WSLH PROFICIENCY TESTING

HANDBOOK

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General Information

What Is PT

Proficiency testing (PT) is the practice of testing samples of unknown values sent from an external PT program. These samples are shipped to a laboratory at various times throughout the year. The samples are analyzed within a specified time frame by testing personnel who must treat them like a patient sample. Once the samples have been tested, results are sent to the PT program for evaluation. The evaluated results are sent back to the laboratory in a report that compares the results obtained with the actual results and compares your laboratory to other laboratories using identical or similar methodology. Participation in PT allows a laboratory to identify procedural problems and take corrective action before patient results are affected. Successful completion of proficiency testing can serve as a benchmark for quality.

About WSLH PT

Founded in 1966, WSLH Proficiency Testing (PT) has over 50 years of experience in providing exceptional customer service, innovative programs, and quality samples. We are the only PT provider that is part of a working laboratory and one of the top public universities in the US. Because of this uniqueness, our mission is focused on promoting education and public health to laboratories nationwide. Our services include:

- Personal account management assistance
- Troubleshooting and consultation available from our staff of Medical Technologists
- Flexible ordering options with competitive pricing
- Wide array of quality assurance options
- Web based management tools

Contact Us

Mail: 2601 Agriculture Drive, Room 233, Madison, WI 53718
Phone: (800) 462-5261
Fax: (608) 265-1111
Email: ptservice@slh.wisc.edu
Office hours: Monday through Friday 8:00 AM to 4:30 PM (CT) - closed on all major holidays

General Information

Regulations Regarding PT

Regulated Analytes/Procedures

The Centers for Medicare & Medicaid Services (CMS) regulates clinical laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires laboratories to participate in PT for all analytes regulated under CLIA and tested by non-waived methods. Laboratories must enroll with a CMS approved PT provider that provides 5 challenges in each of 3 shipments per year.

Non-regulated Analytes/Procedures and Waived Methods

CLIA dictates that laboratories must have a quality assurance plan that establishes the accuracy and reliability of testing for non-regulated analytes at least twice per year. In addition, laboratories located in certain states or those accredited by private organizations such as CAP, COLA, or The Joint Commission may be required to enroll in PT for CLIA non-regulated analytes and/or testing performed by waived methods. A convenient way to fulfill these requirements is to utilize the products and services offered by WSLH PT.

Although PT is not routinely required for waived testing, there are many benefits of participating in a PT program.

PT provides:

- Regular external assessment of testing quality
- Motivation to improve performance
- Comparison of performance with peers
- Feedback and advice from trained laboratory professionals
- Evaluation of methods and instrumentation
- Monitoring of outcomes from staff education and training
- Assessment of staff competence

PT Enrollment Requirements

- Laboratories must enroll on an annual basis.
- Laboratories must notify CMS of their chosen PT provider(s).
- Laboratories must authorize the PT provider(s) to release test scores to their accreditation agency (s).
- CMS must be notified of any PT provider changes.
- CMS generally requires a laboratory to participate for one year before changing PT providers.

Laboratory Accreditation

Score Transmission

Rules governing which scores to send vary depending on the test methods used, accrediting agency requirements and/or the state in which testing facilities are located.

CAP information: If enrollment in PT is required by the CAP Laboratory Accreditation Program (LAP) for an analyte, WSLH PT will send enrollment records and scores electronically to the LAP. If PT is not required, WSLH PT will not send records to the LAP. However, customers may enroll in PT and use that documentation to satisfy the alternate assessment requirement (which would be reviewed during on-site surveys/inspections). For example, a LAP accredited lab is not required to enroll in PT for sedimentation rate and occult blood; they are required to perform an "alternate assessment" for these tests. Enrollment in PT is often the easiest and most cost effective way to document "alternate assessment".

CMS information: Scores for waived methods or those tests not defined in CLIA (e.g. whole blood glucose, urinalysis) will not be sent to CMS. Only scores for regulated analytes/procedures by non-waived methods will be sent. However, some states and accrediting agencies require us to provide scores for non-regulated analytes or tests performed by waived methods.

Quality Evaluation (QE) Products

QE products offer samples to validate secondary instrument/method performance, as well as providing simple and valuable competency challenges. Participants will test and report QE product samples AFTER the primary set due date.

QE products will be shipped to participants along with PT samples for primary instruments. The testing and reporting dates for the QE product samples will be specified in your shipment. The results reported for QE product samples will be evaluated by WSLH PT, and a separate Evaluation Report will be sent back to the facility. QE programs/analytes are not assigned scores and are not transmitted to any accrediting agencies.

