Preparing Your Laboratory For The CLIA 2024 PT Changes

Bremansu Osa-Andrews

PhD, DABCC, NRCC.

University of Florida

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Disclosures

- Honorarium from QuidelOrtho.

Learning Objectives

At the end of this session, participants will be able to:

1. Summarize the CLIA Proficiency Testing Final Rule's historical aspects and other provisions.
2. Describe the finalized CLIA requirements pertaining to the nonmicrobiological-clinical chemistry and immunoassays, including the acceptable limits/ total allowable error.
3. Explain some applicable steps laboratorians can take to adhere to the CLIA regulatory changes.
4. Describe essential best practices to avoid noncompliance in PT as well as during CLIA inspections.

CLIA 1988

- **"CLIA 88"** is the acronym for the Clinical Laboratory Improvement Amendments of 1988.

- On October 31, 1988 (Effective 1992), US congress enacted CLIA 1988 LAW to ensure the **accuracy** and **reliability** of testing in all laboratories that test human samples with the intention of providing information to aid in diagnosis, prevention and treatment of diseases, or the assessment of health in humans.

- The law also requires all such laboratories to be certified by the U.S. Department of Health and Human Services (DHHS) and those laboratories (approximately 35967, as of January 2020) that perform **nonwaived testing** (moderate to high complexity tests to enroll in the DHHS-approved PT program and comply with the PT regulations).

Testing complexity and Proficiency testing

- **FDA administers CLIA** categories (testing complexity) based on 7 criteria:

  1.Knowledge; 2. Training and experience; 3. Reagents and materials preparation; 4. Characteristics of operational steps; 5. Calibration, quality control, and proficiency testing materials; 6. Test system troubleshooting and equipment maintenance.

  Each criterion is assigned Levels 1-3 and added up. 12 is the cutoff.

- **Nonwaived testing**: Collectively moderate (</=12) and high complexity testing (>12). The Lab needs a CLIA certificate.
- Manufacturer of Moderate complexity test can then apply for waiver
- **Waived tests:** Simple tests, Low risk, home use or certificate of waiver (COW), **NO CLIA PT required. 142 tests currently have COW.**

- **PPM:** Provider-performed microscopy: PPM certificate required.
- Any test not yet CLIA categorized is automatically >12 high complexity.
- **"CLIA-exempt"** formally refers to a laboratory (not a test system) with stringent state laws.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

