

## **2009 General Information and Policies**

### **Shipping Dates**

The Enrollment Confirmation Form lists the products and services ordered and a customer specific shipping schedule. **Shipping dates cannot be changed.** If your facility is not performing patient testing when a proficiency shipment is due to arrive, it is your responsibility to notify us prior to the due date to request excused status. Failure to do so will result in a score of “0%”. Excuse Requested status will not be granted for delayed or non-delivery of samples caused by routing/receiving problems within your institution.

Our samples are sent via courier (DHL, UPS, or FedEx) for second day delivery. Customers who have provided a valid e-mail address for the shipping contact will receive e-mail reminders that samples are en route. If you do not receive samples within 3 days of the ship dates listed on the schedule, please contact us for package tracking/delivery information.

### **Changing Your Order**

Modifications should be directed to PT Customer Service at 800-462-5261, ext 0 or submitted by fax, mail or e-mail. Please be prepared to provide the following information:

- Your WSLH PT identification number (SL number).
- Facility name, address and telephone number.
- Products added or dropped.
- Identification of authorized person requesting the change.
- Purchase order number if required by your institution for the order process.

A “Change Order Form” is included in the enrollment confirmation packet and is also available on the catalog and order form page of our website.

Please note: The price listed on the order form and in the catalog is the annual cost for a calendar year. This price is prorated by the number of shipments/year. Products added during the year will be charged only for the number of shipments received from enrollment date through the end of the calendar year.

### **Cancellation/Refunds**

- **Full** refunds will be made for cancellations requested at least 30 calendar days **before** the **first** shipment date.
- **Partial refunds** will be made for cancellations requested at least 30 calendar days **before** each **subsequent shipment**.
- The annual enrollment fee is **non-refundable**.
- Credits will be applied to your account within 1 week. Refund checks, if requested, will be issued within 6 to 8 weeks.

### **Seasonal Participation**

As mandated in CLIA ‘88, laboratories must “participate in an approved proficiency testing program for one year before designating a different program.” We interpret this to mean that laboratories must maintain active enrollment throughout an entire year and not assume an inactive or discontinued status during periods of temporary closing (e.g. student health labs). Since active annual enrollment status must be maintained, we will not rebate fees due to temporary closings. To avoid unwanted deliveries during a temporary closure period, please specify closed dates on your re-enrollment form or notify us at least **2 weeks** prior to the seasonal closure(s).

“Excuse Requested” will be printed on any reports for shipments scheduled during the times of temporary closing. A 100% score with appropriate reason code will be transmitted to the accrediting agency. It is your responsibility to document the closing/opening dates to the satisfaction of your accreditation agency.

### Payment/Billing

PT is a pre-paid service. Invoices are issued on a monthly basis. Payment can be made by check or credit card. If paying by credit card, please submit order, wait for the invoice to be received and then call the phone number printed on the invoice with credit card information.

Our prices include standard shipping costs for the “lower 48” US shipping sites. A separate yearly shipping fee (based on the number of shipments expected to be sent) will be added for labs located outside the continental US.

Our services require verification of accreditation information assigned to customer numbers (SL#s) before an order/change can be processed. Do NOT send payment or purchase orders without ensuring that an order/re-enrollment/change form has been submitted to us! Purchase Order numbers will be referenced on invoices if supplied to us at the time of the order.

Payments should be sent to the following address:

WI State Lab of Hygiene  
Accounts Receivable  
PO Box 78770  
Milwaukee WI 53278-0770

Our customer (SL) numbers are assigned based on the CLIA ID under which testing is performed. Because of this it is quite common for large institutions to have multiple SL numbers. When using a single check to pay for multiple customer numbers, it is important that all SL and invoice number(s) be referenced on the check stub to ensure payment is applied to the correct account(s).

We do not charge interest; however, if payment is not received within 60 days of the receipt of your first invoice, you will be notified that we consider the enrollment incomplete and a hold will be placed on your account. No further shipments or reports will be issued until payment has been received. **Since this will put your laboratory in regulatory jeopardy, it is important that payment be prompt.**

Billing questions/credit card information should be directed to Fiscal Services, 800-862-1065.

### Receiving & Testing Samples

PT packages contain samples (e.g., culture devices, bottles, vials, ampules, glass slides, etc.), testing instructions and result forms to fill out for returning results to us. **Most PT “failures” can be avoided if participants follow a few basic steps:**

- Open the packages immediately upon receipt. Compare contents to items listed on the packing slip.
- Check for leaking, broken, damaged or missing samples. Replacement requests must be made by the date indicated in the instructions.
- Read all instructions thoroughly before testing.
- Observe the sample storage conditions listed in the instructions.
- Follow sample preparation directions carefully. Don’t assume that all samples within a set are handled in the same manner.
- Test the samples as soon as possible and/or within any time frame specified in the instructions.
- Report results in the units requested even if different from how patient results are normally reported. This is an exception to the “treat PT samples like you would patient samples” rule and is allowable by CLIA in order to provide PT programs a means for reasonable evaluation of data.

