2024 ASHI HT Survey Volume Reduction & 1 HT Group Summary

In 2024, the ASHI PT Program is reducing the volume of blood provided to HT survey participants from 2.5ml to 1.5ml per sample and will be capping the number of supplemental modules ordered to 1 HTS (supplemental module) per lab. In addition, all HT subscribers will receive samples from the same group beginning in 2024.

Rationale:

1) Beginning in 2024, serology will no longer be a part of the ASHI PT Program testing requirements. This feature is being removed after several years of serology being ungraded due to too few participants in the serology category. HLA Typing methods have evolved and laboratories do not require large amounts of DNA as they did in the past. Current molecular HLA typing methods can obtain HLA typing with lower volumes of blood and PT reporting is only required for the highest resolution used in the laboratory (other methods must be correlated twice a year).

2) The ASHI PT program offers supplementary HT modules for laboratories that wish to order additional blood, however, feedback received from a select number of labs in the U.S. and Canada confirmed that, in many cases, supplementary HT modules are being ordered for purposes other than to meet PT requirements. In some cases, HLA laboratories order supplementary modules to be consistent with practices established many years ago rather than because the extra volume is needed or they order additional volume for validation purposes. Laboratories that order 1 HT module (1.5ml) will have enough volume to meet PT requirements and have extra volume that can be used for validation purposes. (Data to support this can be found under “Results” section further below.) Laboratories that do not find this amount to be sufficient, have the option to order 1 supplemental volume.

3) There is an ongoing issue of blood supply from blood suppliers across the country. Currently, the participants of the HT Survey are divided into two groups to accommodate the current volume of blood supplied to participating laboratories. Each group receives 5 samples per survey (10 samples per survey for both groups). It is becoming more difficult each year to obtain enough donor blood to maintain the two HT Survey groups. Reducing the volume will allow the PT committee to combine all participants into one group (5 samples per survey) which will reduce the risk of testing delays (by the vendor) which directly impacts the timeliness of specimen shipments.

4) The transition from two groups to one group does not need to raise major concerns for laboratories that have ordered modules from both groups in the past. Laboratories can meet CMS requirements and ASHI requirements while ordering a single HT module from a single HT group. Laboratories subject to CMS regulations should perform proficiency testing as recommended by CMS. The same analyte within a given PT survey should not be tested on more than one instrument or by more than one method unless your laboratory tests patient specimens in such manner and written procedures are in place to reflect these testing strategies. However, for HLA typing, laboratories should use their highest resolution method for a PT survey then once the PT survey closes, use the same specimens to correlate other methods. By following this process, laboratories that may have, at one time, ordered HT modules from two different groups can satisfy testing requirements while adhering to CMS guidelines (see excerpts below).
5) Lastly, to address concerns of directors that oversee (and review PT results) for more than one laboratory, the ARB was consulted during the discussion of this topic. The ARB confirmed it would not be an issue for a director to review PT results for more than one laboratory even if they are in the same group for a PT survey. The ARB Operations Manual states that directors should have a policy in place for keeping information for both laboratories separate and “to preclude communication” among the two labs. In addition, inspectors and/or commissioners should be notified. Another alternative for directors in this situation is to delegate the task of reviewing PT results for one of the two laboratories to a co-director or assistant director, if necessary.

**Additional details:**

To assess the feasibility of this volume reduction, the PT EC conducted a survey that collected feedback and/or data on HT Survey blood volume usage and DNA amount requirements from 14 laboratories. Specifically, data on DNA extraction methods, blood volumes used for extraction and DNA yield from ASHI PT specimens were collected from 12 laboratories and two additional laboratories provided valuable feedback on HT volumes used by their laboratories.

**Results:** The desired amount of DNA for all purposes (PT/QC/validation) reported by the 12 laboratories that submitted data was 10 µg. The survey shows that laboratories typically perform 1-2 DNA extractions using 250-500 µl of whole blood. The data demonstrate that the average DNA yield per sample ranges between 3,000-30,000ng, depending on laboratory practice (e.g., extraction from whole blood vs a buffy coat). Even for laboratories with lower DNA yield, the desired amount of 10 µg may be easily achieved with 2-3 DNA extractions using 250-350 µl of whole blood. Therefore, 750-1050 µl of whole blood should suffice for participants that perform NGS and rSSO HLA typing. This finding was confirmed by two laboratories that submitted feedback only, stating that 1 ml of blood would be more than sufficient for ASHI PT requirements for the HT survey. Laboratories that use other methods or combinations of methods may choose to order a supplemental HT module.

**Conclusion:**

The data collected in this survey serve as evidence that laboratories can perform the necessary testing (including the new ABO challenge) with the new blood volume suggested, and that this reduction is in the best interest of the ASHI PT Program.