Wisconsin State Laboratory of Hygiene

UNIVERSITY OF WISCONSIN–MADISON

Oh no! I've failed a proficiency test. Now what?

- Meet our panelists from WSLH Proficiency Testing
- Identify PT best practices & common scenarios
- Submit questions by using the Q & A feature in Zoom
  Q & A will take place at the end of the program

Today's objectives

At the end of the session, the participant will be able to:

- Describe some of the most common proficiency testing failures.
- Explain what a laboratory must do when they have a proficiency testing failure.
- Identify and implement preventative practices into your PT routine.

Meet our panelists

Ann Hennings, MLS (ASCP)

Rhonda Stauske, MLS (ASCP)

Megan Flowers, MA

WSLH Proficiency Testing
Wisconsin State Laboratory of Hygiene

YOUR LAB
OUR MISSION

Reliable,
affordable,
& easy-to-use
proficiency testing

A division of the Wisconsin State Laboratory of Hygiene, which is an affiliate of the School of Medicine and Public Health at the University of Wisconsin-Madison

PT provider established in 1966, serving clinical labs in all 50 states, and globally

CMS-Approved. Accepted by: CAP, COLA, and Joint Commission

What we'll discuss

- Common PT Failures
- Not Scored Situations
- Follow-up and Prevention

Common PT Failures/Deficiencies

- Clerical errors
- Missing results
- Switching samples
- Data bias
- Not following CLSI guidelines
- Not following PT instructions
- Not following lab protocol
- Improper storage of samples
- Improper mixing of samples
- Reporting results in incorrect units
- Temperature issues

Clerical errors

Analyte	Reported Method
Module: 1080, Blood Lead - 5 samples	
Subspecialty: Chemistry	**Analyte Score: 20%**
Blood lead ug/dL	***LeadCare II Analyzer (Waived)***

Sample	Result	Mean	SD	SDI	Range	Scoring Group	Status	Comments
PB-1	>6.2	5.4	1.13	0.71	1.4 - 9.4	PG-LeadCare II Analyzers	**Fail**	Results submitted in incorrect format
PB-2	>36.4	33.2	3.43	0.93	29.2 - 37.2	SG-LeadCare II Analyzers	**Pass**	Not scored - non-consensus
PB-3	>28.4	26.0	3.01	0.80	22.0 - 30.0	PG-LeadCare II Analyzers	**Fail**	Results submitted in incorrect format
PB-4	>18.4	16.4	1.96	1.02	12.4 - 20.4	PG-LeadCare II Analyzers	**Fail**	Results submitted in incorrect format
PB-5	>5.6	4.5	0.90	1.22	0.5 - 8.5	PG-LeadCare II Analyzers	**Fail**	Results submitted in incorrect format

Missing results

Analyte	Reported Method
Module: 1080, Blood Lead - 5 samples	
Subspecialty: Chemistry	Analyte Score: 0%
Blood lead ug/dL	*LeadCare II Analyzer (Waived)*

Sample	Result	Mean	SD	SDI	Range	Scoring Group	Status	Comments
PB-6	--	--	--	--	--	---	Fail	No result(s) received
PB-7	--	--	--	--	--	---	Fail	No result(s) received
PB-8	--	--	--	--	--	---	Fail	No result(s) received
PB-9	--	--	--	--	--	---	Fail	No result(s) received
PB-10	--	--	--	--	--	---	Fail	No result(s) received

Switching samples

Subspecialty: Chemistry **Analyte Score: 60%**

Alanine Aminotransferase (ALT) U/L ***Roche cobas c 501 / Roche ALTL without P5P / NADH without P5P***