- Review and update (if needed) method information to ensure you are scored with the correct peer group.
- Report results by the due date listed on the result form(s). In some cases programs that ship together may have differing due dates because of the types of testing procedures covered (e.g. Special Microbiology).
- Call the program coordinator *prior to the due date* if you have any questions or problems.

### **Handling Samples**

PT samples should be considered potentially infectious. Follow the current local, state, and federal regulations for handling biohazardous materials when processing or disposing of these samples. Most samples, with the exception of those sent for Anti-HIV and Hepatitis B testing, are tested and found to be non-reactive for hepatitis B surface antigen, HCV and HIV-1 antibodies. However, no known test method can offer complete assurance that products derived from human blood will not transmit infection. Please contact us for MSDS information in the event of an exposure.

### **Replacing Samples**

Replacement sample requests must be made by the date specified in the instructions. Supplies are limited. It is your responsibility to examine each package as soon as it arrives and report any missing/damaged samples.

Replacement requests for reasons within the participant's control (e.g. lab accident, improper storage, internal routing problems) must also be made by the specified date. A fee to cover the cost of the additional samples, plus shipping and handling, will be charged for samples that have been mishandled after they have been delivered to your facility.

Failure to call for replacement samples is not considered a valid excuse for unreported results.

### **Extended Storage and Disposal of PT Samples**

Microbiology and most whole blood based samples (e.g. hematology, whole blood glucose) do not lend themselves to storage after analysis. These samples should be disposed of in a timely manner

Some serum or plasma based samples may be stable at freezer temperature (-20°C) for extended periods. Samples which have extended stability will be identified in the instructions. Please follow instructions for long term storage (including mixing prior to re-analysis). Identify separate storage space for already analyzed PT samples to decrease the possibility of a mix-up with current PT samples.

All proficiency testing samples should be disposed of in the same manner as other biohazard waste.

### **Requesting Excused Status**

If patient testing is being temporarily suspended during the time when proficiency testing samples are scheduled to be shipped (e.g. extended equipment malfunction or reagent back order of more than 2 weeks), contact us before the due date to discuss the situation. If these circumstances compromise the ability to report timely PT results, "Excuse Requested" will be noted on the evaluation report.

It is your responsibility to file written documentation of the reasons for "Excuse Requested" status with this evaluation report. The excuse will be valid only if your documentation is accepted by your accrediting agency's surveyor.

Short term due date extensions are not allowed. Customers must either report results by the published due date or request an excuse for that shipment.

## **Reporting Test Results**

Instructions and forms for reporting results accompany proficiency testing samples. The due date is specified in the instructions and on the result forms. Due dates are strictly enforced.

Customers have three options for reporting results to us:

**#1: Online result entry via a secure web portal account.** Customers who have activated their WSLH PT portal accounts may log onto the portal via the teal Customer Login button on the bottom of our home page and select the Results Entry module. If you would like to obtain a web portal account for staff members who will be entering PT results, please contact our customer service staff or download and submit a Portal Account Request form from our website.

Please note: Online result entry test order may be different from the test order on the paperwork received with PT samples. We strongly recommend printing and using the online worksheets instead of those included with the samples.

**IMPORTANT:** Results entered online must go through an electronic submission process which includes printing the final worksheet and attestation page verifying the date, time and confirmation number of submitted results.

Online results can be edited and re-submitted at any time prior to the due date. However:

**Faxed data/corrections will not “overwrite” data which has been submitted online!**

**#2. Faxing results.** If you prefer submitting your results by fax, please use the result forms included with the samples. Fax completed forms to: 608-265-1111. Forms must be received by midnight CST of the due date. Our fax server is available 24 hours/day, every day of the week. If you experience problems, please contact us immediately.

Optical Character Recognition (OCR) software is used to “read” result forms that are faxed. This software records the date and time received as well as the phone number from which the fax was sent. To help with tracking, please be sure your fax machine is correctly programmed to print your institution’s name and current fax number. It is also helpful to have information on the fax machine which indicates the correct “up” side of the paper during the fax process so that blank pages are not submitted to us.

Retain your dated fax log, fax confirmation report or phone bill as verification of transmission.