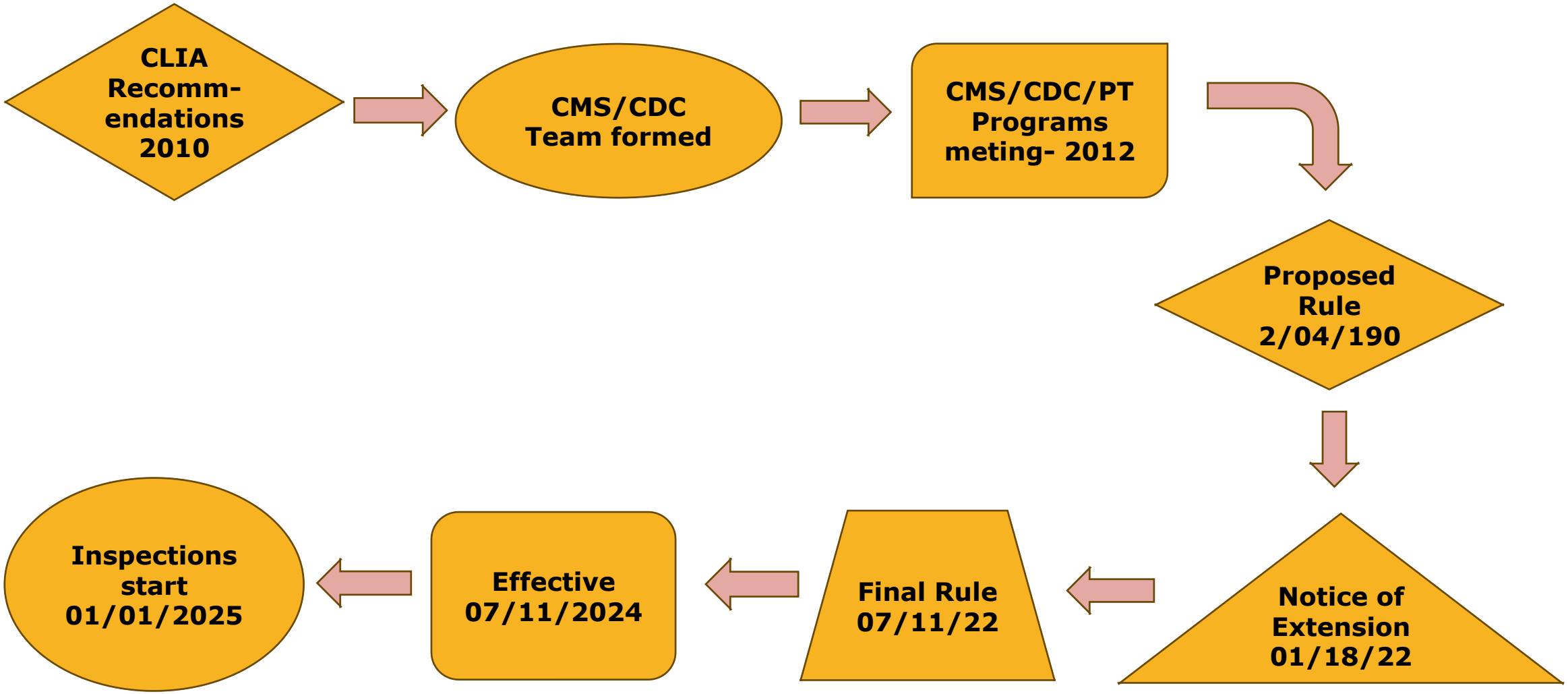
2024 CLIA approved PT programs

- American Association of Bioanalyst – Medical Laboratory Evaluation (AAB-MLE)
- American Proficiency Institute (API)
- ACCUTEST, INC. (One world Accuracy, Vancouver, Canada)
- The College Of American Pathologists – SURVEYS
- Commonwealth Of Pennsylvania
- Puerto Rico Proficiency Testing Service Program
- WSLH Proficiency Testing (PT)

CMS 2024 approved list as of 12/19/2023.

https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ptlist.pdf

CLIA rule at a glance



CLIA PT Final Rule: Categories

Microbiology PT changes

Non-Microbiology PT changes

Addition/Deletion of Analytes

Definitions

Criteria for Acceptable Performance

Testing of Samples, PT Referral for Waived Tests

Other changes, PT Programs

Non-microbiology PT changes

Toxicology: PT programs must provide samples that cover the full range of samples that could occur in patient specimens.

Immunohematology: Criteria for acceptable performance for unexpected antibody detection revised from **80%** to **100%.**

Hematology

- Units of reporting for prothrombin time includes seconds and INR; laboratories must report prothrombin time in the same manner as they report patient results.
- Laboratories performing both cell counts and differentials must enroll and participate in PT for both.
- Criteria for acceptable performance for “cell identification” changed from 90% to 80%.

Non-microbiology PT changes : Definitions

- **Peer group:** A group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems ***and is not to be assigned using the reagent lot number level.*** Must be >=10 labs.

- **Acceptance limit:** The symmetrical tolerance (plus and minus) around the target value.

- **Target value** (>=10 labs)
  - The mean of all participant responses after removal of outliers (>3SD);
  - The mean established by a definitive method or reference method (Eg. HgA1C).
  - For <10 labs, the mean of all participant responses (minus outliers) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate. **3-9 lab category.**

Analytes added/deleted non-microbiology PT changes

- Current availability of PT materials and the number of PT programs offering PT.
  - **3 PT *programs carry the analyte*.** *199 initial analytes identified (96 in routine chemistry, 27 in endocrinology, 28 in toxicology, 25 in general immunology, 21 in hematology, 2 for antibody identification).*

- Volume of patient testing performed nationwide.
  - ***Threshold: 500000 tests (68 of 81 analytes meet threshold)***

- Impact on patient health and/or public health
  - ***Review of LPGs, critical values and analyte's classification by the FDA. 34 analytes***

- Cost and feasibility of implementation
  - ***Final 29 analytes***

Non-Microbiology PT Changes: Analytes added

- 60 LPGs listed in the NGC for LDL cholesterol
- 31 LPGs for hemoglobin A1c
- 27 LPGs for troponin

TABLE 1: Analytes Proposed for Addition to Subpart I

CLIA Regulation	Analytes
General Immunology § 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry § 493.931	B-natriuretic peptide (BNP) ProBNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T
Endocrinology § 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactin Parathyroid hormone Testosterone Vitamin B12
Toxicology § 493.937	Acetaminophen, serum Salicylate Vancomycin

Non-microbiology PT changes : Deleted analytes

- **§493.931**
  - LDH isoenzymes

- **§493.93**
  - Ethosuximide
  - Quinidine
  - Primidone
  - Procainamide (and its metabolite, N-acetyl procainamide)

Criteria for Acceptable Performance

- Many limits changed from standard deviations to **percentage-based limits.**

- **Fixed Concentration** Units have been added to Fixed Percentage Units to address lower concentrations, for example:
  - Bilirubin total: ±20% or ±0.4 mg/dL (Common Ref Int: 1–1.2 mg/dL)
  - Thyroid-stimulating hormone: -±20% or ±0.2 mIU/L
  - Lithium: ±15% or ±0.3 mmol/L

- **Hemoglobin A1C:** Controversial 8% of the target. CAP (6%).

- PT referral, waived testing policy.