CET-1	18	18	1.1	0.00	14 - 22	SG-Roche cobas Instruments/ NADH without P5P/ Roche ALTL without P5P	Pass
CET-2	251	257	6.2	-0.97	206 - 308	SG-Roche cobas Instruments/ NADH without P5P/ Roche ALTL without P5P	Pass
CET-3	14	14	1.3	0.00	11 - 17	SG-Roche cobas Instruments/ NADH without P5P/ Roche ALTL without P5P	Pass
CET-4	77	163	4.1	-20.98	130 - 196	SG-Roche cobas Instruments/ NADH without P5P/ Roche ALTL without P5P	Fail
CET-5	160	80	2.1	38.10	64 - 96	SG-Roche cobas Instruments/ NADH without P5P/ Roche ALTL without P5P	Fail

Continued on next slide…

Switching samples

Subspecialty: Chemistry **Analyte Score: 60%**

Albumin g/dL ***Roche cobas c 501 / Roche Diagnostic Systems / Bromcresol green (BCG)***

CET-1	1.6	1.8	0.09	-2.22	1.6 - 2.0	SG-Roche cobas Instruments/ Bromcresol green (BCG)/ Roche Diagnostic Systems	**Pass**
CET-2	5.0	5.5	0.15	-3.33	5.0 - 6.0	SG-Roche cobas Instruments/ Bromcresol green (BCG)/ Roche Diagnostic Systems	**Pass**
CET-3	6.5	7.1	0.46	-1.30	6.4 - 7.8	SG-Roche cobas Instruments/ Bromcresol green (BCG)/ Roche Diagnostic Systems	**Pass**
CET-4	2.6	4.2	0.09	-17.78	3.8 - 4.6	SG-Roche cobas Instruments/ Bromcresol green (BCG)/ Roche Diagnostic Systems	**Fail**
CET-5	3.7	2.8	0.07	12.86	2.5 - 3.1	SG-Roche cobas Instruments/ Bromcresol green (BCG)/ Roche Diagnostic Systems	**Fail**

Data Bias (caused by improper calibration, deferred maintenance, etc.)

SDI

Analyte	Reported Method	Sample	Result	Mean	SD	SDI	Range	Scoring Group	Status	Comments
Module: 1314, Chemistry/Endocrinology/Therapeutic Drugs 12-21										
Subspecialty: Chemistry	**Analyte Score: 100%**									
Alanine Aminotransferase (ALT) U/L	***Siemens Dimension EXL / Dimension ALTI / NADH with P5P***									
		CET-6	235	235	4.8	0.00	188 - 282	PG-Siemens Dimension EXL/ NADH with P5P/ Dimension ALTI	Pass	
		CET-7	21	23	1.9	-1.05	18 - 28	PG-Siemens Dimension EXL/ NADH with P5P/ Dimension ALTI	Pass	
		CET-8	170	166	3.6	1.11	133 - 199	PG-Siemens Dimension EXL/ NADH with P5P/ Dimension ALTI	Pass	
		CET-9	112	110	3.0	0.67	88 - 132	PG-Siemens Dimension EXL/ NADH with P5P/ Dimension ALTI	Pass	
		CET-10	226	223	4.7	0.64	178 - 268	PG-Siemens Dimension EXL/ NADH with P5P/ Dimension ALTI	Pass	
Subspecialty: Chemistry	**Analyte Score: 80%**									
Albumin g/dL	***Siemens Dimension EXL / Dimension reagent / Bromcresol purple (BCP)***									
		CET-6	2.9	2.8	0.06	1.67	2.5 - 3.1	PG-Siemens Dimension EXL/ Bromcresol purple (BCP)/ Dimension reagent	Pass	
		CET-7	1.6	1.3	0.06	5.00	1.2 - 1.4	PG-Siemens Dimension EXL/ Bromcresol purple (BCP)/ Dimension reagent	Fail	
		CET-8	2.5	2.3	0.08	2.50	2.1 - 2.5	PG-Siemens Dimension EXL/ Bromcresol purple (BCP)/ Dimension reagent	Pass	
		CET-9	2.1	1.9	0.07	2.86	1.7 - 2.1	PG-Siemens Dimension EXL/ Bromcresol purple (BCP)/ Dimension reagent	Pass	
		CET-10	2.7	2.7	0.07	0.00	2.4 - 3.0	PG-Siemens Dimension EXL/ Bromcresol purple (BCP)/ Dimension reagent	Pass	