**#3: Mailing results.** Make a copy of the result forms to keep on file (CLIA requirement) and mail the originals to us. Results must be postmarked on or before the due date. If you mail results, we strongly encourage you to use registered or priority mail so that you have the documentation of delivery.

Results received after the due date may be evaluated, but will receive a score of zero (0%).

Please return only result forms and those comment pages and/or methodology forms which contain information needed to evaluate your results.

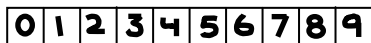
If no method information is on file or provided on the result and/or methodology update form, your results will be scored against an “All Methods” group.

If circumstances prevent participation in one or more proficiency testing shipments, you must notify us before the due date.

### General Tips for Completing Result Forms

- Use a black or blue pen. Do NOT use pencil.
- Review method code information for correctness. Follow information in instructions to report changes in methods or tests added/dropped.
- Print numbers and letters using block style. Do not cross zeros or sevens. Do not put “X” in blank boxes.
- Report only one number in each box. Do not use leading zeros.
- Honor the decimal point provided.
- Report in the specified units even if these are different from what is reported for patients.
- Use “Comment” section to report error codes or unusual analytical situations

Print numbers using block style avoiding contact with edges of boxes:



Shade circles like this:  
Not like this:



### Dropping/Discontinuing/Moving to Waived Test Procedures

It is your responsibility to notify both us AND your accreditation agency of any changes in your test menu. Please follow the instructions provided with the result forms and samples or the information on the portal to indicate permanent removal of an **analyte/procedure** from your test menu. For temporary test suspensions (e.g. reagent back-order), please request “excused” status. If you are dropping one or more **products/programs**, contact us as soon as possible to receive any applicable credits or refunds.

Unless we are informed that testing has been discontinued, results that have previously been reported for an analyte or program will list a score of zero (0%) on reports. This score may also be sent to your accreditation agency.

If a method in use (usually in microbiology) changes to waived status during the enrollment year, be advised that CMS expects the laboratory to adjust their PT enrollment to maintain the “five samples per testing event” for any remaining non-waived tests in the subspecialty.

Example: Your lab is enrolled in a microbiology program which contains a combination of samples for antigen and culture testing each event. If the antigen method becomes waived, your lab must change its enrollment to a program which provides 5 cultures for the remaining shipments of the year. You may also need to enroll in a separate PT program for the waived antigen. Please check with your accreditation agency prior to adjusting your enrollment in these situations.

A list of current waived methods can be obtained from the FDA or Joint Commission websites:  
<http://www.fda.gov/cdrh/clia> or [www.jointcommission.org](http://www.jointcommission.org)

### Assessing PT Performance

Your proficiency testing results are analyzed with results submitted by all customers participating in that program and are scored according to CLIA '88 regulations. We make every attempt to provide a specific peer group when applicable and allowed by CLIA regulations. A current event performance report, a cumulative report summarizing performance over the past 3 events and in some cases a statistical report covering all scored methods and analytes are mailed approximately 15-40 days after the due date. Please review these reports as soon as possible after receipt.

Reports are posted to the Reports Catalog on our web portal the day they are released for printing. At the same time they will be sent via e-mail if the customer has indicated they wish to receive this service and their e-mail server does not block pdf attachments. Instructions can be provided to customers who wish to set up their e-mail Inbox to auto-forward our reports/notifications to other staff within their institution. Electronic reporting will not replace the paper reports but will allow customers to receive information several days earlier.

Event Notes are also included when reports are released. This summary contains general information and grading observations for a specific program or group of programs and may include information to help you evaluate results. Questions or comments should be directed to the coordinator at the extension listed on the bottom of the Evaluation Report.

### **Scoring Information**

Regulated analytes analyzed by non-waived methods are scored according to criteria defined in CLIA '88. These criteria are used by all CMS approved proficiency testing providers. An overview of the scoring types used by WSLH PT, along with specific criteria applied to individual analytes, can be found on our website under "General Information". Hard copy is also available upon request.

### **Correcting Reports**

Reports are mailed within 1 or 2 days of the Report Run Date listed on the bottom of the cumulative summary report; usually 30-45 days after the due date.

Scores are sent to accreditation agencies 60 days after the due date.

Therefore, it is important that you review reports as soon as possible after receipt. If you note an error on our part (e.g. wrong number entered; analyte data missing), immediately contact the coordinator at the number and extension listed on the bottom of the Evaluation Report. Errors on the part of WSLH PT (e.g. incorrect result entered/scanned in or comment overlooked), when brought to our attention, will usually result in a corrected report.