CLIA New Acceptable Limits

2025 Criteria for Acceptable Performance

Analyte or test	Current CMS or CAP criteria for acceptable performance	New CMS or CAP criteria for acceptable performance to be implemented on January 1, 2025	Comments
Alpha-fetoprotein (AFP)	Target value ± 3 SD	Target value ± 20%	Criteria changed
****Cancer antigen (CA) 125**	Currently offered in the Tumor Markers (TM) program with target value ± 3 SD	Target value ± 20%	New for this program as newly CMS regulated analyte for 2025.
Carcinoembryonic antigen (CEA)	Target value ± 25% or ± 1.2 ng/mL (greater)	Target value ± 15% or ± 1 ng/mL (greater)	New CMS regulated analyte for 2025. *Criteria changed
Cortisol	Target value ± 25%	Target value ± 20%	Criteria changed
Ferritin	Target value ± 3 SD	Target value ± 20%	New CMS regulated analyte for 2025. *Criteria changed
Folate, serum	Target value ± 3 SD	Target value ± 30% or ± 1 ng/mL (greater)	New CMS regulated analyte for 2025. *Criteria changed
Human chorionic gonadotropin (hCG)	Target value ± 3 SD	Target value ± 18% or ± 3 mIU/mL (greater)	Criteria changed
Immunoglobulin E (IgE)	Target value ± 3 SD	Target value ± 20%	Criteria changed
Prostate-specific antigen (PSA), total	Target value ± 3 SD or ± 0.2 ng/mL (greater)	Target value ± 20% or ± 0.2 ng/mL (greater)	New CMS regulated analyte for 2025. *Criteria changed
Prostate-specific antigen PSA, complexed (cPSA)	Target value ± 3 SD or ± 0.2 ng/mL (greater)	Target value ± 3 SD or ± 0.2 ng/mL (greater)	No change
PSA, free	Target value ± 3 SD or ± 0.2 ng/mL (greater)	Target value ± 3 SD or ± 0.2 ng/mL (greater)	No change
p2PSA	Educational	Educational	No change
Prostatic acid phosphatase (PAP)	Target value ± 3 SD	Target value ± 3 SD	No change
Triiodothyronine (T3)	Target value ± 3 SD	Target value ± 30%	Criteria changed

Endocrinology

Endocrinology CLIA 2024		
Analyte or Test	NEW Criteria for AP	OLD AP
Cancer antigen (CA) 125	TV ± 20%	None
Carcinoembryonic antigen (CEA)	**TV ± 15% or ± 1 ng/dL (greater)**	None
Cortisol	TV ± 20%	TV ± 25%
Estradiol	TV ± 30%	None
Folate, serum	TV ± 1 ng/mL or ± 30% (greater)	None
Follicle stimulating hormone	TV ± 2 IU/L or ± 18% (greater)	None
Free throxine	TV ± 0.3 ng/dL or ± 15% (greater)	TV ± 3SD
Human chorionic gonadotropin	**TV ± 18% or ± 3 mIU/mL (greater) or positive or negative**	TV ± 3SD or positive or negative
Luteinizing hormone	TV ± 20%	None
Parathyroid hormone	TV ± 30%	None
Progesterone	TV ± 25%	None
Prolactin	TV ± 20%	None
Testosterone	TV ± 20 ng/dL or ±30% (greater)	None
T3 uptake	TV ± 18%	TV ± 3SD
Triiodothyronine	TV ± 30%	TV ± 3SD
Thyroid stimulating hormone	TV ± 20% or ± 0.2 mIU/L (greater)	TV ± 3SD
Thyroxine	TV ± 20% or ± 1.0 mcg/dL (greater)	Same
Vitamin B12	**TV ± 25% or ± 30 pg/mL (greater)**	TV ± 30%

Link to the New 2024 CLIA Acceptable Limits: **https://westgard.com/clia-a-quality/quality-requirements/2024-clia-requirements.html**
Accessed 10/03/2024

Practical steps

- Know the CLIA changes
- Train all your staff
- Register with approved PT program
- Revisit old validations
- Calibration/Linearity verification

Calibration/Linearity verification

Linearity verification evaluation

CAP Linearity evaluation results can be Linear, Nonlinear or Imprecise.

Focus: Lab mean
REa= TEa/4 or about 1SD.

Calibration verification

Linear and not Verified and not Linear or Verified.

