AMERICAN SOCIETY FOR
HISTOCOMPATIBILITY AND IMMUNOGENETICS

PROFICIENCY TESTING PROGRAM

OPERATIONS MANUAL

June 2018

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HISTORY

The ASHI Proficiency Testing Committee (now Program) was originally and still remains voluntary, with the exception of Association Headquarters management participation.

1981 Establishment of the ASHI Proficiency Testing Committee and agreement with the College of American Pathologists (CAP) to partner in supplying proficiency testing materials to the Histocompatibility and Immunology testing community. This ASHI-CAP Program was run through joint efforts of the ASHI and the CAP Proficiency Testing Committees with materials and data analyses provided by the University of Pittsburgh under contract to the CAP office.

2002 Entrance into (after an RFP was published and applications reviewed) a direct agreement with University of Pittsburgh Physicians (UPP) to provide specimens, materials and related services to be used in the modules of the PT Program pursuant to design and oversight by the ASHI Proficiency Testing Committee. The agreement was signed for 3 years beginning with the 2003 program year and lasting until the end of the 2005 program year.

2003 Availability of “on-line” results reporting for each Survey.

2006 Renewal of the agreement with University of Pittsburgh Physicians (UPP) to provide specimens, materials and related services for 1 more year.

The PT program structure was revised to include two co-chairs in addition to the Program Director.

2007 Entrance into (after an RFP was published and applications reviewed) an agreement with the American Foundation for Donation and Transplantation (AFDT) to perform data collection and analysis with samples provided by ASHI PT Committee members and other Volunteers. In addition, the survey instructions and data entry instructions were completely revised; new Participant Performance Reporting formats were proposed.

2008 Entrance into (after an RFP was published and applications reviewed) an agreement with GTI to become the vendor providing PT samples with data submission and analysis still supported by the AFDT for the 2009 Survey year (Vendor contract in effect for 3 years, starting with the 2009 Survey year).

2009 Entrance into an agreement with SmithBucklin (already under contract to ASHI for other data management services) to provide a complete ASHI based system for the reporting and analysis of all ASHI PT results (target completion for use with all ASHI Surveys in 2010).

2010 Successful implementation of a totally in-house system for on-line order, results submission and availability of Performance and Summary Reports to participants; entrance into a revised Vendor contract agreement with more detailed specifications and requirements (in effect for 3 years).

2012 Transfer of data management from Smith Bucklin to a contract arrangement with a private contractor.

2014 The PT program structure was revised to include a third co-chair and all three co-chairs (junior, middle and senior co-chairs) have different defined responsibilities.

2016 Transfer of data management from private contractor to Association Headquarters programmers.

2017 The data management agreement with Association Headquarters was extended to create a new and comprehensive ASHI managed software system for all order entry, reporting, ASHI PT survey result analysis and generation of Summary and Performance Reports. This system will be available for 2018 surveys.

MISSION, PURPOSE AND GOALS

The mission of the ASHI Proficiency Testing Program is to promote quality laboratory practice in clinical Histocompatibility and Immunogenetics through the objective and consistent evaluation of competency and performance.

The purpose of the ASHI Proficiency Testing Program is to supply specimens and materials that challenge laboratory personnel, procedures and facilities to determine if they are in compliance with those published Standards of ASHI, and with those Standards of organizations for which ASHI has deemed status to assess compliance, that apply to the clinical testing activities of that laboratory. Laboratories are evaluated for the technologies utilized to report clinical results.

The goals of the ASHI Proficiency Testing Program are:

1. To provide specimens, materials and related services that can be used to document subscriber laboratories are accurately performing all aspects of their clinical testing.

2. To perform the evaluation process in an ethical, objective and timely fashion.

3. To promote the educational aspects of the proficiency testing process.

4. To provide to various committees of the Society data, obtained in the proficiency testing process, that are useful in maintaining the Society's awareness of the performance characteristics of different test methods and of standard and novel procedures and methodologies.

The ASHI Proficiency Testing Program is accepted as an alternative PT Program provider by the CAP (College of American Pathologists). Use of the ASHI Proficiency Testing Program is accepted by several other accrediting agencies that have given ASHI deemed status for accreditation of their laboratories, notably the state of Florida, the EFI (European Federation for Immunogenetics) and the APHIA (Asia-Pacific Histocompatibility and Immunogenetics Association). In addition, ASHI PT is accepted for use by laboratories that are licensed by the states of California and/or New York for use by laboratories that are approved for membership in the OPTN/UNOS (Organ Procurement and Transplantation Network/United Network for Organ Sharing) or that serve as HLA laboratories for Transplant Programs that use NMDP (National Marrow Donor Program) donors and/or are accredited by FACT (Foundation for the Accreditation of Cellular Therapy).

I. CONFLICT OF INTEREST POLICY

A. In accepting a position with the ASHI Proficiency Testing Program, each individual member makes a commitment to perform his/her duties honestly, responsibly and in good faith.

B. No Program committee member shall use his/her position with ASHI for personal gain; all members shall exercise particular care that no detriment to ASHI results from conflicts between an Individual’s interests and those of ASHI.

C. Any conflict of interest or potential conflict of interest should be reported to the Program Director and/or the ASHI Director of Operations and noted in the individual's profile.

D. Each Program committee member will sign a Conflict of Interest and Statement of Confidentiality annually.

II. CONFIDENTIALITY STATEMENT

Each PT Program committee member recognizes and acknowledges that, by reason of his/her position in the Program, he/she may acquire or have access to information pertaining to ASHI business, and said information and material are of a proprietary, confidential and secret nature and are valuable and unique assets of the organization (the "Confidential Information"). Each individual agrees that he/she will not, both during and after his/her term, whether intentionally or otherwise, use to his/her own or another's advantage any Confidential Information. Information pertaining to any individual laboratory will not be disclosed to any person outside the Program or to any other Laboratory.

III. PERSONNEL

The ASHI Proficiency Testing Program (PTP) is administered by the ASHI PT Office Manager with guidance from the ASHI Executive Director and run by a Program Director, three Co-Chairs (Senior, Middle and Junior), a Data Manager, an Assistant Data Manager, the Immediate Past Program Director and 8-14 additional Program committee members to assist with Survey reviews (total Program Members = 18-22). The PTP Executive Committee (EC) will include the Program Director, the Senior Co-chair, the Junior Co-Chair, the Data Manager and the Immediate Past Program Director. Additional participants in meetings and Program conference calls will include, as appropriate, members of the Advisory Committee, other Committee members, the ASHI PT Office Manager, the ASHI Executive Director, the ASHI Executive Committee Division Head, a liaison from the ARB, a representative(s) from the contracted Software provider and a representative(s) from the contracted sample Vendor.

The Proficiency Testing Program (PTP) works closely with the Accreditation Review Board (ARB).