Errors on the part of the customer (e.g. results reported in the wrong order, wrong number copied from instrument readout, wrong units reported) are considered by CLIA to be post-analytical mistakes and cannot be corrected.

If "No Results Received" is listed on the report and you feel it is in error, you must provide proof of timely response/submission of results (fax log, telephone bill) in order to request a correction.

### **Obtaining copies of Past Reports**

It is your responsibility to keep records of proficiency testing participation for a minimum of two years [42CFR 493.801, *Federal Register*, pg. 7146]. This includes enrollment confirmation, results sent to us, reports sent to you and any documentation of review and/or corrective actions taken in the event of unsatisfactory performance.

Customers with portal accounts can access and reprint results submitted online as well as reports released after data analysis at any time.

If you do not have a portal account, we will provide reports or copies of results submitted to us at no cost with 2 days of a request. However, requests for immediate service or retrieval of raw data submitted to us may be subject to a minimum \$25 charge.

## **Other Services**

### **WSLH PT Website**

You can find us at: <http://www.wslhpt.org>. Menu items are listed on the left side of the home page. Customers with portal accounts can login on the bottom of the home page.

Our “virtual catalog” contains the most current services available. Please check the website frequently. We often add PT programs in mid-year as new technologies emerge. Our shipping schedule, order forms and report interpretation keys are also available in pdf format.

The “PT images” section contains a multi-year library of high quality images sent as PT challenges (e.g. hematology cell ID, urine sediment, PPM procedures) and targets for rabies and emergency response.

Customer feedback is always welcome and encouraged.

### **WSLH PTPlus Products**

WSLH PT is a department of Wisconsin’s public health laboratory and the University of Wisconsin-Madison. This gives our business the unique position of being part of a working laboratory in a major university setting. We have a long history of sponsoring and co-sponsoring seminars and continuing educational opportunities for clinical labs, public health nurses and physicians in Wisconsin. Staff members are actively involved with professional associations at the state and national levels. We also sponsor seminars, teleconferences and training materials in association with the National Laboratory Training Network (NLTN).

Given this history, we expanded our PT business to include educational offerings for all our customers through our *PTPlus* products. These include an online Training Library and bi-annual lab and PPMP competency assessment modules.

VeriSamp sample sets are another *PTPlus* product line intended to help laboratories and POCT sites meet method evaluation, compliance and training requirements. Each set contains samples with known characteristics and target values to independently verify method performance. These samples sets are currently available only for a small number of specialties. These products do not replace required proficiency testing but can be used to assess and document employee competency, train employees on new procedures, perform correlation studies when changing methods and validate methods in use.

These services are outlined in detail on our website and in the catalog, under the *PTPlus* section. Order forms for these products are available online or by calling 800-462-5261, ext 0.

We also offer a variety of no-cost, time saving services for managers or POCT coordinators who have responsibility for multiple sites. Services include copies of reports sent to customer sites and options to have re-enrollment and/or confirmation forms sent to the manager/coordinator instead of the individual customer sites. Management reports (Excel format) covering multiple PT events are also available.

### **Additional Samples**

Samples from past events, summaries and statistics for uses other than proficiency testing (e.g., evaluating new tests or methods, trouble-shooting PT failures, staff training or assessing staff competency) may be purchased if supplies are available. The price will include the cost of samples, printed materials, shipping and handling. Contact the appropriate program coordinator for further information.

### **Unsatisfactory Performance/Troubleshooting Assistance**

Request the “TEN STEPS TO SUCCESSFUL PROFICIENCY TESTING” checklist from our customer service staff or contact the coordinator of the program for help in resolving questions about PT failures.

### **Off-schedule PT**

Samples for remedial/reinstatement of late/missed enrollment situations are available on a limited basis. The price will include the cost of samples, printed materials, shipping and handling and reporting to your accreditation agency. Contact the appropriate program coordinator for further information.

### **Reporting PT Scores to Accreditation Agencies**

A proficiency testing provider is not an accreditation agency and does not inspect your laboratory or testing site. However, participation in an approved PT program may be part of accreditation requirements for your facility's quality assurance (QA) plan.

In order to be a CMS approved proficiency testing provider under CLIA '88 law and be listed as an accepted provider for other accrediting agencies (e.g. CAP, COLA, Joint Commission), we are obliged to report PT scores in a manner that meets federal and state laws and accreditation agency requirements. In general, requirements of non-CMS accreditation agencies and state statutes are more stringent than what is defined as "reportable" to CMS under CLIA (federal) law.

If your site is not defined under, or is considered exempt from, CLIA law [e.g. military, veterans administration, veterinary, manufacturer, foreign country, etc.] nothing is reported to CMS.