Not following Bacteriology CLSI guidelines

- Use correct breakpoints
- Reporting of inappropriate anti-microbials
- Add comment to result if diverging from CLSI,

  include reason, such as following FDA guidelines

Levofloxacin	MC-14	Using MICROSCAN breakpoints different than CLSI guidelines.
Levofloxacin	MC-14	Follow FDA guidelines

Not following PT instructions

Hematology – Comprehensive - (AF5) Supplemental Instructions
Modules: 2290, 2300
Event: HemeReg

Testing Procedure:

- Test samples following manufacturers' instructions.
- Samples must be run in **QC mode**.

Hematology proficiency testing (PT) samples are manufactured material. Because of this, most PT samples for hematology have to be tested in the quality control (QC) mode instead of patient mode to recover the correct values.

Not following PT instructions

Subspecialty: WBC Auto Differential	**Analyte Score: 20%**							
Lymphocytes %	***Sysmex Corporation XN2000***							
	AF5-1	22.8	28.9	0.79	-7.72	26.5 - 31.3	SG-Sysmex XN series	Fail
	AF5-2	9.0	13.4	0.95	-4.63	10.6 - 16.3	SG-Sysmex XN series	Fail
	AF5-3	11.0	13.4	0.99	-2.42	10.4 - 16.4	SG-Sysmex XN series	Pass
	AF5-4	15.9	20.0	0.40	-10.25	18.8 - 21.2	SG-Sysmex XN series	Fail
	AF5-5	21.6	28.8	0.96	-7.50	25.9 - 31.7	SG-Sysmex XN series	Fail
Subspecialty: WBC Auto Differential	**Analyte Score: 0%**							
Monocytes %	***Sysmex Corporation XN2000***							
	AF5-1	7.3	2.5	0.30	16.00	1.6 - 3.4	SG-Sysmex XN series	Fail
	AF5-2	5.2	1.1	0.29	14.14	0.2 - 2.0	SG-Sysmex XN series	Fail
	AF5-3	2.7	1.2	0.26	5.77	0.4 - 2.0	SG-Sysmex XN series	Fail
	AF5-4	7.4	1.6	0.17	34.12	1.1 - 2.1	SG-Sysmex XN series	Fail
	AF5-5	7.2	2.5	0.30	15.67	1.6 - 3.4	SG-Sysmex XN series	Fail
Subspecialty: WBC Auto Differential	**Analyte Score: 0%**							
Eosinophils %	***Sysmex Corporation XN2000***							
	AF5-1	0.8	13.3	0.46	-27.17	11.9 - 14.7	SG-Sysmex XN series	Fail
	AF5-2	26.9	16.6	0.32	32.19	15.6 - 17.6	SG-Sysmex XN series	Fail
	AF5-3	27.0	16.7	0.30	34.33	15.8 - 17.6	SG-Sysmex XN series	Fail
	AF5-4	1.3	15.0	0.42	-32.62	13.7 - 16.3	SG-Sysmex XN series	Fail
	AF5-5	1.1	13.5	0.45	-27.56	12.2 - 14.8	SG-Sysmex XN series	Fail

In this particular instance, the lab did not use the barcode provided on the PT sample. Instead, the lab applied their own barcode which triggered the sample to be tested in patient mode leading to failures on the differential parameters. The barcode provided by the PT provider would have triggered the sample to be tested in the correct QC mode and the lab would have recovered the correct values.

