THE RECOGNIZED LEADER IN CLINICAL HISTOCOMpatibility TESTING

2023 ASHI Proficiency Testing Program

www.ashi-hla.org
ASHI is pleased to announce the 21st year of its comprehensive proficiency testing program.

Our program utilizes clinically-based samples to assess a laboratory’s ability to accurately perform its analyses. All surveys are graded using established criteria with oversight by ASHI’s Proficiency Testing Committee.

The Proficiency Testing (PT) program is designed to fully meet the latest ASHI standards for laboratory accreditation.

ASHI is accepted by the College of American Pathologists (CAP) as an alternative proficiency testing program provider.

There is international participation by laboratories in 30 countries.

The ASHI PT program:

- Offers a user-friendly data submission website featuring easy results entry.

- Current survey categories include: HLA Typing (HT), Engraftment Monitoring (EMO), and Antibody Screening/Identification and Crossmatching (AC). The HLA-B27 Detection survey is now offered within the HT survey using the HT samples. (See HT section for further details.)

- Cells provided for crossmatch are typed for HLA-A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, and DPB1 at high resolution level.

- The Virtual Crossmatch (VXM) challenge is offered to subscribers of the AC survey for educational purposes only. The optional challenge gives subscribers from each AC survey region the opportunity to utilize their own AC survey antibody results in conjunction with donor cell typing from another region (assigned by the PT Committee) to perform virtual crossmatch assessments that can be compared to actual crossmatch results from AC survey responses.

Instructions for participating in the VXM challenge are sent to AC participants following the shipment of each AC survey. Data analysis of each challenge will be released following the completion of the Summary Reports for each AC survey.

- Summary Reports and concurrent individual Performance Reports present data in a concise and informative fashion, with emphasis on the educational goals of the ASHI Proficiency Testing Program.

- The HT survey is for serology, low resolution and/or high resolution typing. Historically, samples have included new alleles, and sequencing of non-traditional exons have been performed by experts in the field to confirm the correct results.

- To reflect routine clinical testing, results for Class I and Class II typing or for antibody identification and crossmatching are reported using the same samples during the HT and AC surveys, respectively.

- If your laboratory is accredited by CAP, ASHI is able to report your ASHI PT Survey Performance scores directly to CAP for the HT, HLA-B27 Detection, EMO, and AC surveys.

For further information, please contact Cheryl Hartman at ASHI headquarters at chartman@ashi-hla.org.

www.ashi-hla.org
1. HLA TYPING FOR HLA-A, B, C, DRB1, DRB3/4/5, DQB1, DQA1, DPB1 and DPA1

Two shipments annually, for a total of 10 whole blood specimens, are designed to assess laboratory performance in HLA typing by serological and/or molecular methods. A single basic blood volume will be provided.

- If additional specimen volume is desired, one or more supplemental volume modules (HTS) may be ordered. An HTS module may not be ordered without also ordering the basic HT module.
- Laboratories who wish to purchase a second HT module from a different group (HTG) can do so by purchasing 1 HT module and 1 HTG module. Ordering the HTG module along with the HT module will allow your laboratory to receive the HT module from one group and the HTG from a different group.
- Laboratories ordering the HTG module can order an HTGS (supplemental module from the second group) if additional volume is needed from the second group.
- The HT-B27 Detection survey will be offered within the HT survey using the HLA typing (HT) samples (no additional samples are required). Laboratories that wish to receive a B27 Summary Report and Performance Report should subscribe to the HT-B27 module to submit results and receive the reports.

<table>
<thead>
<tr>
<th>MODULE CODE</th>
<th>DESCRIPTION OF EACH SHIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HT</td>
<td>Five - 2.5 ml whole blood samples in CPDA-1</td>
</tr>
<tr>
<td>HT-B27</td>
<td>(No additional samples provided; HT samples are also used for B27.)</td>
</tr>
<tr>
<td>HTS</td>
<td>Five - 2.5 ml whole blood samples in CPDA-1</td>
</tr>
<tr>
<td>HTG</td>
<td>Five - 2.5 ml whole blood samples in CPDA-1 (samples will be from a group different than the HT module)</td>
</tr>
<tr>
<td>HTGS</td>
<td>Five - 2.5 ml whole blood samples in CPDA-1 (from same group as HTG; must be ordered with HTG)</td>
</tr>
</tbody>
</table>

2. ENGRAFTMENT MONITORING

Two shipments annually are designed for laboratories determining engraftment following bone marrow/stem cell transplantation and/or monitoring chimerism after organ transplantation. Each kit contains whole blood specimens from two different individuals and five unknown admixtures of those cells.