At the request of ASHI Board and/or the Program Director, the Proficiency Testing Program will utilize the consultation of various individuals acting as liaison(s) to relevant Committees of the Society or to other societies.

All Proficiency Testing Program members must be members of ASHI and must be employed in clinical histocompatibility laboratories. The Program Director, Co-Chairs and the Data Manager must be employed in ASHI accredited laboratories and must be from laboratories that subscribe to at least one of the major ASHI Proficiency Testing Program Surveys (HT and/or AC).

All members of the Proficiency Testing Program will be evaluated annually for their level of participation and team member effectiveness.

If any member is unable to complete his or her term on the committee, the EC may fill this position by EC committee vote.

A. Program Director

1. Appointment and Term

    a. Recommended by previous Program Director and members of the PT Executive and Advisory Committees.
    b. Will usually be the individual who has been serving as the Senior Co-Chair
    c. Appointment contingent upon ASHI Board approval.
    d. Term will begin immediately following the Annual ASHI meeting.
    e. Term is for (usually) one (1) year or two (2) years, depending on successor availability.

2. Qualifications

    a. Has provided outstanding service as a Co-Chair or Program committee member.
    b. Able and willing to commit the time necessary to fulfill responsibilities and to represent ASHI in a positive light.
    c. Is a CHS, CHS-qualified, qualified director, or has comparable expertise.
    d. Has no known conflict of interest – to include holding comparable office in another national society.

3. Responsibilities

    a. Oversees the PT Program's operations, survey evaluations and grading processes to ensure timelines are met.
    b. Prepares PT Program reports and presents them to the ASHI Board, the ASHI membership, deeming agencies, contract organizations and others, as applicable.
    c. Ensures that all reports to the ASHI Board of Directors include, as applicable:

        1. An up-to-date PT survey count and revenue report categorized by survey and module type (ASHI office staff driven).
        2. A summary of the resolution or status of any controversial recent grading appeals.
        3. A summary of any complaints received and actions taken.
        4. A summary of actions taken after meetings, teleconferences with the committee or meetings with other organizations.
        5. The status of software operations for data entry and results evaluations.
        6. A summary of any recent policy changes, grading criteria changes and PT survey reporting changes.
        7. All items requiring ASHI board review or action.

    d. Presents the Annual PTP Report at the Annual ASHI Business Meeting, and during any special PT Program update session that may be scheduled, including:

        1. Changes to the PT program surveys (i.e. grading criteria, reporting).
        2. A report from the vendor (if applicable).
        3. A discussion of any outstanding issues.
        4. Q&A Session.

    e. Other responsibilities
        1. Organizes and chairs meetings and Executive committee conference calls; ensures follow-up on outstanding issues and projects.

2. Ensures maintenance and revisions of Program policies and procedures as described in the PTP Operations Manual. Works with the junior co-chair on Operations Manual updates.
3. Mentors, provides guidance to, and consults with Co-Chairs.
4. Provides guidance to and consults with the Data Manager.
5. Tracks software updates, changes, and requests to the software programmer for changes. Reviews the budget for software maintenance and updates.
6. Consults with the PTP Executive Committee to resolve problems.
7. Communicates information to Program committee members.
8. Makes committee member assignments after consultation with the PTP Executive Committee.
9. Appoints interim committee members when necessary.
10. Reviews and signs grading appeals in cases when requested to do so by a Co-Chair.
11. Works with the ASHI office staff to coordinate committee meetings and/or conference calls.
12. Requests ASHI Board approval for new Program Executive Committee members and position changes during the June ASHI Board meeting.
13. Reviews and edits the CAP materials, as required, to maintain the ASHI PTP status as an alternative PT Program provider after consultation with the PTP executive committee.
14. Provides PT updates for the ASHI Quarterly with co-chair and committee member involvement.
15. Participates in authorship of ASHI PT Program data publication, when appropriate, in the format of ASHI Annual meeting posters or journal article submissions.
16. Serves as liaison to other ASHI Programs, Committees and individuals (e.g., the ARB, the ASHI web-master) as applicable. Responds to questions from other ASHI Committees or other Societies, as appropriate, within 2 weeks or sooner, if indicated.
17. Ensures that Vendor contract obligations are being met and initiates new or revised RFP preparation, as warranted, with input from the PTP Executive Committee and ASHI PT Office Manager.

B. Co-Chairs

There are three co-chairs: junior, middle, and senior. At the end of a 1 or 2-year term, the Senior Co-Chair is expected to serve as the new Program Director, the Middle Co-Chair is expected to serve as the new Senior Co-Chair, and the Junior Co-Chair is expected to serve as the new Middle Co-Chair. The Senior Co-Chair will serve as “back-up” for the Program Director, if necessary. The other Co-Chairs are also eligible for appointment as Program Director if the Senior Co-Chair is not able to accept that position. In the event that a co-chair will be unable complete his or her term in the PT executive, alternate arrangements such as shared co-chair or PD roles may be deemed the best option by the EC. Decisions such as these would be evaluated by the executive committee and include factors such as timing in the PT calendar year and whether or not the person filling this role would have sufficient exposure to PT activities to successfully move into subsequent positions in the executive. The PT EC has the authority to fill these positions as required and will keep The ASHI Board informed.

1. Appointment and Term

a. Recommended by the Program Director and members of the PT Executive and Advisory Committees.
b. Appointment contingent upon ASHI Board approval.
c. Term will be for 1-2 years and will begin immediately following the Annual ASHI meeting. However, the task of overseeing the second survey will remain the task of the co-chair that was assigned to the specific survey.

2. Qualifications

a. Senior Co-Chair: Has provided outstanding service as a Junior/Middle Co-Chair or committee member, preferably for at least 2 years, usually with experience reviewing both HT and AC Surveys.
b. Middle and Junior Co-Chair: Has provided outstanding service as a committee member, preferably for a minimum of 2 years, usually with experience reviewing both HT and AC surveys.
c. Able and willing to commit the time necessary to fulfill responsibilities and to represent ASHI in a positive light.
d. Is a CHS, CHS-qualified, qualified director, or has comparable expertise.
e. Has no known conflict of interest – to include holding comparable office in another national society.
f. Has appropriate leadership skills; has the ability to make decisions and to work with laboratories to resolve problems.