Focus: Peer target
REa= TEa/2 or about 2SD

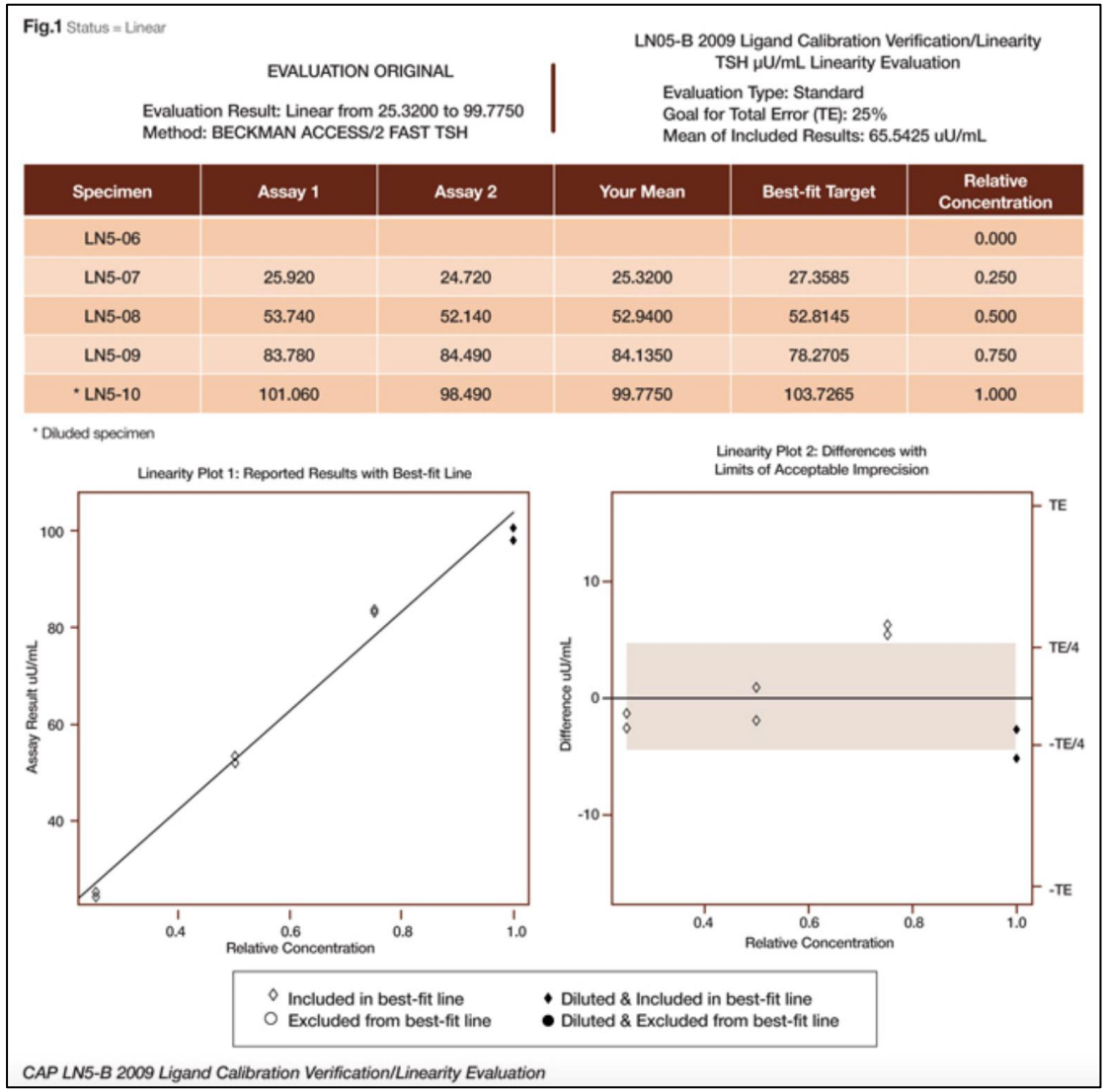


Fig.1 Status = Linear

EVALUATION ORIGINAL

Evaluation Result: Linear from 25.3200 to 99.7750
Method: BECKMAN ACCESS/2 FAST TSH

LN05-B 2009 Ligand Calibration Verification/Linearity
TSH µU/mL Linearity Evaluation

Evaluation Type: Standard
Goal for Total Error (TE): 25%
Mean of Included Results: 65.5425 uU/mL

Specimen	Assay 1	Assay 2	Your Mean	Best-fit Target	Relative Concentration
LN5-06					0.000
LN5-07	25.920	24.720	25.3200	27.3585	0.250
LN5-08	53.740	52.140	52.9400	52.8145	0.500
LN5-09	83.780	84.490	84.1350	78.2705	0.750
* LN5-10	101.060	98.490	99.7750	103.7265	1.000

* Diluded specimen

CAP LN5-B 2009 Ligand Calibration Verification/Linearity Evaluation

Improving accuracy

- Error management
- Method comparison
- Recovery experiments
- Regression
- Hypothesis

Improving accuracy

Your method validation impacts your PT performance.

- Total allowable (TEa) for each analyte is published by CLIA and usually the same as the PT ALs

The TEa has 2 components: Systematic error allowable- **(SEa) and** Random error allowable **(REa).**

The TEa is the maximum amount of error allowed for your analytical assay experiments; both random and systematic. Basically, how much error is medically acceptable.

- Calculate the error in your system as: **Total Analytical Error (TAE) = Bias + 1.96SD**

- Copies of the list of the CLIA Acceptable performance limits of analytes can be found here.
  - https://www.clinlabnavigator.com/clia-acceptable-test-performance-criteria.html

Allowable systematic error/bias/recovery

	N	Slope	Intercept	Error
Overall	6	1.034	-0.062	0.093 ng/dL (conc) or 6.5%

LINEAR within SEa of 0.143319 ng/dL (conc) or 10.0%

Statistical Analysis

	Assigned	Pct	Mean	Percent Recovery	Accuracy	Reportable Range	Linearity
Cal-01	0.00	--	0.000	100.0	--	--	Pass
Cal-02	0.55	--	0.550	100.0	--	--	Pass
Cal-03	0.95	--	0.960	101.1	--	--	Pass
Cal-04	2.00	--	1.885	94.2	--	--	Pass
Cal-05	2.98	--	3.230	108.4	--	--	Pass
Cal-06	6.21	--	5.975	96.2	--	--	Pass