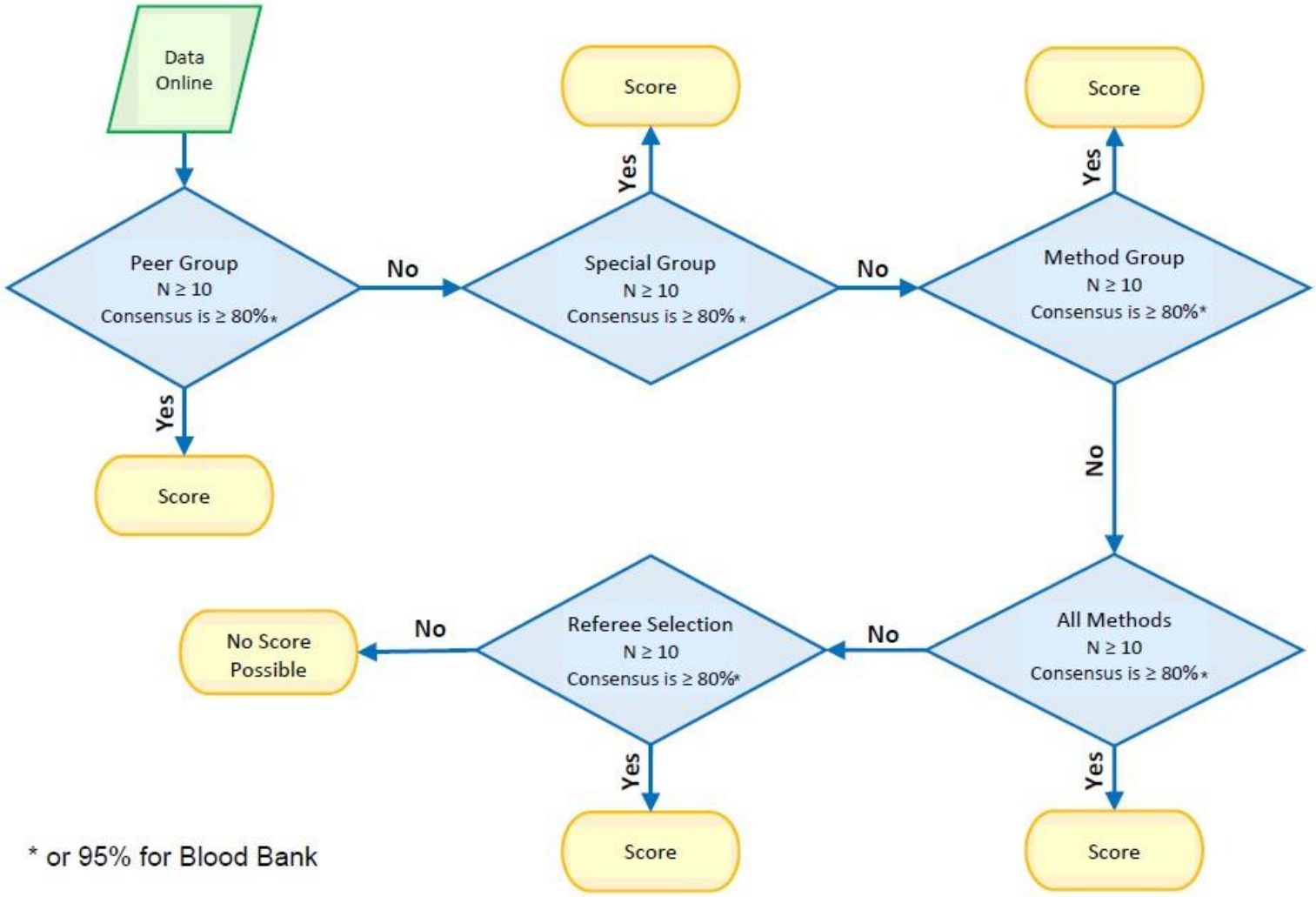
Not following lab protocol

- Repeating PT samples if you would not repeat similar results of a patient
- Referral of PT samples to another lab
- Splitting PT samples to run on multiple analyzers
- Sharing results with other labs
- The tech with the most experience always runs the PT samples
- Reviewing the PT images as a group, or with the pathologist