References:

http://www.cms.gov/CLIA/

http://wwwn.cdc.gov/dls/waivedtests/

Ten Steps to Successful Proficiency Testing

1. When you receive your Enrollment Confirmation:
   - Review your Enrollment Confirmation packet.
   - Post the shipping schedule and list of WSLH PT phone numbers in a prominent place.
   - Keep the information in an accessible location known to all staff involved with testing.
2. Frequently refer to the shipping schedule to ensure that:
   - Someone will be present to receive the shipment, route it promptly and store it appropriately.
   - Someone will be available to perform the testing within the required time limit.
   - Preventive maintenance is up-to-date.
   - Sufficient in-date supplies and reagents will be available.
3. When the package arrives:
   - Document the date of receipt and open package immediately.
   - Check for damage and/or completeness of samples and forms.
   - Call WSLH PT immediately if there is any problem. If you wait, a replacement may not be available and the delay may cause you to miss the deadline for reporting results.
   - Read storage information immediately and store samples as directed.
4. Prior to testing:
   - Use your PT shipping and staff schedule to ensure all personnel who perform patient testing are scheduled to participate in PT testing on a rotating basis.
   - Schedule testing well in advance of the due date so that any unanticipated problems can be resolved in time to meet the deadline.
5. On the day of testing:
   - Perform instrument checks, quality control, etc. in the same manner as you would for patient testing.
   - If a problem is noted that will temporarily suspend patient testing and delay reporting of PT results until after the due date, contact WSLH PT immediately to request excused status.
6. Actual testing:
   - Prepare samples exactly as directed.
   - Log and test PT samples with the same frequency and, as closely as possible, in the same routine manner as patient samples.
   - Do Not Refer Proficiency Testing Samples. If your protocol for similar patient samples requires referral of the sample, either upon receipt or after preliminary work-up, indicate by result code or comment that the proficiency sample would be referred to another laboratory if it were a clinical/patient sample.
   - If possible, store left over samples to aid in troubleshooting any unsuccessful performance.
7. Resulting PT samples:
   - Verify that the sample ID matches the sample ID you are resulting.
   - Report in the units requested. Alternate units may be available for a module, please contact WSLH PT for assistance.
   - Report results to the requested decimal places.
   - Refer to sample instructions for direction on reporting out of range results (i.e., use of > or < symbols).
   - Verify Instrument/Method/Reagent information
   - Have the attestation statement signed by the testing personnel and the laboratory director.
8. Submit the results before the due date:
   - Enter your results online.
   - Print/Save a copy of your data submission report for your records.
9. When your report comes back:
   - Review the entire report (evaluation, event notes and statistics) carefully noting the following:
     - "Not scored" or "Non consensus"
     - Analytes scored by an "All Methods" scoring group.
     - Scores less than 100%
     - "No Results Received"
10. Post event follow-up:
    - Investigate and document corrective actions taken on scores less than 100%.
    - Perform a self evaluation of ungraded results (e.g., "Not scored" or "Non consensus").

Enrollment and Ordering

General Ordering Information

Verify products ordered are appropriate for the test menu defined by your CLIA certificate and compatible with your test system(s)!
Enrollment can be adjusted during the year if tests are added or dropped.
Call WSLH PT if you need assistance to enroll properly.

WSLH PT ID Number

Each facility is assigned an identification number. Please have this available when you contact our office to allow our staff to quickly access your account.

Enrollment and Order Forms

Current customers will receive a Re-Enrollment Form. Please edit (if necessary) and return.
New customers will need to complete the New Customer Enrollment Form.
To assure participation in all shipments, enrollment and order forms should be received by December 1st. Payments or purchase orders referencing your enrollment may be submitted at a later date.

Pricing Information

Each product price includes all shipments in the calendar year. Customers enrolling after the first of the year will be charged only for the number of shipments they will receive from the order process date through the end of the year. Prices are divisible by the number of shipments per year.
Two-day shipping via UPS is included in the product price. Products shipped overnight are indicated in the catalog. Additional charges for special services (e.g., overnight delivery, custom packaging) or shipment outside the 48 contiguous states (e.g., Hawaii, Alaska, Canada, etc.) will be applied. Import permits or customs forms must be provided by international customers at least 30 calendar days prior to the first scheduled shipment.

Enrollment Confirmation

Expect to receive a confirmation letter and a customized shipping schedule within three weeks of order receipt.

Invoicing / Payment Information

PT is a prorated subscription service. Invoices are issued on a monthly basis.
For facilities that require a Purchase Order number (PO#) be assigned when placing an order, please list the PO# on the order form(s). PO#s will be printed on the invoices, if provided at the time of order.
Important: Purchase orders CANNOT be used in place of order forms.

Payment may be made by check, credit card or ACH.