See User's Specifications on the next page for Pass/Fail criteria

Supporting Statistics

Corr Coef (R)	0.9952	SubRange Bounds	None
Bias	0.052 (5.100 %)	Points (Plotted/Total)	36/36
X Mean ± SD	1.024 ± 0.656	Outliers	Not Tested
Y Mean ± SD	1.076 ± 0.645	Scatter Plot Bounds	None
Std Dev Diffs	0.065		

User's Specifications

Allowable Total Error	0.43 ng/dL (conc) or 30.0%
Systematic Error Budget	33.33%
Allowable Systematic Error	0.143319 ng/dL (conc) or 10.0%

Supporting Data

Analyst	DW
Date	11 Apr 2023
Units	ng/dL
Reportable Range	0.25 to 6 ng/dL
Value Mode	Pre-Assigned
Controls	FT4 Cal 234069 exp 30 Nov 2023
Reagent	--
Calibrators	--
Comment	

It's safe to consider the CLIA AL as the TEa. Many labs do this.

Decide what % of TEa to allocate for SEa and REa.

CLIA SEa Budget is 25-50% of the TEa. In this example, 33% was used.

CLIA REa Budget is 16-25% of the TEa.

What if I obtain a poor regression statistics?

Regression Analysis

	Deming	Passing-Bablok	Regular
Slope	1.206 (1.167 to 1.245)	1.108 (1.073 to 1.147)	1.200 (1.161 to 1.239)
Intercept	-8.14 (-13.58 to -2.69)	-1.02 (-1.82 to 0.55)	-7.61 (-13.05 to -2.17)
Std Err Est	12.69	--	12.67

95% Confidence Intervals are shown in parentheses

1. Check samples' integrity.
2. Increase sample size.
3. Justifiable elimination of outliers.
4. **Hypothesis testing of method comparison experiments.**

Hypothesis testing

Paired t-tests

Method comparison – *same* samples performed using two different instruments or methods.

Unpaired t-tests

Method comparison – *different* samples performed using two different instruments or methods.

Ho: There is no difference between the 2 means.
H1: There is a difference between the 2 means
The absolute t-statistic (magnitude) is LESS than T critical so, fail to reject the null hypothesis.
If the absolute t-value is greater than the critical value, you reject the null hypothesis.
The pValue is GREATER than the standard 0.05, so even if there was a difference, it is not significant. Simply, no significant difference between the two means.
The pValue is LESS than the standard 0.05, so even if there was a difference, there is a significant difference between the two means.

Best Practices For Proficiency Testing

- The PT checklists
- Activity menu

- Evaluate bias
- Review PT relative distance graph

- Ungraded challenge: Exception codes, Participant summary
- Investigate PT failures thoroughly

Activity menu and Checklist

- **Activity menu**: Ensure that your test menu is update. Remove old tests, include new tests.

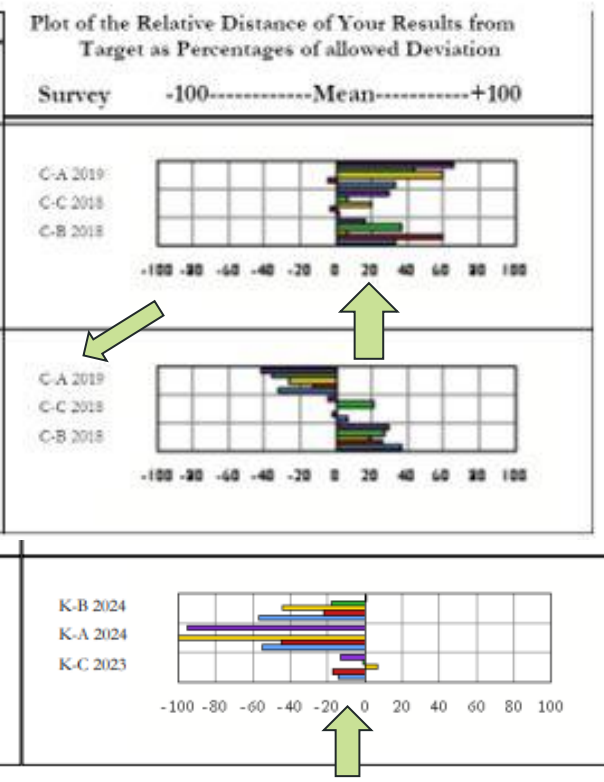
- **Checklists**: All commons, chemistry and toxicology, blood gases.
- **Phase I**: No serious risk on patient care.
- **Phase II**: Poses serious risk on patient care.