Other common PT failures:

- Improper storage of samples
- Improper mixing of samples
- Reporting results in incorrect units
- Temperature/humidity issues in lab

PT Scoring Cascade



Non-graded situations

- Non-consensus
- Insufficient peer group
- Not scored samples

Non-consensus

6230- KOH Slides	KOH-4			KOH-5		
KOH slide	Result	N	%	Result	N	%
Fungal Smear	*Yeast/fungal elements present	18	64.29%	*Yeast/fungal elements present	28	100.00%
	No yeast/fungal elements	10	35.71%			
	**not scored, non-consensus					

- **Non-consensus - Self-assessment needed:** Consensus [agreement ≥80% (or ≥95% Blood Bank)] is the percent of participant results within the acceptable range or match the expected target. It is calculated by dividing the number of results that match the accepted response(s) by the total number of results in the peer group.

- If consensus and peer size meet the minimum acceptable requirements for the analyte, then the peer group is used as a scoring group.

- If less than 80% of the results fall within the acceptable range, the report will state “Non-consensus - Self-assessment needed".

Insufficient peer group

Sample	Reported Method	Analyte	Result	Acceptable Response(s)	Scoring Group	Status	Comments
Module: 5450, Meningitis Multiplex							
MEP-6	*BioFire FilmArray MEP / Samples 1, 6, 11*						
		Escherichia coli K1	Not detected	Not detected	AG-All Method Group	***	Not scored - insufficient peer group
		Haemophilus influenzae	Not detected	Not detected	AG-All Method Group	***	Not scored - insufficient peer group
		Listeria monocytogenes	Detected	Detected	AG-All Method Group	***	Not scored - insufficient peer group
		Neisseria meningitidis	Not detected	Not detected	AG-All Method Group	***	Not scored - insufficient peer group

Reviewed By: _____ Date: _____
(Lab Director/Designee)

* PG - Peer Group MG - Method Group SG - Special Group AG - All Method Group REF - Referee Group *** - Self-assessment needed

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Not scored - insufficient peer group (*Self-assessment needed):**

WSLH PT may utilize this option in the following cases:

- If there are not enough participants using a specific instrument and/or method to create a statistically significant peer scoring group and results from that instrument/method could not be combined with other related instruments/methods to constitute a valid peer scoring group.
- If a sample matrix or instrument/method incompatibility issues exist and results could not be scored by the AG: All Methods Group.
- If n<10 for quantitative analytes, n<10 for regulated qualitative analytes, or if n<5 for non-regulated qualitative analytes.

Not scored samples

Subspecialty: Chemistry **Analyte Score: 100%**

TIBC, measured ug/dL ***Ortho Diagnostics VITROS 5600 / Vitros dTIBC / Chromazurol B***

CET-1	122	120	4.9	0.41	96 - 144	MG-Chromazurol B	***	Not scored - sample problem
CET-2	<60	60	0.0	---	48 - 72	MG-Chromazurol B	***	Not scored - sample problem
CET-3	543	564	16.8	-1.25	451 - 677	MG-Chromazurol B	***	Not scored - sample problem
CET-4	<60	60	0.0	---	48 - 72	MG-Chromazurol B	***	Not scored - sample problem
CET-5	<60	60	0.0	---	48 - 72	MG-Chromazurol B	***	Not scored - sample problem

TIBC-Measured: this analyte experienced non-consensus this event for all samples.
The reported concentrations were much lower than expected compared to the intended target.

Subspecialty: General Immunology **Analyte Score: 100%**

HBsAg ***Ortho Diagnostics VITROS 5600***

YB-11	Reactive	Reactive	AG-All Method Group	Pass	
YB-12	Reactive	Reactive	AG-All Method Group	Pass	
YB-13	Non-reactive	Non-reactive	AG-All Method Group	Pass	
YB-14	Non-reactive	---	SG-Ortho Diagnostics VITROS Instruments	***	Not scored - see Event Notes
YB-15	Non-reactive	Non-reactive	AG-All Method Group	Pass	

HBsAg: For sample YB-14, Vitros users were not scored. Pre-shipment testing indicated a LOW Positive reaction which could not be detected by Vitros Instruments. All other instruments were able to be scored for this sample.