<table>
<thead>
<tr>
<th>MODULE CODE</th>
<th>DESCRIPTION OF EACH SHIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMO</td>
<td>Two - 3 ml whole blood samples in CPDA-1</td>
</tr>
<tr>
<td></td>
<td>Five - 1 ml admixtures of these samples in CPDA-1</td>
</tr>
</tbody>
</table>
3. SERUM ANTIBODY SCREENING/IDENTIFICATION AND CROSSMATCHING

Two shipments annually are designed to assess laboratory performance in HLA Class I and Class II serum screening/antibody detection and crossmatching (T-cells and B-cells) if desired.

- The AC module consists of 10 serum or recalcified plasma samples plus four whole blood specimens per year. This combination of specimens will result in 20 crossmatch challenges per year. Participants can choose to analyze survey specimens by any method used in their laboratories.

- The AO module provides a discount to laboratories that do not need to perform crossmatching and consists of 10 serum or recalcified plasma samples only per year, with no whole blood samples.

- Subscribers needing additional serum volumes can order ACS modules in addition to ordering the AC or AO modules.

- Subscribers needing additional whole blood volumes can order ACC modules in addition to ordering the AC module.

- The AC and AO surveys include antibody identification by solid phase testing of complement fixing antibodies (C1q).

- The AC and AO surveys also include the option to report antibodies against Angiotensin II Type 1 Receptor (AT1R) as an ungraded, educational challenge.

- Due to the low number of participants, the HLA Class II Antibody Identification by Serology (CDC or AHG) is no longer a CAP-accepted analyte.

### HLA ANTIBODY SCREENING/CROSSMATCHING

<table>
<thead>
<tr>
<th>MODULE CODE</th>
<th>DESCRIPTION OF EACH SHIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC</td>
<td>Five - 1.0 ml serum samples</td>
</tr>
<tr>
<td></td>
<td>Two - 8.0 ml whole blood samples in CPDA-1</td>
</tr>
<tr>
<td>AO</td>
<td>Five - 1.0 ml serum samples only</td>
</tr>
<tr>
<td></td>
<td>(whole blood samples NOT included)</td>
</tr>
<tr>
<td>ACS</td>
<td>Five - 0.5 ml serum samples</td>
</tr>
<tr>
<td>ACC</td>
<td>Two - 4.0 ml whole blood samples in CPDA-1</td>
</tr>
</tbody>
</table>

www.ashi-hla.org
SHIPPING INFORMATION

• International shipping charges reflect major differences in ASHI costs for shipping to each country.

• For shipping label purposes, there is a 35-character limit for each address line of a shipping address.

• P.O. boxes are not acceptable as shipping addresses.

• Participants must include the complete laboratory address, including building number and street name, in the shipping address. An additional fee may be charged if the information is not complete.

• All survey kits will be shipped to addresses in the USA via Priority Overnight Service.

• All survey kits will be shipped to addresses outside the USA via International Priority Service.

• 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 email within 24 hours of sample receipt. Documentation of the time of receipt of samples in the laboratory may be required.

• For further details about replacement samples, please refer to the PT Operations Manual available on the PT page of the ASHI website: https://www.ashi-hla.org/page/PT.

ADDITIONAL INFORMATION FOR INTERNATIONAL PARTICIPANTS

• Prior to the shipment date, international participants must obtain and complete the necessary documents required by their country for the importation of non-hazardous human blood specimens for proficiency testing/medical research use.

• Copies of all such documents must be forwarded to the ASHI PT Program Manager at the time the PT order is placed.

• No replacements will be made for international shipments that are refused entry into a country.

• Due to the unstable nature of target cells, replacement specimens may not be available for some surveys.

• International participants wanting to participate in the AC survey should be aware of the risks associated with shipping AC cells internationally. The risks include low viability and/or suboptimal quality of cells which may interfere with successful testing of the AC survey. Therefore, international labs are encouraged to order the AO module (antibody identification only) rather than the AC module to avoid these potential issues.

• Duties and/or import taxes imposed by the importing country are the receiving laboratory’s responsibility.

• Requests for customized documents must be submitted with appropriate documentation to support the request. Document customization may be subject to an additional processing fee.