Check

Please reference your WSLH PT billing account number and invoice number on your check. Large institutions using a single check to pay for multiple accounts should reference all billing account numbers and invoice number(s) on the check stub to ensure payment is applied to the correct account.

Check payment(s) should be mailed to the following address:

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

Credit Card

Visa and MasterCard payments are accepted through our online payment portal: http://slh.wisc.edu/wslhApps/Charge/order.php.

Please have your account number and invoice number on hand to ensure proper application in your account. For assistance, please call 1-800-862-1065 or email: arbill@slh.wisc.edu. Do not email your credit card information to this address. A member of the accounts receivable staff will contact you for your payment information.

ACH (electronic payment)

To set up ACH payments, please call 1-800-862-1065 or email arbill@slh.wisc.edu for assistance.

Invoice payments are a Net 30 from the date of the invoice. If payment is not received within 90 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. This will put your laboratory in regulatory jeopardy; please submit payment promptly.

Billing and credit card questions should be directed to Accounts Receivable staff at arbill@slh.wisc.edu or by calling 1-800-862-1065.

Cancellations / Refunds

Cancellations and/or adjustments after enrollments and orders have been processed will be handled on a case by case basis. All requests must be submitted in writing at least 30 days prior to a scheduled shipment date. The annual processing fee is non–refundable.

Seasonal Participation

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). To avoid unwanted deliveries during a temporary closure period, please specify closed dates on your Enrollment Form or notify us at least 2 weeks prior to the seasonal closure(s).

Changes To Enrollment

WSLH PT provides a Customer Change Form to update demographic information and make enrollment changes.

In addition to notifying WSLH PT, it is your responsibility to notify your accreditation agency of any changes in your test menu. Changes may include: adding/dropping products or moving to waived test procedures.

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.

Related Forms

These forms may be accessed on our website www.wslhpt.org

- New Customer Enrollment Form
- Customer Change Form

Shipments and Receipt of Samples

Shipping Information

Customers will receive a customized shipping schedule with their enrollment confirmation. Most packages will arrive within 3 days of the scheduled ship date. Customers must make arrangements to accept delivery and have package routed immediately to the appropriate location for proper handling and storage. If you do not receive samples within 3 days of the scheduled ship date, please contact us. Shipping dates cannot be changed.

When Samples Arrive

Inspect Contents of Package Immediately

- Check packing slip to verify package contents
  - Kit label(s) match what is listed under "Modules".
  - Instructions are included where applicable for items listed under "Modules".
- Verify identification on the samples match the sample identification listed on the packing slip under "Samples".
- Verify that all samples are present (no duplicate or missing samples).
- Inspect for sample integrity (adequate volume, cracked or leaking, hemolysis, etc.).
- Verify package received corresponds with your enrollment and shipping schedule.
- Contact WSLH PT immediately at (800) 462-5261 x0 if there are any issues after inspecting package contents.

General Sample Storage

Refer to the Module Supplemental Instructions for proper storage requirements.

Identify a separate storage space for already analyzed PT samples to decrease the possibility of a mix-up with current PT samples.

Sample Handling Precautions

CAUTION: PT samples may be prepared from blood or other human or animal source material. All proficiency testing samples should be treated as if potentially infectious and thereby Universal Precautions must be followed. Precautions described in CDC and FDA recommendations and OSHA blood borne pathogen rules should be followed when handling and disposing of these materials.

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 antibodies. However, no known test method can offer complete assurance that products derived from human blood will not transmit infection.
In the event of an exposure from PT samples, follow your internal laboratory exposure protocol. Contact WSLH PT for Material Safety Data Sheet (MSDS) information.