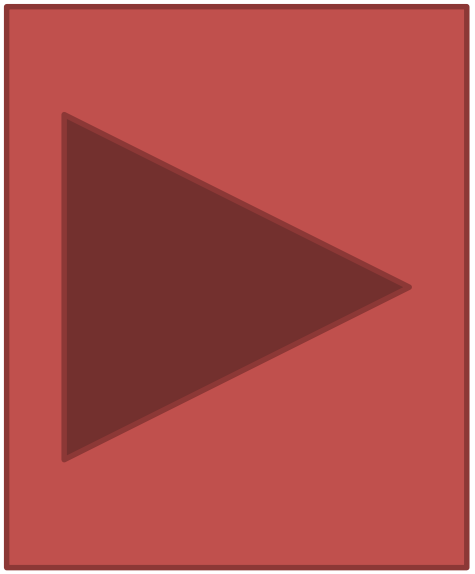
Referee scoring example

Sample	Reported Method	Analyte	Result	Acceptable Response(s)	Scoring Group	Status
Module: 6240, Respiratory Multiplex						
RP-6	*BioFire Respiratory Panel RP2.1 / Samples 1, 6, 11*					
		Adenovirus (RP)	Not detected	Not detected	PG-BioFire Respiratory Panel RP2.1	Pass
		Bordetella (RP)	Not detected	Not detected	REF-Referee	Pass
		Chlamydophila pneumoniae	Not detected	Not detected	PG-BioFire Respiratory Panel RP2.1	Pass
		Coronavirus	Not detected	Not detected	PG-BioFire Respiratory Panel RP2.1	Pass

Referee Scoring Group: A referee group consists of laboratories that have satisfactory proficiency testing performance for all testing events for at least one year. The referees selected (a minimum of ten labs) represent a cross-section of the participants for the purpose of determining the correct response for the specimens in a testing event for a specific test, analyte, subspecialty, or specialty.

Follow-up & Prevention

- Follow up process after report received
- Troubleshooting
- Reasons for following up
- Actions to prevent future failures



Follow up

- Review Evaluation report for failures or not scored situations
- Review Event notes, statistics, and peer data
- Troubleshoot, as needed
  - Repeat sample if possible
  - Request available sample from PT provider, if necessary
  - Call PT provider for troubleshooting assistance, if necessary
- Document corrective action

Why follow up?

Preparing for CMS Inspections:

- Documentation is key!
- Compliance & Following PT rules (see resource PT flyer)

Improving Laboratory Quality:

- Ensuring staff is trained and competent
- Strengthening lab protocols & procedures