- **COM.01100** Ungraded PT Challenges **Phase II**:
- COM.01200 Activity Menu **Phase I**:
- PT Attestation Statement **Phase II**
- COM.01700 PT and Alternative Performance Assessment Result Evaluation **Phase II**
- COM.01800 PT Interlaboratory Communication **Phase II**
- COM.01900 PT Referral **Phase II**

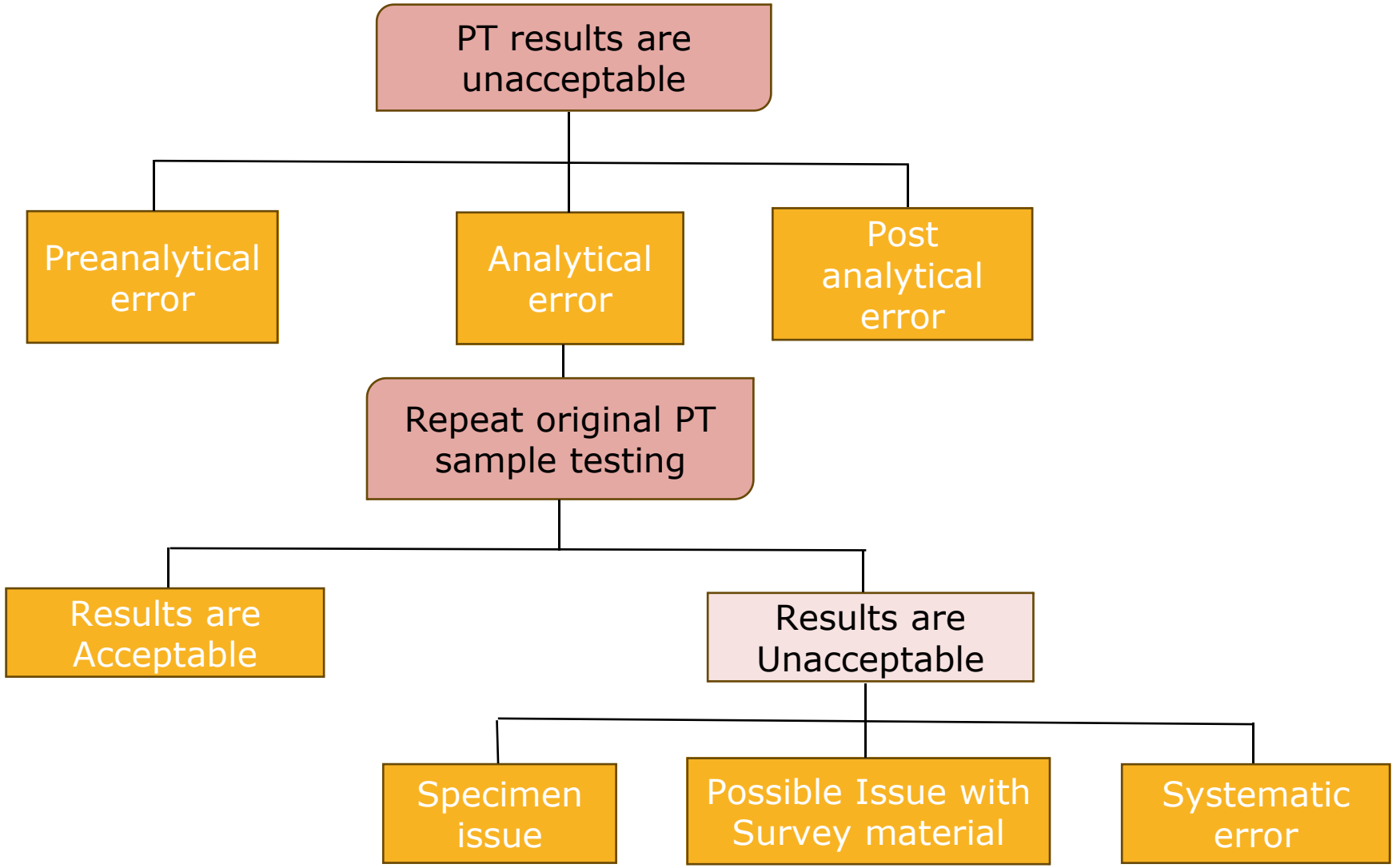
Evaluate bias

- **Albumin** and T3 need to be investigated for **persistent** + and – bias respectively.
- Albumin CHM-01: SDI = **+2.4** (>2.0). **Establish a 2.0 SDI-investigate policy for the Lab.**
- Alkaline phosphatase has several CHM-01, CHM-02, CHM-05: **SDI < –2.**
- Alkaline phosphatase current survey C-A 2019 does have significant NEGATIVE bias

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Albumin	CHM-01	2.8	2.60	0.08	526	+2.4	2.3	2.9	Acceptable
g/dL	CHM-02	2.8	2.64	0.09	528	+1.8	2.3	3.0	Acceptable
DYE BINDING-BCG	CHM-03	5.2	4.89	0.19	527	+1.6	4.4	5.4	Acceptable
VITROS 5,1 FS/4600/560	CHM-04	1.5	1.51	0.06	524	-0.1	1.3	1.7	Acceptable
1	CHM-05	2.7	2.60	0.08	522	+1.1	2.3	2.9	Acceptable
Alkaline Phosphatase	CHM-01	100	114.5	4.9	524	-2.9	80	149	Acceptable
U/L	CHM-02	225	252.7	10.8	527	-2.6	176	329	Acceptable
VITROS 5,1 FS/4600/560	CHM-03	103	112.0	5.4	530	-1.7	78	146	Acceptable
VITROS/37 C	CHM-04	35	36.5	2.5	530	-0.6	25	48	Acceptable
2	CHM-05	103	114.3	5.0	528	-2.3	80	149	Acceptable
Triiodothyronine (T3)	K-06	263.0	261.99	24.07	183	0.0	189.7	334.2	Acceptable
ng/dL	K-07	65.0	69.99	8.84	180	-0.6	43.4	96.6	Acceptable
BECKMAN UNICEL DxI	K-08	285.0	321.07	26.83	182	-1.3	240.5	401.6	Acceptable
	K-09	140.0	148.36	12.54	183	-0.7	110.7	186.0	Acceptable
	K-10	82.0	98.43	9.55	183	-1.7	69.7	127.1	Acceptable