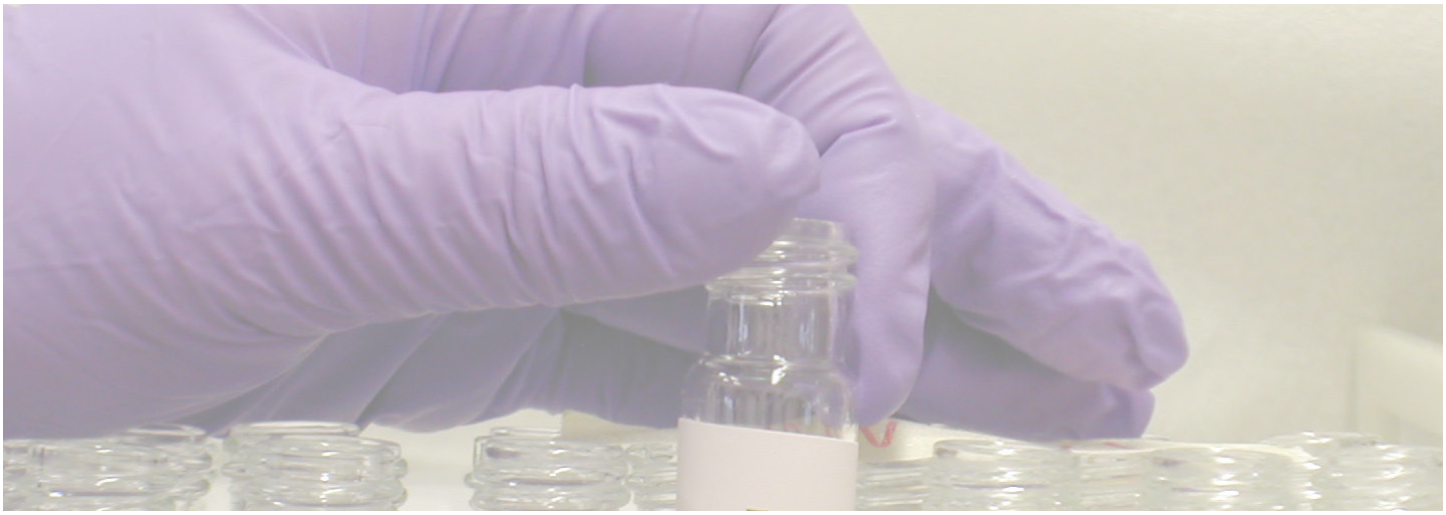
Sample Replacement

It is your responsibility to examine each package as soon as it arrives and report any missing/compromised samples to WSLH PT. If any samples are missing or compromised, contact WSLH PT immediately and request a replacement.

A fee will be charged to cover the cost of replacement sample requests made for reasons within the participant's control (e.g., lab accident, improper storage, internal routing problems).

Replacement samples are available only as long as quantities last. Make any replacement requests in a timely manner to allow sufficient time for shipping and completion of analysis by the scheduled due date. Requests received in the final week may incur an extra fee for expedited shipping and handling.

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



Testing Samples and Reporting Results

Testing OverView

Follow the specific sample handling instructions that accompany your shipment. Do not assume that all samples within a shipment are handled in the same manner.

- Use routine test procedures and personnel.
- Ensure all personnel who perform patient testing are scheduled to participate in PT testing.
- Report only those analytes/procedures you normally perform in-house on patient samples.
- Test the PT samples the same number of times as done routinely for patient samples.
- PER CLIA, DO NOT REFER PROFICIENCY TESTING SAMPLES UNDER ANY CIRCUMSTANCES. Sending PT samples to another laboratory for testing may result in revocation of your CLIA certificate. Refer to the individual sample instructions to properly code or comment if a sample would be referred if it were a real patient situation.

Reporting Results

Report results online at www.wslhpt.org. Click the Customer Login button and access PT Central using the assigned login name and password. Login information may be found on the shipment cover sheet.

Refer to General Instructions and module specific Supplemental Instructions for detailed information. General Instructions can be found at www.wslhpt.org.

Review Analyte & Instrument Information

You must review/update your Analyte(s) and Instrument/Method/Reagent listed prior to submitting results.

If ALL information is correct, no changes are required.

If instrument, method, or reagent is incorrect click the CONTACT US link to request an update. Do not enter results until WSLH PT has made requested changes.

If you need to drop or add an analyte refer to the module specific Supplemental Instructions.

If you are unable to report an analyte or sample you will need to provide an exception. Refer to module specific Supplemental Instructions or contact the appropriate coordinator for more information.

Analyte(s) and instrumentation/method/reagent changes requested after the due date WILL NOT BE ACCEPTED for the current event but will be changed for subsequent events.

Report in Requested Units

Report results in the units requested. 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.

Alternate units may be available for a module, please contact the program coordinator for assistance.

Report in Requested Decimal Places

Do not exceed the number of decimal places indicated. Follow your in-house protocol if rounding or truncating is necessary.

Alternate decimal places may be available for a module, please contact the program coordinator for assistance.

Out of Range Results

Results above reportable range: If proficiency testing results exceed the highest reportable range of your instrument upon initial testing, treat them as you do your patient samples.

If you dilute patient samples, then dilute PT samples. After applying the appropriate multiplication factor, enter your results.

If you do not dilute patient samples, record the highest numeric limit of the instrument as your result including the "greater than" (>) sign.

Results below reportable range: If proficiency testing results exceed the lowest reportable range of your instrument upon initial testing, record the lowest numeric limit of the instrument as your result Including the "less than" (<) sign.

Identifier

Some result formats provide a field to record an identifier. Identifiers are applicable if a laboratory wants to capture where the result came from (e.g., result set number, instrument location/designation). Identifiers will appear on the Data Submission Report and the Evaluation Report and may be used to assist tracking performance from event to event. Contact WSLH PT for assistance.