3. General Responsibilities, each Co-Chair

a. Oversees assigned survey sets (Senior Co-Chair: HT; Middle Co-Chair: AC; Junior Co-Chair: EMO and B27) and is a member of the relevant review subcommittees.
b. Presents annual summary reports for assigned surveys at the annual PTP meeting during the annual ASHI meeting. This review shall include:
    1. Subscriber numbers
    2. Discrepancy rates
    3. Grading queries and responses
    4. Recommendation for action
c. Ensures that Committee members review Survey results in a timely manner and participates in the initial reviews.
d. Consults with the Program Director and PTP Executive Committee to resolve problems.
e. Reviews and updates the relevant survey instructions before survey shipment.
f. Drafts relevant survey summary reports for review by the PTP Executive Committee within the established time-line.
g. Answers grading challenges with input from the regional reviewers, the Program Director, or the PTP Executive Committee, as applicable. (If the question is complicated or might involve policy change, consultation with the Program Director and Executive Committee is mandatory.) Writes the first draft of responses to grading challenges and other inquiries.
h. Trains new Committee members to act as survey reviewers.
i. Recommends Committee members who may potentially advance to Co-Chair positions for appointment to different Survey review positions.
j. Maintains consistency in grading.
k. Serves as an active member of the PTP Executive Committee by participating in conference calls and e-mail queries as needed to accomplish PTP functions.
l. Recommends changes in policies for discussion by the PTP Executive Committee.
m. Assists the ASHI PT Office Manager in maintaining documentation at the

n. ASHI Headquarters office that includes:
    1. Order confirmation reports
    2. Survey summary reports
    3. Individual survey reports
    4. Grading challenges
    5. Copies of critical communications and complaints from/with laboratories/subscribers

n. Prepares the CAP ungraded summaries for their assigned surveys.

o. The Junior Co-chair will have the additional responsibilities of:
    1. Maintaining and updating the Operations Manual.
    2. Taking minutes for the regular EC teleconferences calls. The ASHI PT Office Manager will assist in recording, storing, and distributing minutes.

p. The Senior co-chair will take minutes at the national conference meetings. The ASHI PT Office Manager will assist in recording, storing, and distributing minutes.

C. Committee Members (Regional Reviewers) – 8 -14 individual positions

1. Appointment and Term

a. Selected by the PT Executive Committee with advice from the Advisory Committee.
b. Term will begin immediately following the annual ASHI meeting– both newly appointed and retiring members can attend but only current and retiring members may vote during any Committee meeting held during the annual meeting.
c. Serves a 2 year term with option for serving an additional 2-year term.
d. Regional reviewers' terms may be extended to the end of the calendar year if necessary so they may complete any survey reviews that are not yet completed by the annual ASHI meeting.
e. Appointments are staggered so that four to seven members are appointed (or re-appointed) at each Annual ASHI meeting.
f. Additional members may be added during the year as non-voting, ad hoc members (i.e. term not beginning immediately following the annual ASHI meeting) if volunteers request to join the committee, the timing of these additional members is logical, and there is a benefit to adding members to the PT committee. These individuals would be voted in as full voting members at the next Annual ASHI Meeting.

2. Qualifications

a. Is a CHT, CHA, CHT/CHA-qualified, qualified director, or has comparable expertise.
b. Has no known conflict of interest – to include holding comparable office in another national society.
c. Has appropriate skills and able and willing to commit the time necessary to fulfill responsibilities of position.

3. Responsibilities

a. Is assigned by the Executive Committee to review reported results for the AC (3-9 reviewers (1-3/region)), HT (3-9 reviewers (1-2/region)), B27 if necessary (1 reviewer) or EMO if necessary (1 reviewer) Surveys.
b. Looks for inconsistencies, errors or possible trouble spots that might need further evaluation.

c. Consults with the other reviewers (HT or AC Surveys) for like surveys as well as with the appropriate co-chair to ensure that all regions are evaluated consistently.
d. Sends grading results to the appropriate Co-Chair in keeping with the established time-line.
e. Assists with the review and editing of final Summary Reports.
f. Assists with the training of new Committee members.
g. Reviews survey instructions and reports. Suggests corrections and updates for approval.
h. Reads and reviews the policies and procedures of the PT Program at the time of initial appointment and after any new revisions are approved.
i. Participates in committee meetings annually, or as necessary.
j. Participates in committee conference calls as requested.

D. Data Manager

1. Appointment and Term

a. Selected by the PT Executive Committee.
b. Term will begin immediately following the annual meeting.
c. Serves a 2 year term with an option for serving an additional 2-year term.
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2. Qualifications

a. Is a CHS, CHS-qualified, qualified director, or has comparable expertise.
b. Has no known conflict of interest – to include holding comparable office in another national society.
c. Has appropriate computer software analysis skills; able and willing to commit the time necessary to fulfill responsibilities.
d. Has previously served as an effective PT Program member or as Assistant Data Manager for at least one 2 year term.

3. Responsibilities

a. Serves as the ASHI PT Program Contact person for the organization contracted to ASHI to provide software and software updates to handle PT Survey subscriptions, results in-put, results analyses, and provision of data for Program reports.
b. Prepares or assists the PT Office Manager in preparing respondent data for subcommittee reviews.
c. Suggests improvements for programming operations.
d. Reviews the effectiveness of programming operations.
e. Answers software related questions from subscribers or Program members.
f. Prepares or assists the PT Office Manager in preparing Individual Performance Reports.
g. Assists Co-Chairs in the production of Survey Summary Reports.
h. Trains a replacement Data Manager, as needed.

E. Assistant Data Manager

1. Appointment and Term

a. Selected by the PT Executive Committee.
b. Term will usually begin immediately following the annual meeting.
c. Serves a 2 year term with an option for serving an additional 2-year term.

2. Qualifications

a. Is a CHS, CHS-qualified, qualified director, or has comparable expertise.
b. Has no known conflict of interest – to include holding comparable office in another national society.
c. Has appropriate computer software analysis skills; able and willing to commit the time necessary to fulfill responsibilities.

3. Responsibilities

a. Undergoes training to perform functions of Data Manager
b. Assists Data Manager in all functions as training for that function is completed.
c. Prepares or assists the PT Office Manager in preparing respondent data for subcommittee reviews.
d. Suggests improvements for programming operations.
e. Reviews the effectiveness of programming operations.
f. Answers software related questions from subscribers or Program members.
g. Prepares or assists the Data Manager or PT Office Manager in preparing Individual Performance Reports.
h. Assists Data Manager and/or Co-Chairs in the production of Survey Summary Reports.

F. Advisory Committee – This Committee is composed of the previous two PT Program Directors and may include additional members with specific terms appointed by the Program Director on an ad hoc basis as warranted.

1. The most recent Program Director serves as a voting member of the Executive Committee.
    i. Responsibilities include assisting the Program Director in:
        1. Preparing the CAP report material. Completed the CAP annual renew paperwork.
        2. Writing articles for ASHI publications (i.e. ASHI Quarterly, etc) and Board Reports.
2. All members of this Committee will be asked to review and comment on any proposed policy changes and to serve as consultants to the PT Program as needed.
3. Previous Program Directors serve a 2-4 year term, 1-2 years as the immediate past Program Director and 1-2 years as the previous immediate past Program Director.
4. Past Committee Members may be selected to serve in advisory roles.

