person related to the tested alleged parent is the biological parent, and there is a failure to exclude, the laboratory shall test eight or more genetic systems.	1
5.3.1	This group of tests shall, with rare expectations, provide a non-excluded alleged parent with a relationship index of at least 100.	1
5.3.1.1	With other relationship testing, the laboratory shall establish reporting policies for the indices obtained (avuncular index, sibling index, etc.).	4
5.3.5.1	Before the laboratory changes a process or procedure for an existing test method or adds a new process or procedure it shall be validated.	1
5.4.2.2 #2	**Nucleic Acid Amplification Testing for STR Analysis** The conditions for amplification, hybridization, and detection shall be defined and controlled to ensure accurate allele determination.	1
5.4.2.2 #5	**NAT Testing for STR Analysis** Exclusions that are based on closely spaced alleles shall be evaluated by co-electrophoresis or other appropriate methods.	2
5.4.2.2 #6	**NAT Testing for STR Analysis** Negative control(s) shall be processed with samples from extraction through analysis to monitor for sample contamination and NAT product contamination.	2
5.4.2.2 #7	**NAT Testing for STR Analysis** The laboratory shall have policies and procedures to evaluate contamination and preferential amplification for each sample.	7

5.5.3	If only manual calculations are performed, they shall be performed by two individuals, one of whom shall be the laboratory director or a director designee.	2
6.0	Documents and Records (subs)	2
6.1.2	Use of standardized formats for all policies, processes, and procedures. Additional procedures (such as those in an operator's manual) may be incorpo-rated by reference.	2
6.1.3	Review and approval by the laboratory director of new and revised documents before use.	1
6.1.4	Annual review of each policy, process, and procedure by the laboratory director.	1
6.2.1A	Retention of Records	1
6.4.2.1	There shall be a process in place for routine backup of all critical data.	1
6.4.2.1.1	Procedures shall be in place to ensure that data are retrievable and usable.	5
6.3.1	Unusual Findings A finding of no relationship shall not be rendered on the basis of a single indirect exclusion or on the basis of an exclusion at a single DNA locus. The laboratory shall have policies and procedures to distinguish genetic inconsistencies that may lead to a false opinion of no relationship.	1
6.3A. A) 1)	**Requirements for Testing Reports** Date of collection for each sample.	1
6.3A. B) 3) d)	Findings IF: There is a failure to exclude…THEN: The report shall include a statement that the calculations compare the tested individuals to a defined population.	1
6.3A B) 3) e)	Findings IF: There is a failure to exclude…THEN: The report shall include, as appropriate, a statement that the calculations compare the tested individual to either an unrelated or related individual.	1

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 challenges that have reached 80% consensus.	2
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.	4
8.0	Assessments: Internal And External The laboratory shall have a process to ensure external assessments are obtained and that internal assessments of operations and the quality system are scheduled and conducted annually.	2
8.1	Management of Assessment Results (subs)	1
8.1.2	Corrective and/or preventive action shall be implemented to address deviations and nonconformances discovered through internal and external assessments.	1
8.1.3	Follow-up action shall verify the implementation and effectiveness of corrective and preventative action.	1
9.1.1	The laboratory's process for corrective action shall include documentation of deviation reports, reports of non-conformances, and complaints.	1
9.1.5	The laboratory's process for corrective action shall include initiation of corrective action and review of the effectiveness after implementation.	1
10.0	Facilities and Safety The laboratory shall have policies, processes, and procedures to ensure the provision of safe and adequate environmental conditions in the work place. (Safety Manual must be reviewed)	1

GREAT RESOURCES

- The Relationship Testing Standards Committee has completed the 9th Edition of *Standards for Relationship Testing Laboratories* and they became effective January 1, 2010. This edition has the Guidance Document included as a compact disk located in the back of the publication. For non members and members seeking additional copies the Standards are currently available for purchase on the AABB web site at http://www.aabb.org/.

- 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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WANTED

Topics for the AABB Annual Meeting Relationship Testing Sessions

At the upcoming AABB Annual Meeting in Baltimore, Relationship Testing Program Unit has 2 sessions scheduled for Saturday, October 9, 2010. The morning session (10:30 AM – noon) is devoted to Forensics and the afternoon session (2:00 PM– 5:30 PM) features Relationship Testing topics. We are asking for your suggestions for topics and speakers for these sessions. Please contact Nikki Bass-Jeffrey at nikkib@aabb.org by **3/15/2010**.

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