Attestation

An attestation statement with an accompanying signature area is provided so the lab director/designee and individuals performing testing can document that PT samples were tested in the same manner as patient specimens.

You are not required to return the signed attestation statement with your PT result submission. However, you are required to keep it for your record/inspection purposes.

Testing Samples and Reporting Results

Submitting Test Results

IMPORTANT: All test results, requests for excused status, and/or discontinued analyte testing notification must be submitted by midnight of the due date.

Refer to the General Instructions at www.wslhpt.org for detailed result entry information.

If you require assitance during the result entry process contact WSLH PT at 800-462-5261 x0

When submitting results:

- Be sure to click "Save" in the data entry screen after entering results.
- Build your Data Submission Report and reveiw for accuracy.
- You may make edits to your submitted results until miidnight of the due date.
- Re-build and reveiw your Data Submission Report if you make any edits.
- Save a copy of your Data Submission Report for your PT records.

Can't Report Results?

Temporary Suspension of Testing (Excused Status)

Requesting excused status is appropriate when patient testing is temporarily suspended due to equipment malfunction or out of reagent/reagent backorder and you are unable to test PT samples. For other temporary testing suspensions, please contact WSLH PT for instruction.

Per CLIA regulations, all of the following circumstances must be met before an excused status can be considered:

- Patient testing has been suspended.
- The laboratory notifies its inspection agency and PT program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing.
- The laboratory has successfully participated in the previous two proficiency testing events.

If you need to request excused status you must:

- Provide a documented exception code with your result submission as to the reason(s).
- Notify your accreditation agency.
- Keep a copy of your documentation with your PT event records to be available for on-site inspection(s).

"Excuse Requested" with a 100% score will be printed on your reports. However, the final determination of the acceptability of your requested excused status is up to your accreditation agency.

PT Sample vs. Test System Compatibility

WSLH PT samples are tested on several commonly used systems prior to shipment. However, since PT samples may not always behave exactly like patient samples, we cannot guaranty compatibility with every test system available on the market.

If you cannot achieve a reportable result due to potential sample compatibility problems, contact WSLH PT for further guidance.

Discontinued Analyte Testing

If you have discontinued testing for any analyte(s) you must:

- Provide a documented exception code/comment with your result submission in one of the following ways:
  - Contact WSLH PT via email to indicate which analyte you want dropped from a module.
  - Enter an exception code online to indicate which analyte you want dropped.
- Notify your accreditation agency of any test menu change(s).
- Keep a copy of your documentation with your PT event records to be available for on-site inspection(s).

Evaluation Process

Definitions for underlined words can be found on the next page.

Quantitative Scoring (Peer)

1. For each analyte, data is sorted into scoring groups.
2. Mean, SD, and CV are calculated for each scoring group.
3. Statistical Outliers are identified and removed.
4. Statistics are recalculated.
5. Acceptable ranges are calculated by applying a specific tolerance factor to the mean.
6. Consensus is calculated.
7. Each result is compared to the acceptable range for its appropriate scoring group.
   a. Result is first attempted to score by peer group (PG).
   b. If no valid peer group exists, result is attempted to score by special group (SG).
   c. If no valid special group exists, result is attempted to score by all methods group (AG).
   d. If all methods group is not valid, result is attempted to score by referee laboratory group (REF).
   e. If referee laboratory group is not valid, result may be Not Scored or Non-Consensus.

Quantitative Scoring (Referee)

1. For each analyte, the mean, SD, and CV are calculated from the referee laboratory group.
2. Acceptable range is calculated by applying a specific tolerance factor to the mean.
3. Consensus is calculated.
4. Each result is compared to the acceptable range of the referee laboratory group. If this group is not valid, result may be Not Scored or Non-Consensus.

Qualitative Scoring (Peer)

1. For each analyte/procedure, data is sorted into scoring groups.
2. Frequency is counted for each reported result in each scoring group.
3. Consensus is calculated: frequency / total results x 100.
4. An acceptable result is determined.
5. Each result is compared to the acceptable result(s) for its appropriate scoring group.
   a. Result is first attempted to score by peer group (PG).
   b. If no valid peer group exists, result is attempted to score by special group (SG).
   c. If no valid group exists, result is attempted to score by all methods group (AG).
   d. If all methods group is not valid, result is attempted to score by referee laboratory group (REF).
   e. If referee laboratory group is not valid or no acceptable result was able to be determined, result may be Not Scored or Non-Consensus.