G. ASHI PT Office Manager (with guidance from the ASHI Executive Director)

1. Responsibilities for Subscriptions and Grading Processes:

a. Subscriptions
    i. Issues subscription materials to PT participants and potential new PT participants annually to include:
        - A Subscription form and brochure
        - The Survey schedule for each shipment

- CAP and other “release” forms, as applicable

ii. Monitors subscription orders via the database and monitors issuance of subscription confirmations to labs.
iii. Issues invoices for subscription orders, as necessary and monitors payment collection.
iv. Supplies the Vendor, a spreadsheet of all subscription orders, including: all laboratory and contact information, shipping information and survey subscription information for each order entered into the database.
v. Provides the PT committee and ASHI Board of Directors subscription order reports on a regular basis.
vi. Maintains meeting minutes, summary records/communications regarding ASHI PT Survey sample issues, communications regarding ASHI PT Survey grading questions and survey grade appeals.

b. Grading Processes
i. With assistance from the Data Manager, as necessary, processes and forwards all documentation and performance reports for grading to the PT committee for review.
ii. Issues Performance Reports and Summary Reports to participants after they are approved by the PT Executive Committee.
iii. Communicates all grading questions to the Executive Committee for review.
iv. Prepares responses relating to grading questions at the Direction of the PT Executive Committee.
v. Notifies participants about any changes to grades that are newly available on-line after review by the PT Executive committee.
vi. Retains all graded survey reports for each subscriber evaluated.

2. Evaluation/Grading Tracking

a. Sends reminders to labs about when Survey Results are due.
b. Sends reminders to Co-Chairs about when Grading Results and Reports are due.
c. As needed, translates survey results and transmits reports to the CAP within required timeframe.
d. Prepares and submits additional reports to the CAP upon request.
e. Transmits Performance Reports to the ASHI and the CAP, as authorized, when required.

3. Database Maintenance

a. Maintains databases for:
Survey Subscriptions
Shipping & contact information (for ASHI and Vendor)
Invoicing Information

b. Designs queries and reports for databases as requested by the Executive Committee and including:
Survey subscription information
Survey revenue
Outstanding balances

4. Program Management

a. Provides day to day management of the Program.
b. Arranges for and attends Committee Meetings and Conference Calls.
c. Assists the assigned co-chair in taking minutes for all meetings and Conference Calls for review and subsequent distribution, as warranted, by the Executive Committee.
d. Provides Financial Information as needed in relation to:
   Budget development and monitoring
   Survey pricing
   CAP fees
   Vendor fees
e. Fields telephone and on-line questions from subscribers, including questions relating to receipt of letters from the CAP to the appropriate member(s) of the Program Executive Committee and facilitates the preparation and sending of formal responses to such questions.
f. Ensures that information in the PT section of the ASHI website is current and correct with input from the PT Executive Committee.
g. Assists in providing Reports and Communications as needed in relation to:
   Board reports
   Survey Subscription summary reports
   Letters to subscribers
h. Assists the ASHI Executive Director in ensuring that forms are completed for the retention of the agreement with the CAP as an alternative PT provider.
i. Communicates with the CAP, as appropriate, and plans and participates in the CAP audits as may be required.
j. Facilitates communications between:
   PT Program Director and co-chairs
   PT Executive Committee and Committee members
   PT Executive Committee and the ASHI vendor

5. CAP - Assists the ASHI Executive Director in interfacing with the CAP as an alternative PT program provider.

6. Vendor Contact – Serves as the primary contact person with the PT Vendor in relation to subscriptions, participant queries, shipping dates and specifications after consultation, as applicable, with the PTP Executive Committee.

7. Record Retention

   a. Maintains PT survey subscription records.
   b. Maintains all survey subscription confirmation files and follow up communications with labs “on-site” for a minimum of 5 years.
   c. Maintains copies of all critical correspondence with laboratories and regulatory agencies indefinitely.
   d. Maintains copies of previous and current Forms and Operations Manuals.

8. Invoices and Reimbursements

   a. Invoices and processes all payments received for/from survey participants.
   b. Receives and processes all reimbursements for survey participants.
   c. Maintains accurate records of all requests for reimbursement, all invoices issued, all payment received and all expenses paid which are related to the PT program.

d. Issues appropriate notification to any survey subscriber whenever payment has not been received in a timely manner.

H. ASHI Executive Director

1. Provides guidance for all responsibilities of the ASHI PT Office Manager.

2. Interfaces with the CAP as an alternative PT program provider. (The executive director will notify the ASHI board of directors and the PT committee when the CAP requests compliance reports and/or requests an audit of the program).

3. Interfaces with the PT Program Vendor in the renegotiation and maintenance of the agreement with the vendor for the administration of the PT program.

4. Ensures that the PT Program Director provides regular reports to and responds to directives from the ASHI Executive board.

5. Ensures that the PT Program operates within budget restraints.

6. Interfaces with the Company that provides programming support for the PT Program and is responsible for the renegotiation and maintenance of agreements for the provision of services.

I. Program Vendor Responsibilities

1. Furnishes all necessary services, qualified professional and technical personnel, materials, equipment, and facilities as needed to perform the work set forth in the contracted agreement.
2. Utilizes the software provided by ASHI. This web-based program will provide subscriber information, survey information, and order information. The vendor will use this software to develop survey lots and shipments for each survey, create manifests and labels and provide QC/QA data as requested. The vendor will provide assurance that subscriber data will not be used outside of the scope of its ASHI contract.
3. Provides test sample specimens that meet the specifications described in the Current Contract.
4. Ensures that specimens have been tested for and are free of the following infectious agents, using the most sensitive and appropriate methods available: syphilis, HIV, HBV, HCV, and HTLV. Written evidence of such must be provided upon request.
5. Ensures that cell specimens are processed and shipped within 24 hours of collection to arrive within 24 hours of shipping to domestic subscribers and are shipped by the most expedient methods to international subscribers. The vendor should remain apprised of Customs regulations to minimize shipping delays.
6. Notifies ASHI of the amounts of all remaining available survey samples not shipped (within 48 hours of survey sample shipment), for potential use or replacement to subscribers or other ASHI needs.
7. Provides replacement samples in case of defect or loss at least up to 10% of the volume of any affected shipment or lot, as requested.
8. Ensures that at least the following sample QC/QA data are documented and available for inspection for each cell sample, within one week of survey shipment:

a. Date and time of blood collection

b. Donor ethnicity

c. Temperature of sample storage, including ambient temperature, if applicable

d. Length of blood storage until processed

e. Anti-coagulant used

f. Cell count

g. Cell viability

h. Preservatives added, if any

i. Diluents and volumes, if applicable

j. Date and time of shipment

k. Relevant Instrument calibration and maintenance records

l. Instrument temperature monitoring

m. Donor Consent forms

9. Collaborates with the Proficiency Testing Committee in developing new surveys or reformatting existing surveys.
10. Is willing to permit on site and/or paper inspections, by ASHI representatives, of facilities and documents at least two times a year.
11. Provides Customer support that includes but is not limited to:
    a. Assistance with Shipping issues: overnight versus two day versus ground; domestic versus international
    b. Responses to questions about samples: lymphocyte preparation techniques, cell concentration and viability
    c. Provision of Replacement samples (up to 10% of any lot volume) noting that without immediate notification by the subscriber to ASHI (within 24 hours of receipt) of sample problems, no replacement samples will be shipped.
12. Maintains or has access to appropriate, signed and witnessed consent forms for every individual from whom a new blood specimen is obtained (historically stored specimens are exempt).
13. Works with the PT Committee to add value to the surveys by provision of clinical scenarios, information about the relatedness of individuals contributing samples, and other information as may be requested.