Investigate PT failures thoroughly



Investigating failure

- Gamma glutamyl Transferase: GGT
- CHM-02 failed (SDI: >3.0). **Evaluate CHM-02 as failure.**
- CHM-01, CHM-03, CHM-05 are (SDI: >2.0). Evaluate.
- Repeat test all 5 samples. If results are closer to target, investigate the cause of random error.
- If results don't improve, there is systematic error.
- Correlate with QC, look up patient report during the survey period to evaluate potential patient impact.

Test
Unit of Measure
Peer Group

Gamma Glutamyl Trans
U/L
VITROS 5,1 FS/4600/560
VITROS/37 C

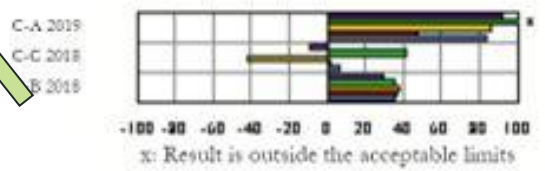
3

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	Limits of Acceptability S.D.I	Lower	Upper	Your Grade
CHM-01	176	164.5	4.0	408	+2.9	152	177	Acceptable
CHM-02	384	354.0	9.4	414	+3.2	325	383	Unacceptable
CHM-03	192	179.2	4.7	414	+2.7	165	194	Acceptable
CHM-04	55	52.3	1.6	414	+1.7	47	58	Acceptable
CHM-05	175	164.2	4.2	412	+2.6	151	177	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100



x: Result is outside the acceptable limits

Ungraded evaluation

- Evaluate exception Codes
- Use participant Summaries
- Mean is given for peer group
- Median for <10 labs

Evaluation

- K-06: Error 1.5% of median
- K-06: Error 0% of median
- K-06: Error 5.2% of median
- K-06: Error 10% of median
- K-06: Error 4% of median
- Grading: (+/-3SD, Old CLIA)
- New CLIA: 20% or 0.2 mIU/L

EVALUATION
ORIGINAL

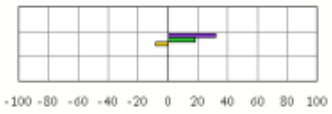
K-B 2024 Ligand-General

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Thyroid Stim Hormone	K-06	13.80			7				See Note [20]
uIU/mL (mIU/L)	K-07	0.02			6				See Note [20]
SIEMENS IMMUL 2000/XPi	K-08	20.20			7				See Note [20]
	K-09	4.02			7				See Note [20]
	K-10	0.65			7				See Note [20]