Determining how and what scores are reported is defined by a combination of 5 parameters: the customer's accrediting agency and their requirements, the state statutes under which the business operates, CLIA rules, the complexity of the testing performed (e.g. waived/moderate/high), and whether enrollment with more than one PT provider is required by the customer's own QA plan.

The following may help explain what PT scores are reported:

- All **regulated** analyte scores [e.g. those listed in black in our catalog] tested by non-waived methods are reported to the CMS national computer using electronic OSCAR format. Surveyors conducting on-site inspections have access to PT scores from this computer. The CMS computer will accept only one score/analyte/CLIA ID/event.
- Scores for analytes that are not listed in CLIA '88 (e.g. troponin, BNP, hemoglobin A1c, etc) or testing done by waived methods are not reported to the CMS computer.
- Although no scores are sent to the CMS computer for waived testing/unregulated analytes, some states may have state laws which regulate these tests and these will be enforced by the state CLIA office. State CLIA offices, COLA, AOA and VA regional commissioners have "view only" access to all PT reports on our website.
- If your lab resides in or is licensed to do business in the state of CA, OR, PA, or WA, scores for all tests are transmitted electronically to the state CMS office using CA format.
- If your lab is accredited by the CAP's Laboratory Accreditation Program, scores for analytes for which we are an accepted provider are transmitted electronically using LAP format.
- If your QA plan requires enrollment with more than one PT program and you have notified us that we are not your primary PT provider, voluntary status is indicated on your enrollment confirmation and no scores are sent.

### **Lab Director/Technical Consultant Reports**

Copies of reports can be sent to a lab director, technical consultant, POCT coordinator or QA officer if the information is supplied to us. Consultant copies are mailed at the same time as the lab reports. Other management services are listed under Management Services in the PTP<sub>us</sub> section of our catalog.

### **Waived Method Lists**

Information on waived methods can be obtained from the FDA or Joint Commission websites:

<http://www.fda.gov/cdrh/clia> or [www.jointcommission.org](http://www.jointcommission.org)

## WSLH PT Business Hours & Contact Information

Telephone numbers and other contact information are listed below. We are available to assist you Monday through Friday, 7:30 am to 4:30 pm, CST/CDT at **800-462-5261**. Our fax server operates 24/7 so you may fax us anytime. Alternatively, you may leave voice mail or e-mail messages.

Customer Service: 800-462-5261, ext 0 or [PTService@mail.slh.wisc.edu](mailto:PTService@mail.slh.wisc.edu)

Business Hours: 7:30-4:30, CST/CDT

Fax: 608-265-1111

Website: <http://www.wslhpt.org>

## Telephone List/Electronic Mail Addresses

NAME	TITLE	EXT	E-MAIL ADDRESS
Dave Hassemer, M.S.	Director	48	<a href="mailto:hassemer@mail.slh.wisc.edu">hassemer@mail.slh.wisc.edu</a>
Barb Hill, MT(ASCP)	Manager	45	<a href="mailto:bmh@mail.slh.wisc.edu">bmh@mail.slh.wisc.edu</a>
Barb Burmeister, MT(ASCP)	Supervisor	46	<a href="mailto:burmie@mail.slh.wisc.edu">burmie@mail.slh.wisc.edu</a>
Mike Argall, MT(ASCP)	Coordinator	52	<a href="mailto:argallmg@mail.slh.wisc.edu">argallmg@mail.slh.wisc.edu</a>
Becky Briggs, MT(ASCP)	Coordinator	51	<a href="mailto:briggsbl@mail.slh.wisc.edu">briggsbl@mail.slh.wisc.edu</a>
Chelli Gosda, MLT(ASCP)	Coordinator	54	<a href="mailto:gosdamk@mail.slh.wisc.edu">gosdamk@mail.slh.wisc.edu</a>
Judy Nichols, MT(ASCP)	Coordinator	56	<a href="mailto:listwaje@mail.slh.wisc.edu">listwaje@mail.slh.wisc.edu</a>
Vicki Sasso, MT(ASCP)	Coordinator	55	<a href="mailto:sassovl@mail.slh.wisc.edu">sassovl@mail.slh.wisc.edu</a>
Tracy Servey, MT(ASCP)	Coordinator	53	<a href="mailto:serveytl@mail.slh.wisc.edu">serveytl@mail.slh.wisc.edu</a>
Colleen Urben, MT(ASCP) NCA	Coordinator	49	<a href="mailto:urbencm@mail.slh.wisc.edu">urbencm@mail.slh.wisc.edu</a>