IV. SURVEYS

Each Survey send-out will include Instructions for reporting results and information about how results will be graded. These materials will be reviewed at least annually and updated as needed by the PT Executive Committee with input from other members of the PT Committee.

Laboratories that authorized their Performance Scores to be reported to the CAP should note that the CAP expects all samples to have been tested for any analyte/method for which any results are submitted.

The following four surveys are currently offered:

A. Engraftment Monitoring (Survey EMO)

The purpose of the survey is to determine the percentage of each specimen in unknown admixtures of 2 different specimens using multiple informative genetic markers.

Each Engraftment Monitoring Survey (EMO) consists of two whole blood samples (designated as "R" and "D") and five unknown admixtures of these specimens. Two surveys are sent annually.

Grading Criteria: Valid grading requires a minimum of 10 participants. The mean and standard deviation are determined after removal of "outlier" values using a standard statistical two-pass outlier exclusion process. The percentage admixture values are evaluated based on ranges defined by the mean percentage of all remaining quantitative results ± 3 standard deviations. The lower limit of the range is truncated to the corresponding integer while the upper limit of the range is rounded up to the next integer.

There are three performance grades:

Good: A "Good" grade is generally assigned to results that fall within 2 standard deviations (SD) of the mean (rounded to integer values as described above)**.** If a survey sample consisted of only one specimen (no admixture), a "Good" grade will only be assigned to those results reported as "0%" or "100%" of D (no detectable admixture).

Acceptable: An "Acceptable" grade is generally assigned to results that fall outside of the range determined by 2 SD from the mean, but are within the range of 3 SD from the mean (rounded to integer values as described above). If a survey sample consisted of only one specimen (no admixture), only a "good" or "discrepant" grade can be assigned.

Discrepant: Results outside of 3 SD from the mean will generally be graded as "Discrepant". If a survey sample consisted of only one specimen (no admixture), any value other than 0% or 100% will be graded as "Discrepant".

B. Serological and/or Molecular HLA Typing (Survey HT)

The purpose of the survey is to assess laboratory performance in HLA typing by serological and/or DNA based methods. Results reported by laboratories clinically using both methods independently are expected to have been interpreted independently in accordance with the way in which patient samples would have been handled.

Each survey shipment consists of five whole blood specimens sent for determination of HLA class I and/or class II polymorphisms by serological and/or molecular typing methods. Two surveys are sent annually, for a total of 10 samples. Class I (HLA-A,B,C) and Class II (HLA-DR,DQ,DP) are considered to be separate analytes for grading purposes.

Grading Criteria: Grading of Class I and Class II molecular typing results requires a minimum of 5 participants per analyte/method group results, as well as 80% or higher consensus between participants for each analyte/method. If fewer than 5 results are submitted for any challenge, those results will be ungraded, however, the results will be provided to the laboratories for comparison with the consensus results as an ASHI and CMS accepted mechanism for PT participation when graded PT is not available.. Performance grades are assigned for serological, low resolution and high-resolution typing results. Each

assigned antigen or allele is analyzed separately but the composite grade considers each complete Class I or Class II typing for each sample.

The composite grade is the lowest grade assigned to an individual allele or antigen within that analyte. For example, if grades for all HLA-A and B alleles and one HLA-C allele are all “Good”, and the grade for the second HLA-C allele is “Acceptable”, the composite grade for Class I typing will be “Acceptable”. If any allele at any locus receives a “Discrepant” grade, the composite grade for that analyte will be “Discrepant”.

In addition to reporting results, there are Not Tested (NT) codes that may be resulted as follows:

NT 1: Not tested, method not used in laboratory (DEFAULT)
NT 2: Not tested due to sample quality problem
NT 3: Not tested due to reagent problem/ technical failure (e.g. unavailable from vendor, QC failure, dropped tray)
NT 4: Not reported due to ambiguity of high resolution typing
NT 5: Not reported due to limitations of serology typing
NT 6: Other, specify why in comments

These options will allow labs to better document the different reasons that a gradable result was not submitted. All “NT” codes will be ungraded.

Serological Typing Results

Good: The assignment of each single correct serological antigen will receive a “Good” grade. The assignment of a null type that is correct (per high-resolution consensus) will receive a “Good” grade, even if there is not ≥80% consensus among serology participants. In that case, laboratories that fail to report the null will not be graded for that antigen. If there is not 80% serology result consensus for the correct molecularly defined split antigen, both the split antigen (e.g. DQ5, DQ6) and corresponding broad antigen (e.g. DQ1) that corresponds to the correct molecularly defined assignments will receive a “Good” grade.

Acceptable: An “Acceptable” grade is assigned to a broad antigen (e.g. DQ1) if at least 50% of the participants correctly assign the corresponding subtype (e.g. DQ5, DQ6) and the combined consensus for both is at least 80% and is in agreement with the consensus for the high resolution molecular typing results.

Discrepant: All other assignments are graded as “Discrepant” provided participant consensus is met.

If grading criteria are not met, responses will be “Ungraded”

Note: All serological results submitted, including WHO-defined serological HLA-C types (i.e., only Cw1, w2, w3, w4, w5, w6, w7, w8, w9, w10) will be graded provided grading criteria are met. HLA-C ‘”molecular” antigens cannot be entered in the serological typing results.

Low Resolution Typing Results

Good: The assignment of a single correct two-digit allele (with no available “split” serologic equivalent) or the correct two-digit allele and correct “split” serological equivalent will receive a “Good” grade based on ≥80% consensus among participants and based on agreement with consensus high resolution results.

Acceptable: ”Acceptable” grades will no longer be assigned for low resolution typing results.

Discrepant: All other assignments are graded as “Discrepant” provided participant consensus is met.

If grading criteria are not met, responses will be Ungraded.