Ultimate Goal: Provide accurate, reliable results to clinicians

Prevention

1. Save ship dates/due dates to lab calendar
    - Shipping notifications
    - Missing results notifications

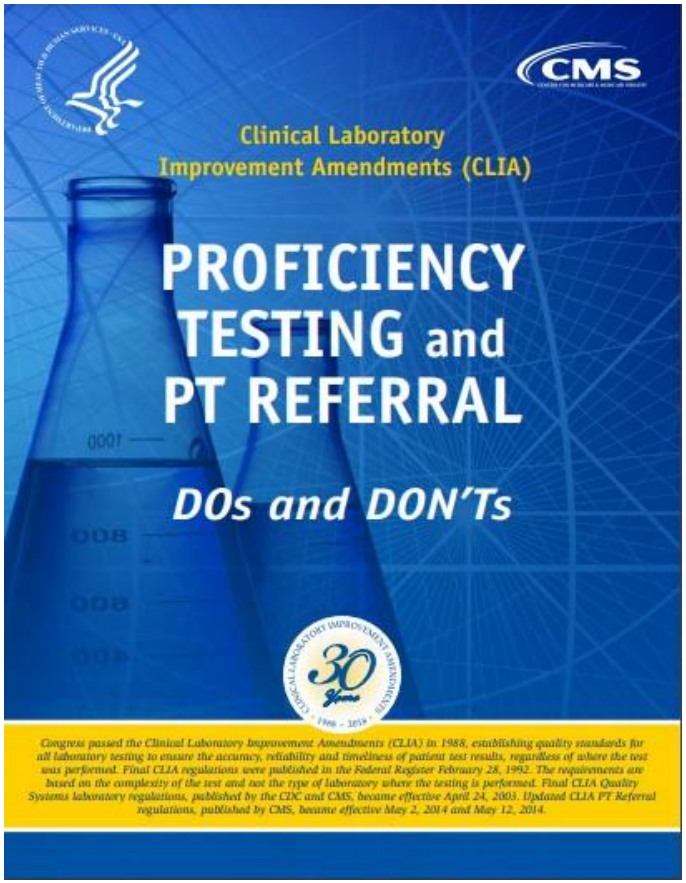
2. Check samples as soon as received in lab
    - If broken/missing contact PT provider right away
    - Store samples per cover sheet instructions

3. Read general and supplemental instructions before testing; instructions may have changed

4. Confirm setup information is correct

5. Create and review data submission report to confirm results are all entered, and entered correctly by the due date

Resources



[CLIA Proficiency Testing Printout]

WSLH Proficiency Testing www.wslhpt.org
2601 Agriculture Drive • Madison, WI 53718 • (800) 462-5261 • Fax (608) 265-1111

Proficiency Testing (PT) Failure Corrective Action Worksheet

Year:	Date Samples Received:
Event Name:	Date Samples Tested:
Sample ID(s):	Date Results Submitted:
Analyte(s):	Date Results Due to PT provider:
	Personnel Who Performed the Testing:

Sample Storage and Handling:

Yes ☐	No ☐	Were the samples received on time and in an acceptable condition?
Yes ☐	No ☐	Were the samples stored according to the instructions?
Yes ☐	No ☐	Were the samples hemolyzed (if whole blood)?
Yes ☐	No ☐	Did the samples contain excessive precipitate, turbidity, or bacterial contamination?
Yes ☐	No ☐	Were the samples at the proper temperature before analysis (per instructions)?
Yes ☐	No ☐	Were the samples properly mixed?
Yes ☐	No ☐	Were the samples tested according to the instructions?
Yes ☐	No ☐	Was there a time delay before or during analysis?

Notes:

Clerical Errors:

Yes ☐	No ☐	Were results submitted by the due date?
Yes ☐	No ☐	Were the correct samples used and/or reported (sample mix-up)?
Yes ☐	No ☐	Were the results reported under the correct analyte?
Yes ☐	No ☐	Were the results reported with the correct instrument/kit?
Yes ☐	No ☐	Was the correct method principle and reagent selected (if applicable)?
Yes ☐	No ☐	Was there a dilution/calculation error?
Yes ☐	No ☐	Were the results reported in the designated units?
Yes ☐	No ☐	Were all the samples reported with a result or exception code (not left blank) for each listed analyte?
Yes ☐	No ☐	Do the results on your evaluation report match the results from the instrument printout and/or worksheet?

Notes:

Quality Control (QC):

Yes ☐	No ☐	Were the QC results within range on the date the PT samples were tested?
Yes ☐	No ☐	Were there any shifts or trends in the QC values the week before, on the day, or after the PT samples were tested?

Notes:

[Corrective Action Worksheet]

Q & A time

Thank you for your time!

Your Q&A submissions will be read in the order we've received them. We will do our best to get to all of your questions.

Thank you!
How Can We Help?

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Questions? Contact:

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