Qualitative Scoring (Referee)

1. For each analyte/procedure, data from the referee laboratory group is used.
2. Frequency is counted for each reported result.
3. Consensus is calculated: frequency / total results x 100.
4. An acceptable result is determined from the referee results.
5. Each result is compared to the acceptable result(s) from the referee laboratory group. If no correct result could be determined, this group is not valid for scoring and the result may be Not Scored or Non-Consensus.

Scoring and Evaluation

Definitions/Explanations

Acceptable range: The mean plus or minus the tolerance factor.

Acceptable result: Acceptable results, for qualitative scoring, are determined as follows:

- If a single result meets acceptable consensus, it is considered valid to use for scoring.
- If no single result meets acceptable consensus, more than one result may be determined as correct by using the results with the highest frequency.
- If result is expressed in concentrations: When result with highest frequency falls between two dilutions, the correct responses will also include one dilution higher and one dilution lower.
- If result is an Equivalent Result: Correct responses may vary depending on the complexity of the testing performed by the participant.

  For example, acceptable responses for Pseudomonas aeruginosa may include: Gram negative bacterium, Gram negative rod, Pseudomonas species or Pseudomonas aeruginosa.
- When more than one result is determined as correct, the frequency of these results added together must meet acceptable consensus.

Coefficient of variation (CV): SD expressed as a percentage of the mean CV = SD / Mean x 100

Consensus: In order for a scoring group to be valid to use for scoring, 80% (95% for Immunohematology regulated analytes) of all participants included in that scoring group must be within the acceptable range or be in agreement of the same result.

Frequency: Number of occurrences.

Mean: The arithmetic average of a group of numbers.

Median: The middle number of an ordered list of numbers in which there is an equal amount of values above and below.

Non-Consensus: May be used if the only possible scoring group or all possible scoring groups for a result does not meet acceptable consensus.

Not Scored: May be used when all possible scoring groups have less than ten members and result does not fit into all methods group or all methods group is not valid. Not Scored may also be used when sample/instrument compatibility issues exist.

Scoring group: A group of results that is used to determine an acceptable response to any given analyte or procedure. A valid scoring group must have a minimum of ten members and reach acceptable consensus.

A scoring group may be any of the following.

Peer group (PG): This group is made up of specific test systems. (same instrument/kit, same reagent, same measurement principle)

Special group (SG): This is a group of instruments or kits with something in common. Examples of a special group include various models of an instrument series, instruments or kits from the same vendor, instruments using the same reagent, method or principle.

All methods group (AG): This group is made up of all methods of all participants. All methods may not be an option in situations where there is excessive result variation among peer groups for a particular analyte or procedure.

Referee laboratory group (REF): This group is made up of PT participants whose scores over the previous three events are satisfactory (for most analytes 80% or greater). Candidate referee laboratories are selected by the database and presented to the PT coordinator for final approval. Care is taken to select a slate of referees (minimum of ten) that represents a crosssection of the participants reporting a particular analyte or procedure.

Standard deviation (SD): A measure of variation of values around the mean.

Statistical Outliers: Statistical outliers are identified and removed from the final calculations using the following rules:

- Discard any result that is greater than ± 3 SD from the mean.
- Recalculate mean, median, SD and CV
- Discard any result that is greater than ± 3 SD from the mean.

Tolerance factor: Allowable variation from the mean as determined by CLIA regulations for each analyte. This can be ± SD, %, or a fixed value.

Antibiotic Susceptibility Scoring

The Antimicrobial Identification

1. Appropriate antimicrobials are identified based on the target pathogen, the sample source, and the CLSI document M100. Because the M100 is reviewed and edited by the CLSI each year, all target pathogens are cross-checked against the most current version of the M100 when determining appropriate antibiotics and breakpoints.
2. Any reported antimicrobial selections identified as inappropriate for the organism and/or source are flagged as "Fail" on the Evaluation Report. When the antimicrobial is inappropriate, the comment of "**Inappropriate Antibiotic**" is added and is specifically identified in the event notes.
3. All antimicrobials not included in the M100 for the target pathogen are manually reviewed:
   a. Those selected based on incorrect identification of the target pathogen which are not also appropriate for the target pathogen are flagged as inappropriate. AST score is reduced.
   b. Newer antimicrobial agents not yet addressed by the M100 are accepted if references/ literature and in-house expertise support its selection as appropriate. If insufficient information is available, the agent is flagged as "Not scored". There is no reduction of the AST score for either action.
   c. Antimicrobials selected on the data entry screen without a corresponding interpretation or comments are considered incomplete and are processed as a missing result. The total AST score is reduced even if the antimicrobial selection would have been appropriate.