Note - Every effort should be made to define the antigen "split" for low-resolution molecular results. Assigning only the low-resolution type or only a parent “broad” antigen may not be sufficiently definitive in certain clinical situations. ASHI Standard D.5.2.6.1 states that, “UNOS laboratories using low resolution DNA methods must resolve types required for serology equivalents (e.g., B62 vs. B63, 70, 75, 76, 77; B60 vs. B61). This only applies when a “split” serologic equivalent is available. As an example, C*03 is associated with “split” serologic equivalents by WHO nomenclature (Cw9 and Cw10) and should be resolved to identify the correct “split” serologic equivalent and reported at low resolution as C*03(9) or C*03(10). Some HLA-C*03 types, however, are not associated with any “split” serologic equivalent (example: C*03:05). If a C*03 type is identified that is not associated with a “split” serologic equivalent, then C*03 should be reported without a “split” serologic equivalent noted.

> If 80% consensus is met for a single allele, at a given locus, and consensus indicates the presence of a low resolution allele with a “split” serologic equivalent available (example: C*03(10)), laboratories reporting the parent “broad” antigen without reporting the correct “split” serologic equivalent will be assigned NG3 for that allele. This NG3 assignment will only impact the allele in question, and will not impact the overall grade for the sample in which that allele was reported. In other words, a laboratory receiving an NG3 for one allele in a sample can still receive a “Good” grade for the sample overall.

Note – Laboratories supporting NMDP and UNOS should be aware of specific requirements for resolving common null alleles from expressed antigens. For the most current list of NMDP defined “common” null alleles refer to the “*NMDP Policy for Adult Donor and Patient HLA Confirmatory Typing”* at https://bioinformatics.bethematchclinical.org/Policies. For the most current list of the “common” null alleles that must be distinguished by OPTN/UNOS labs refer to the guidance for ASHI standard **D.5.3.2.2.7.**

> When a null allele reaches consensus for grading, laboratories that report a correct low resolution type but fail to report the presence of the null allele will not be graded for that allele.

Note- In relation to HLA-DPB1 results: No space for reporting low-resolution results is provided because there are no low-resolution DPB1 types identified by the WHO Nomenclature Committee.

High-Resolution Typing Results

Grading criteria for high-resolution typing are based on the identification of the single correct allele or allele group, Note, the alleles are currently required to be resolved are those considered to be “Common and Well Documented” as listed in the updated CWD list (Version 2.0.0) which is posted on: http://cwd.immunogenomics.org. For Class I, CWD allele ambiguities within exons 2 and 3 must be resolved; for Class II, CWD allele ambiguities within exon 2 must be resolved in order to qualify as high-resolution typing. The inability to exclude rare alleles is expected to be noted in the comments, or, where applicable, by indicating the presence of an allele group. Comments are not considered for grading.

Participants have the option of reporting the allele groups that consist of alleles that are identical within exons 2 and 3 for class I, and exon 2 for class II. The definitions of these groups can be found at http://hla.alleles.org/alleles/index.html. Participants reporting the correct P or G group (identical protein or DNA sequences as the consensus type for exons 2 and 3 for class I and exon 2 for class II) will receive “good” grades. Additionally, all laboratories are expected to be able to distinguish the “common null alleles”; if that includes both expressed and common null alleles in those circumstances, the result will not be graded. The online HT survey results form allows the reporting of these common null alleles (N) and other null and low expression (L) alleles at both the low and high-resolution typing levels and the addition of appropriate letters.

High-resolution typing results have the following performance grades:

Good: The assignment of the correct single allele will receive a "Good" grade based on ≥80% consensus among participants.

If the committee determines that consensus results appear not to be correct based on sequencing results, none of the single allele results will be graded. This determination will be based on results from at least 2 laboratories that have sequenced more than the standard exons (i.e. more than exons 2 and 3 for Class I; more than exon 2 for Class II alleles). Sequencing labs that report a non-consensus allele may be contacted by the committee during the review process to clarify which exons were sequenced. P and/or G allele group assignments may receive "Good" grades if the group includes both the consensus specificity and the specificity determined to more likely be correct.

If there is not 80% consensus for a single allele, the single allele results will be graded by a separate sub-consensus among laboratories that reported single allele results (provided that at least 5 laboratories reported single allele results), and P and/or G allele group assignments may receive "Good" grades, as appropriate.

Discrepant: All other assignments will be graded as "Discrepant" provided participant consensus is met. G or P groups not officially recognized by WHO nomenclature will be graded as 'Discrepant'.

If grading criteria are not met, responses will be "Ungraded".

Note – Careful discretion should be taken when utilizing sequencing or other methodologies which include data outside of traditional exons in assigning "NEW" alleles.

> If data which cannot be supported by IMGT sequences are utilized in assigning a "NEW" allele, the grade assigned may be "NG3" for the reported "NEW" allele. For "NEW" alleles with polymorphisms outside of exon 2 and 3 (class I), and exon 2 (class II), laboratories are encouraged to report the corresponding "P" or "G" groups and comment on the possible new allele identification in the comments section.

When sequences are not present in IMGT for a portion of a previously characterized allele, it is considered unknown if sequences discovered in previously IMGT unsequenced areas truly define a "NEW" allele or simply complete the sequence of the previously defined allele.

The ASHI Proficiency testing committee reserves the right to rely on reference laboratory results to determine appropriate grades if indicated.

C. HLA-B27 DETECTION (Survey HT)

The purpose of the survey is to assess laboratory performance of HLA-B27 typing by any technology (i.e., lymphocytotoxicity, ELISA, flow cytometric and/or molecular methods).

The same samples sent for the HT survey will be used for HLA-B27 detection. A minimum of one HLA-B27 sample will be included each year in the HT surveys for each region. Separate HLA-B27 reports will be generated for the labs that have subscribed to the HLA-B27 survey.

Grading Criteria: Valid grading requires a minimum of 10 participants.

Good: The assignment of the correct result (B27 present or absent) will receive a "Good" grade based on ≥80% consensus among all participants regardless of the test method used.

Discrepant: All other assignments will be graded as "Discrepant" provided participant consensus is met.

The ASHI PT Program reserves the right to rely on reference laboratory results to determine appropriate grades.

D. SCREENING AND CROSSMATCHING FOR HLA ANTIBODY AND SPECIFICITY IDENTIFICATION (Survey AC)

The purpose of this group of surveys is to assess laboratory performance in serum screening for the presence of HLA antibody, HLA antibody specificity identification, the presence of Angiotensin II Type I Receptor (AT1R) antibody (an ungraded analyte), crossmatching and virtual crossmatch assessments (educational only/ungraded). Participants can choose to evaluate T-cell and/or B-cell crossmatching and report crossmatch results using one or more methods: 1) complement dependent-lymphocytotoxicity; 2) AHG augmented lymphocytotoxicity, 3) solid-phase and/or 4) flow cytometry methods.