Evaluation and Comparative Method Statistics

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100



Participant Summary

Thyroid Stimulating Hormone (TSH) - µIU/mL (mIU/L)	K-06				K-07				K-08				K-09				K-10			
METHOD	N	MEAN	SD	CV%	N	MEAN	SD	CV%	N	MEAN	SD	CV%	N	MEAN	SD	CV%	N	MEAN	SD	CV%
ABBOTT ALINITY CI SER	323	11.357	0.458	4.0	288	0.020	0.000	0.0	320	15.673	0.592	3.8	323	3.799	0.142	3.7	326	0.533	0.022	4.2
ABBOTT ARCHITECT i	189	11.797	0.537	4.6	171	0.020	0.000	0.0	188	16.357	0.746	4.6	188	3.930	0.187	4.8	187	0.548	0.026	4.8
BECKMAN ACCESS,LXi,DxC	143	12.432	0.532	4.3	140	0.020	0.002	12.1	147	17.413	0.800	4.6	146	4.054	0.175	4.3	145	0.592	0.026	4.3
BECKMAN UNICEL DxI	328	12.070	0.556	4.6	314	0.020	0.001	7.5	325	16.838	0.796	4.7	329	3.956	0.194	4.9	327	0.584	0.026	4.4
MINDRAY CL-SERIES	15	17.321	0.788	4.5	15	0.027	0.005	16.7	14	24.181	0.669	2.8	15	5.371	0.153	2.8	15	0.826	0.014	1.6
ROCHE COBAS e411	74	13.080	0.593	4.5	72	0.038	0.005	13.5	74	17.944	0.751	4.2	74	4.516	0.222	4.9	74	0.771	0.040	5.2
ROCHE COBAS e600 SER	273	13.084	0.376	2.9	266	0.040	0.003	8.0	271	17.984	0.498	2.8	275	4.540	0.126	2.8	272	0.770	0.021	2.7
ROCHE e801/e402	413	12.446	0.322	2.6	400	0.046	0.006	14.0	412	17.178	0.442	2.6	413	4.312	0.113	2.6	412	0.740	0.020	2.7
SIEMENS ADV CNTR XP/XPT	32	15.076	1.300	8.6	31	0.036	0.012	33.3	31	21.273	1.563	7.3	32	4.884	0.431	8.8	31	0.690	0.089	13.0
SIEMENS ADV CNTR XP/XPT UL	38	14.678	0.446	3.0	38	0.034	0.006	16.1	39	20.431	0.784	3.8	38	4.732	0.154	3.2	39	0.651	0.025	3.8
SIEMENS ATELLICA IM	274	14.517	0.596	4.1	277	0.032	0.008	26.3	272	20.377	0.806	4.0	274	4.675	0.201	4.3	275	0.637	0.029	4.6
SIEMENS DIMENSION EXL	80	9.548	0.542	5.7	80	0.024	0.005	21.5	80	13.703	0.729	5.3	80	3.094	0.156	5.0	79	0.570	0.027	4.8
SIEMENS DIMENSION VISTA	103	9.479	0.336	3.5	103	0.020	0.002	10.5	103	13.695	0.539	3.9	102	2.997	0.111	3.7	103	0.532	0.021	3.9
SNIBE MAGLUMI SERIES	26	8.847	0.378	4.3	25	0.044	0.014	32.6	26	12.923	0.844	6.5	24	3.186	0.129	4.1	24	0.772	0.040	5.2
TOSOH ST AIA-PACK	11	16.665	0.777	4.7	11	0.038	0.006	15.8	11	23.025	1.176	5.1	11	5.565	0.268	4.8	11	0.796	0.038	4.8
VITROS 36/56/76,ECi/Q	259	18.959	0.655	3.5	202	0.025	0.009	34.4	259	26.470	0.985	3.7	259	5.943	0.205	3.5	262	0.600	0.030	4.9
VITROS IMMUNODIAG TSH3	10	15.413	0.894	5.8	10	0.027	0.008	30.5	10	21.615	1.445	6.7	10	4.932	0.220	4.5	10	0.640	0.035	5.4
DATA FOR GROUPS OF 3-9	**N**	**MEDIAN**	**MIN**	**MAX**	**N**	**MEDIAN**	**MIN**	**MAX**	**N**	**MEDIAN**	**MIN**	**MAX**	**N**	**MEDIAN**	**MIN**	**MAX**	**N**	**MEDIAN**	**MIN**	**MAX**
BECKMAN DXI 9000 ACCESS	5	13.84	10.29	14.27	5	0.02	0.02	0.02	5	19.10	13.97	20.89	5	4.36	2.99	4.61	5	0.67	0.40	0.74
SIEMENS ADV CNTR CP UL	4	14.34	13.82	15.40	4	0.03	0.03	0.04	4	21.42	18.79	22.15	4	4.74	4.24	4.91	4	0.63	0.59	0.67
SIEMENS ATELLICA CI	7	14.19	12.95	14.89	7	0.03	0.02	0.04	7	18.43	17.96	20.37	7	4.56	4.06	4.75	7	0.61	0.54	0.64
SIEMENS DIMENSION HM	3	10.03	9.16	10.41	3	0.02	0.02	0.03	3	13.34	12.74	13.92	3	2.95	2.89	3.39	3	0.57	0.56	0.61
SIEMENS IMMUL 2000/XPi	7	13.60	11.50	14.40	6	0.02	0.02	0.08	7	19.20	17.30	20.40	7	4.45	3.82	4.92	7	0.68	0.65	0.75

PT Documentation

- Document all investigations
- Document all evaluations
- 30 days limit
- PT audit

Your first inspection: January 2025+

- Be ready for a potentially more stringent inspection.
- Review previous PT data for impacted analytes and re-assess with current acceptance limit.
- Review all validation records for these analytes.
- If they fall short of current limits, repeat at least accuracy/method compare with outside lab.
- Confirm your laboratory is assigned to the correct peer group.
- Mark the shipping dates for proficiency test samples on the calendar.
- Review/enter/verify checklist, Avoid specimen handling and clerical errors; submit results by the due date.
- Review standard deviation index (SDI) data on the evaluation supplied by the proficiency test provider.
- Keep your daily %CV from your day-to-day QCs below 1/3 of the acceptable limit (%).

Preparing for your first inspection in 2025

Algorithm for evaluating SDIs

1. If no more than 1 of the 5 SDIs exceeds the same (+1 or -1) SDI limit, significant error is unlikely and further scrutiny is not needed.

2. If 2 or more SDIs exceed the same (+1 or -1) SDI limit, calculate the average SDI. If the average SDI is greater than 1.5, a significant systematic error is possible.

3. If the average SDI is less than 1.5, check whether 1 observation exceeds 3 SDI or the difference between the largest and smallest SDI exceeds 4.0. If either of these conditions exists, a significant random error is likely.

Algorithm developed by Cembrowski and colleagues

Source: Westgard

'The use of SDIs for many analytes is being phased out for percentages and/or concentrations instead. Ultimately, labs should pay attention to the newly published CLIA acceptance limits for each new or current analyte.' Based on biological variability data available.

Sources

- CLIA Website:
  - https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
- CLIA Communications ListServ:
  - https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12461
- Federal Register:
  - https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to

Q&A