Interpretation

Interpretations are evaluated for appropriate antimicrobials when the peer group size is >10 and consensus has been achieved for a single interpretation. Because all participants are testing aliquots from a single stock culture/strain, it is reasonable to expect that all subcultures will exhibit similar growth and susceptibility testing characteristics. Therefore, if 80% or more of participants appropriately report the pathogen as "Susceptible" to a particular agent, the interpretation "Susceptible" is treated as the most correct response and participants reporting either "Intermediate" or "Resistant" are penalized.

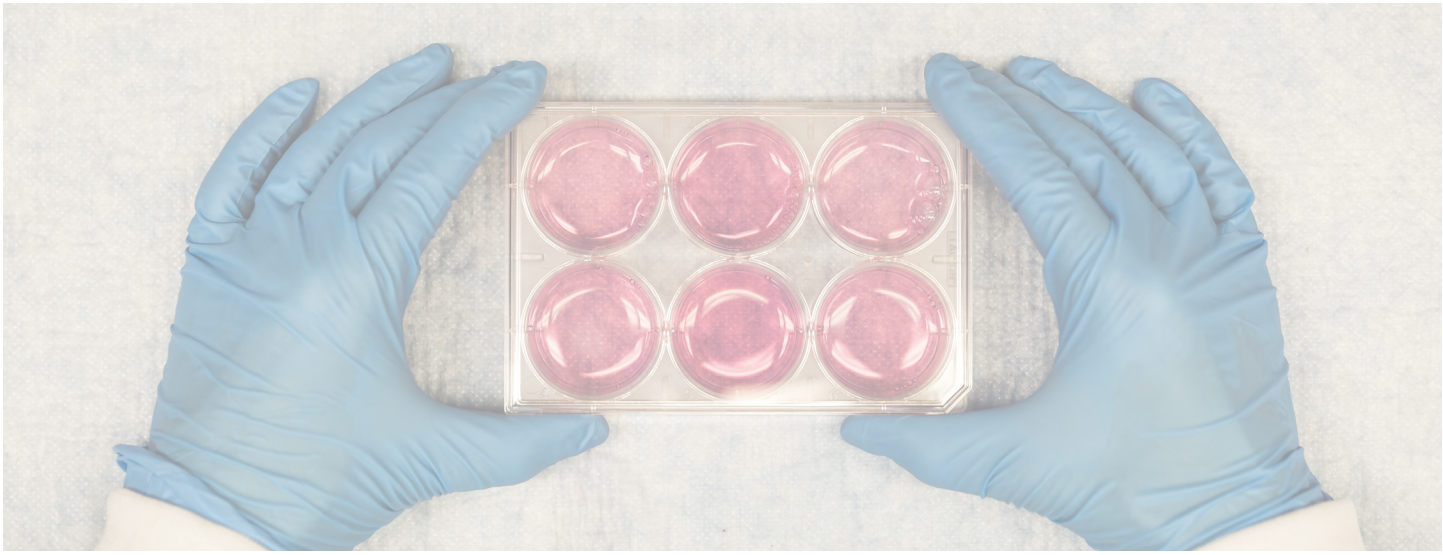
MIC or Disk Diffusion Zone Size

1. Participants reporting Minimum Inhibitory Concentration (MIC) values or disk diffusion zone sizes must give both a correct/ appropriate MIC or zone size and a correct interpretation in order to receive a passing result for that antimicrobial.

   For example, if an MIC of 2 for Ciprofloxacin should be interpreted as "intermediate," a participant reporting an MIC of 2 and an interpretation of "susceptible" for Ciprofloxacin, would receive a score of 0% for that antimicrobial.
2. When fewer than 10 participants report any single agent, or when consensus is not achieved on the interpretation, the agent will still be included in the Evaluation Report, but will not have an interpretation listed in the "Accepted Response" column.

References:

Federal Register, Vol. 57, No. 40, Section 493.941, p. 7159.
Federal Register, Vol. 58, No. 141, Section, p. 39873.
Clinical and Laboratory Standards Institute; Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Fifth Informational Supplement, M100-S25, Vol. 35, No. 3, January 2015.



Scoring and Evaluation

Scores

100% Scores

- Results within acceptable range or an acceptable result
- Results which are Not Scored
- Results which are Non-Consensus
- Excused status requested

0% Scores

- Results outside acceptable range or a non-acceptable result
- Missing and/or incomplete results without an explanatory comment

Note: In the cases of Non-Consensus and Not Scored, results are given a 100% score but the score may not be indicative of instrument/method performance.

Post Event Follow-up

Self-Evaluation

Per CLIA, laboratories are required to perform a documented self-evaluation under the following circumstances:

- Non-Consensus
- Not Scored
- No results were received

Late Submissions: Results will not be accepted after the due date. Laboratories will need to perform a self-evaluation and take corrective action to ensure results are submitted on time.

As part of their follow-up laboratories should:

Compare their results to the intended results provided in the Event Notes/Statistics and/or request peer group specific data (Data Request Form).