Participants can also choose to test for antibodies against Class I HLA-A, B, C and/or Class II (HLA-DR, DQ, DP). They can report antibody screening results and/or antibody specificities using methods in the following broad groups: 1) complement dependent lymphocytotoxicity (combining direct and antiglobulin enhanced methods), 2) solid phase screening methods other than ELISA (antibody detection only, not graded for solid phase, single antigen antibody specificity assignments), 3) solid phase multiple-antigen methods other than ELISA, 4) solid phase single antigen methods other than ELISA, 5) ELISA and 6) complement-fixing solid phase antigen methods. ELISA results will be graded separately as a screening method as well as for multiple-antigen and single antigen antibody identification methods.

Participants can also choose to report AT1R antibody screening results using the ELISA method. Results will be reported as a screening method only and will be ungraded/educational.

Participants can, additionally, choose to report virtual crossmatch results using their own antibody identification data generated from ASHI PT samples combined with ASHI PT assigned donor typing results from a different donor group than that of the responding laboratory. These virtual crossmatch assessments will be performed in real-time in conjunction with the current AC Survey. This approach will make it possible to compare the cell-based crossmatch data collected during the survey to the reported virtual crossmatch results in a blind fashion. These results and comparisons to physical crossmatch data will be presented as educational material to the ASHI PT subscriber community.

Depending on surveys ordered, each shipment will consist of five serum or re-calcified plasma samples plus two whole blood specimens, resulting in 10 crossmatch challenges each for T-cells and B-cells (AC Survey) and/or 5 antibody identification challenges for each shipment (AO Survey orders are for serum only/antibody assessment alone). There are two shipments per year. HLA typing information for the cells used in each survey is made available on the ASHI PT webpage. These results will be posted as soon as they are available, after the shipment of the cells. At a minimum, HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 results will be posted and are provided by PT Committee Member volunteer laboratories.

General Grading Criteria: AT1R Antibody results (ungraded), HLA-Class I and -Class II Antibody results and T-cell and B-cell Crossmatch results are all considered to be separate analytes. Results reported using different methods, as specified in the report form, are graded separately. Within each broad method group, consensus for grading is determined from the combined results for all methods reported within the broad method group. Valid grading requires a minimum of 5 participants per analyte/method group results as well as 80% consensus per analyte/method. For categories with fewer than 5 participants, results are provided so that laboratories can compare their results with the consensus results as an ASHI and CMS accepted mechanism for PT participation when graded PT is not available.

Crossmatch grading:

Good: The assignment of the correct crossmatch response (Positive or Negative) will receive a “Good” grade based on ≥80% consensus among participants. (Exception: Reporting a Positive crossmatch result when ≥80% of participants using the same method reported a Negative result will still result in a “Good”

grade if the same cell-serum combination reached Positive consensus by laboratories using a more sensitive crossmatch method; reporting a Positive crossmatch result when ≥80% of participants using the same method reported a Negative result will be "not graded" if the same cell-serum combination was reported as positive by 60-79% of laboratories using a more sensitive crossmatch method.

Discrepant: All other assignments will be graded as "Discrepant" provided participant consensus is met.

If grading criteria are not met, responses will be "Ungraded".

FOR CROSSMATCH: In addition to reporting results (POS/NEG), there are Not Tested (NT codes) that may be resulted as follows:

NT 1: Not tested, method not used in laboratory
NT 2: Not tested due to sample quality problem
NT 3: Not tested due to reagent problem/technical failure (e.g. unavailable from vendor, QC failure, dropped tray)
NT 6: Other, specify in comments

These options will allow labs to better document the different reasons that a gradable result was not submitted. All "NT" codes will be ungraded.

HLA antibody screening/detection grading:

Good: The assignment of the correct Antibody Screening/Detection response (Present or Absent) will receive a "Good" grade based on ≥80% consensus among participants (Exception: a lab reporting a Positive result when ≥80% of participants in the same method group reported a Negative result will receive a Good grade if the same serum reached ≥80% consensus for Positive by a more sensitive method. If the same serum reached a clear majority (≥60%) but less than 80% consensus for Positive by a more sensitive method, those results are not graded at all.).

Discrepant: All other assignments will be graded as "Discrepant" provided participant consensus is met. If grading criteria are not met, responses will be "Ungraded".

HLA antibody specificity grading:

Antibody specificity identification is a composite analyte in that each individual specificity is separately evaluated for gradable consensus. Only the individual specificities that reach gradable consensus for either a positive result or a negative result are considered together in the composite (overall) analyte grade for the specimen. Specificities called positive by ≥90% of participants meet gradable consensus for positive. Specificities that are reported by ≤ 1 laboratory meet gradable consensus for a negative result.

For example (for simplicity, other specificities have been left out):

	Percentage of Participants Reporting a Positive Result, per Specificity							
	A1	A2	A3	A11	A23	A24	A68	A69
Scenario 1:	0%	99%	0%	0%	15%	20%	95%	90%
Scenario 2:	0%	75%	0%	0%	1 lab	1 lab	65%	60%
Scenario 3:	0%	20%	0%	0%	1 lab	1 lab	15%	10%

In Scenario 1, specificities A2, A68 and A69 reached gradable consensus for a positive result, and specificities A1, A3 and A11 reached gradable consensus for a negative result. Specificities A23 and A24 did not meet gradable consensus for either a positive result or a negative result and are ignored in the grading. A participant's results for A1, A2, A3, A11, A68 and A69 are included in determining the participant's grade for the specimen.

In Scenario 2, although a majority of participants have reported A2 and A68 and A69 as positive, none of these specificities has reached gradable consensus. Only a single participant reported a positive result for A23 and for A24; those two specificities have reached gradable consensus for a negative result. Only the specificities that reached gradable consensus for a negative result (A1, A3, A11, A23, A24) are included in determining a participant's grade for the specimen.

In Scenario 3, a minority of participants reported positive specificities. Only the specificities that reached gradable consensus for a negative result (A1, A3, A11, A23, A24) are included in determining a participant's grade for the specimen.

On the AC Performance Report's Antibody Identification sections, the specificities that reach gradable consensus for a positive result are listed under "Consensus", along with the percentage of participants that reported a positive result. Because the number of specificities that reached consensus for a negative result is typically very large, negative specificities are not listed in these sections, however they are identified in the AC Summary Report.

Discrepant: The assignment of <80% of individual antibody specificities for which there is ≥90% consensus among participants will receive a "Discrepant" grade. For example, if a sample has 5 specificities with ≥90% consensus, and the laboratory reports only 3 of these (60%), the laboratory will receive a "Discrepant" composite grade. In addition, a "Discrepant" grade will be assigned to any laboratory that reports more than 3 different Class I HLA specificities that all other laboratories report as absent by any method or more than 2 different Class II HLA specificities that all other laboratories report as absent by any method.