Follow in-house protocol as set by their laboratory director.

Troubleshooting PT Failures

If your laboratory has a PT failure, you need to:

- Identify the problem (e.g., clerical, technical, etc.)
- Determine if patient results were affected
- Take corrective action to prevent the problem from reoccurring
- Document all steps taken!

Tools offered for post event troubleshooting:

- Suggested Actions for PT Failures – located at the end of this section of the handbook
- Failure Corrective Action Worksheet – located on our website www.wslhpt.org

This information is not intended to replace any existing protocol used by your laboratory, but to offer points for consideration.

All post event actions must be approved by your Laboratory Director/Technical Supervisor/Consultant. Any summary of actions must be documented, signed, dated, and filed with the proficiency testing files for the event.

We suggest the following websites for more information on evaluation protocols and quality standards for the laboratory:

www.clsi.org
www.westgard.com

Record Keeping Requirements

Primary records related to PT (e.g., worksheets, data submission reports, instrument printouts, evaluation reports, corrective action documentation) must be retained for two years unless longer retention is required for specific analytes.

Requesting a Corrected Report

If your Evaluation Reports do not reflect the results that were originally submitted by your lab, contact WSLH PT at 1-800-462-5261 x0 for assistance on requesting a corrected report.

Related Resources

These may be accessed on our website www.wslhpt.org

Data Request Form
Failure Corrective Action Worksheet

Suggested Actions for PT Failure

PT Failure Classification	Examples/Descriptions	Suggested Actions
Preanalytic	• Delivery problem - PT provider to lab • Routing problem - internal • Replacement samples not requested • Misinterpretation of instructions • Samples stored improperly • Wrong samples used	• Have a master calendar that lists your expected PT sample ship dates to know expected arrival time. Call PT provider and ask for tracking information if samples do not arrive on time. • Train staff on proper routing/handling of P samples. • Inform staff to call the PT provider if they find the instructions are not clear.
Clerical/Post analytic	• Transcription error • Transposition error • Wrong method code • Reported incorrect units • Reported results under wrong analyte • Incomplete data submitted • Results submitted after the due date	• Always perform a careful review of your PT results prior to submission. • Note the due date of your PT survey and submit results on time. • Clerical errors are not eligible for correction. • Determine how the clerical error occurred and develop an action plan to prevent recurrence in the future.
Technical	• Personnel not trained on test procedure • Poorly mixed sample • Sample mix up • Dilution/pipetting error • Time delay/testing sequence not followed • Calculation error • Run accepted in non linear range • Run accepted with QC out of range	• Develop a policy for retraining, continuing education an competency assessment. • Verify test procedures are up to date.
Problem with PT material	• Excessive hemolysis (whole blood samples) • Excessive precipitate or turbidity • Bacterial contamination • Poor growth • Unstable • Matrix effect (not compatible with method) • No comparable peer group	• Contact the PT provider regarding sample problems.
Random error	• Random fluctuations in your measurements (e.g., a single sample fails for one analyte only)	• The assumption of random error can only be made when all other potential sources of error have been ruled out. • May be resolved by retesting the PT sample. • Document as random error or normal statisticalvariation.

Scoring and Evaluation

Suggested Actions for PT Failure (continued)

PT Failure Classification	Examples/Descriptions	Suggested Actions
Methodologic	• Instrument mechanical problem • Instrument calibration problem • Faulty standard • Faulty reagent • About to expire or out of date std/reagent/kit used • Bad lot or kit/reagent recall • Improper storage of kit/reagent/std	• Look at your SDI values. General rule is to stay within +/- 2. When looking at all five samples, are all SDI values negative or all positive, +/- 2? Are three of five results outside +/- 1.5? Check calibration records, if applicable, to determine if it is time to recalibrate. • Check to see if there is an action log indicating problems prior to or immediately after running PT samples. • Check the QC, QA and Preventive Maintenance (PM) Records the day that PT was run to be sure daily maintenance was performed, kits/reagents were not expired and the QC was within range. • Check the QC values for the week before and after performing PT to detect any shifts or trends that may have affected PT results. • Check any pipetting or measurement devices, if applicable. Make sure they are calibrated to dispense correctly and are not damaged. • Check to see if there is any remaining PT sample. If there is, retest it. • Run non PT samples which have known target values. Suggested materials include linearity materials, assayed control materials or calibrators not of the current lot used to calibrate the analyzer. • Perform split sample comparisons using patient samples. This is excellent documentation to assure accrediting agencies that patient results reported are accurate. If possible, choose samples that are similar in concentration to the PT samples under review. • If problem cannot be found, contact the instrument manufacturer and or PT program to see if they can help.