Good: All other assignments will be graded as "Good". For example, if a sample has 5 specificities with ≥90% consensus, and the laboratory reports 4 or all 5 of these, the laboratory will receive a "Good" composite grade.

The ASHI Proficiency testing committee reserves the right to exclude the requirement for identification of some specificities to determine appropriate grades.

AT1R-antibody screen ELISA grading:

The assignment of the Antibody Screening/Detection response (High ≥ 17 U/mL, Low 10-16 U/mL or Negative < 10 U/mL) will not be graded (i.e. will be assigned "NG2") until sufficient data have been collected by the PT Program to determine the best method for grading this new assay. However, AT1R ELISA data will be reported in each AC-summary report for educational purposes

Users will also enter the numeric value of the AT1R ELISA antibody result in U/ml that they obtained for each serum sample, but these data will also not be graded.

Virtual crossmatch grading:

Subscribers may choose to submit virtual crossmatch assessments based on their AC Survey antibody identification testing in conjunction with a donor typing from that same AC Survey, assigned to each laboratory by ASHI PT from outside of their sample region. Participants will be able to choose from a variety of potential predictive case outcome responses and/or enter their own comments as well. Participants in the virtual crossmatch challenge will also be required to submit additional data for each serum sample/donor combination to include, but not limited to: HLA-DSA detection, information on the method of DSA detection and the robustness of DSA detected. Participants will be encouraged to add any additional information in free-text comments to clarify each serum/donor challenge.

This virtual crossmatch challenge will not be graded (i.e. will be assigned “NG2”) until sufficient data have been collected by the PT Program to determine the best method for grading this new challenge. Virtual crossmatch data will be reported in an ASHI publication following each AC Summary report. This information is for educational purposes only.

V. ADDITIONAL SURVEY POLICIES

1. Receipt of inadequate or unsuitable samples:

   Upon receipt of any sample, it is the responsibility of the receiving laboratory to inspect the shipment for any damage. If a sample is received broken or in otherwise unsuitable condition, it is the responsibility of the receiving laboratory to notify the ASHI Central Office by phone, fax, or email within 24 hours of sample receipt. Documentation of the time of receipt of samples in the laboratory may be required.

   If notified within 24 hours of receipt of the shipment in the laboratory, the PT program will replace the original sample if there is sufficient volume to do so. If the sample cannot be replaced, it is the responsibility of the laboratory to document its effort to obtain a replacement sample so that can be considered by any accrediting agency in the evaluation of the laboratory's performance.

   Neither the ASHI PT program, nor the vendor providing and shipping samples, can be responsible for samples delayed in delivery to international laboratories due to customs or other governing body regulations and inspections. Survey result submissions deadlines may not be extended for these circumstances, and replacement samples may not be available if samples are delayed in transit. International laboratories are encouraged to research customs and governmental protocols for sample inspection and release prior to selecting and finalizing ASHI PT Survey orders

2. Attestation Statement:

   Each laboratory Director or designee and each participating technologist must sign an attestation statement certifying that all proficiency testing is performed in the same manner as clinical samples. Laboratories are not required to submit these Statements to the ASHI PT Office but should retain copies together with their PT results for Inspector review.

3. Data Submission:

   Each laboratory is responsible for timely and proper submission of data to the ASHI Proficiency Testing Program.

4. Grade Reporting:

   The Proficiency Testing Program will provide laboratories with individual Performance Reports within 6 weeks of the date that Survey results are due.

   a. Participating Laboratories will have 30 days to submit a grading appeal.
   b. Laboratory data entry errors may not be appealed.
   c. Any appeal or challenge of the grading of a survey must be made in writing to the ASHI Proficiency Testing Office Manager who will forward it to the appropriate Co-Chair for consideration.
   d. Appeals must be submitted within 30 days of the Individual Performance Report being sent. Late appeals will not be given consideration.
   e. Each case will be considered individually by the Co-Chair with final review of the Co-Chair's recommendation by the PT Executive Committee.
   f. The Co-Chair will communicate the final decision to the laboratory, explaining the reasons for upholding or altering the grade, with the assistance of the PT Office Manager.

g. Laboratories will be informed that any decision of the ASHI Proficiency Testing committee is final but that they are welcome to request further discussion of any remaining issues at future meetings of the ASHI PT Committee.

Final Summary Reports for each Survey that include the consensus results, the number and % of labs reporting each result and summaries of unusual grading situations will be sent to participating laboratories at the same time that Performance Reports are sent.

5. Results that are Not Graded: The following Codes will be used in Performance and summary Reports to indicate why particular results were not graded:

Not Graded (1) = not graded because of insufficient consensus
Not Graded (2) = not graded because the challenge is educational only
Not Graded (3) = not graded by decision of the ASHI PT Committee
Not Graded (4) = not graded because less than ten participants submitted results

It is best practice and the requirement of many accreditation agencies that laboratories review all instances of non-graded results. They should evaluate and document an explanation for the cause of results that are not in concordance with ≥60% of participants.

6. Errors in Summary or Performance Reports:
If an error that affects grading is identified after a Summary Report is posted, affected laboratories will be notified by email as soon as possible after the Committee is made aware of the error. If possible, a corrected Summary Report will be generated and posted, with the update date at the top.
If an error that affects the grading of only one or a few laboratories is identified, affected laboratories will be notified by email. The Performance reports of those laboratories will be corrected if possible and reposted.
If corrections to Summary or Performance reports cannot be made, affected laboratories will be sent an email describing what their correct grade should be, and they can use that email when submitting results to an accrediting agency. Results that are submitted to the CAP can almost always be easily corrected and resubmitted to the CAP on the laboratory's behalf. .

7. Confidentiality of Performance Reports:

a. Grades for individual laboratories will be kept confidential by members of the PT Program Committee.

b. Grades will be reported to federal regulatory or state agencies only at the written request of the laboratory. Those laboratories that want their results directed to any accrediting or other oversight agencies must provide all pertinent information to the ASHI PT Committee on an annual basis. The ASHI Proficiency Testing is currently accepted by the College of American Pathologists (CAP) for the purposes of the CAP Laboratory Accreditation Program. Laboratories wishing to have ASHI PT results sent to the CAP must provide ASHI with written consent and the laboratory's Laboratory Accreditation Program (LAP) number.

8. It is the responsibility of the laboratory to notify the ASHI PT Office Manager about any changes in laboratory address or contact information.

a. It is the responsibility of any ASHI accredited laboratory to provide the ASHI ARB with copies of Proficiency Testing Individual Performance reports, as may be required.

b. Requests for Data: Any request for data from the PT data base will be reviewed by the PT Executive Committee with consideration of the confidentiality of the data requested, the cost for producing that data and the relation of the request to the PT Program and ASHI missions.