College of American Pathologists

Laboratory Accreditation Program

Getting the Most Out of Your Proficiency Testing

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Chair, Continuous Compliance Committee
January 24, 2007

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Objectives

After participating in today's session, you will be able to:

- **Discuss the regulatory aspects and impact of proficiency testing (PT)**
- **Identify approaches to effectively manage and fully utilize PT in your laboratory**
- **List investigative techniques used to determine causes of poor PT performance and describe effective corrective actions**
- **Use PT summary discussions as continuing education opportunities**

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Proficiency Testing Do's

- **Enrollment**
- **Participation**
- **Evaluation of results**
- **Investigation of failures**
- **Corrective actions**
- **Maintenance of records**

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Proficiency Testing Don'ts

- Test samples differently than patient specimens
- Have same people always do testing
- Refer samples to another laboratory
- Discuss results before reporting
- Use PT samples for other purposes before submission date deadline

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Enrollment

- Required for all analytes listed in the PT Enrollment Guide
  - Updated annually
  - Available at CAP Web site
  - Included with order renewal forms

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Participation

- In addition to enrolling and testing samples, you must:
  - Ensure results are sent
  - Ensure they are sent by the deadline
  - Ensure all faxed pages are received
- Note: non-participation (failure to receive results) = unsatisfactory

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Evaluation of PT Results

To identify any deviation in proficiency testing from external requirements or facility's expectations that requires investigation and follow-up

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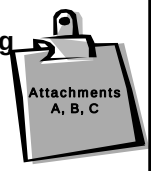
Reading the report

- **Performance on graded (acceptable vs. unacceptable)**
- **Ungraded results (codes)**
- **Bias on quantitative testing**
  - **Level of bias requiring action defined in procedure**



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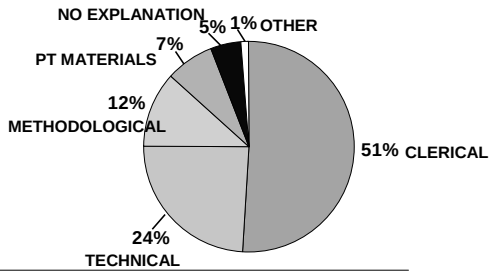
Reported Causes of PT Failures



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Clerical Errors

- Postanalytic phase
- Same importance as testing errors
- Examples:
  - Transcription
  - Method/reagent/instrument codes
  - Missing information (TNP, etc.)

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Technical Issues

Directly attributable to human actions:

- Reconstitution/pipetting/dilution errors
- Specimen mix-up
- Improper specimen handling
- Incorrect instrument set-up
- Failure to follow testing kit instructions
- Morphologic misinterpretation

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Methodologic Issues

- Mechanical difficulties
- Instrument software problems
- Frequency of calibration
- Inadequate reagent performance
- Inadequate maintenance/function checks
- Other instrument malfunction (intermittent electric problems)

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Issues with PT Testing Materials

- Hemolyzed, contaminated
- Unstable PT materials
- Perceived bias
- Matrix effect incompatible with method
- Late shipment

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Investigating PT Failures

- See Attachment "D" Investigation Flowchart

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Investigation

- Review the all-participant report received from your PT Provider
- Review reporting records
- Review sample preparation/handling, testing
- Verify that the PT material was processed in the correct instrument mode
- Review results from previous survey

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Investigation 2

- Review QC performance, instrument calibration, and reagent performance prior to, during, and after the original analysis of the PT challenge
- Contact the instrument/reagent manufacturer for assistance
- Retest the PT specimen(s), if possible or purchase additional specimens with different reagent lot

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Corrective Actions

- Design a process to verify clerical entries prior to PT result submission
  - Verify instrument/method codes
- Retrain testing personnel as to the proper procedures for sample preparation, testing, and reporting
- Modify (narrow) the QC acceptance range to detect problems sooner

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Corrective Actions 2

- Evaluate/increase frequency of calibration
- Perform instrument function verification
- Revise procedure to reflect corrective actions

*For more information, see NCCLS GP-27A "Use of Proficiency Testing to Improve the Clinical Laboratory

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Maintenance of Records

Original records

- Who performed testing/reported results
- Date/time of testing and reporting
- Worksheets/ instrument tapes
- Confirmation results were received

Investigation

- QC records
  - Date of testing
  - Before/after
- Maintenance at defined frequency
- Calibration as defined by procedure

Requirement listed in GEN. 11484

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Closing the Loop

- Include:
  - Explanation of investigation
  - Documentation of external validation
  - Determination of whether there has been impact on patient care
  - Implementation of new processes/procedures to prevent recurrence

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Not Closing the Loop

- May result in sanctions
  - Additional documentation
  - Suspension of testing
  - Cessation of testing

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Satisfactory PT Performance

- Is 80% for regulated analytes
  - and other analytes that have at least 5 challenges per PT event)
- Percentage varies for analytes with fewer than 5 challenges

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Unsatisfactory PT Performance

- Laboratories that have unsatisfactory performance for 1 or more analytes on an event will receive a PT Exception Summary (PTES) report. Labs must:
  - Investigate problem
  - Determine cause
  - Implement corrective actions
- Response to LAP is not required

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Unsuccessful PT Performance

- Is unsatisfactory performance on 2 of 3 PT events
- Laboratory will receive a PT Exception Summary (PTES) report
- Laboratory must suspend testing or implement plan of correction
- LAP must approve laboratory's action

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Case Study

Story line:
Ineffective investigation and corrective actions led to cessation of testing:
2004-C: + bias, all acceptable
2005-A: no results received (fax problem?)
2005B: + bias, all acceptable
2005-C: + bias, 40% acceptable (calibrator problem, almost expired)
2006-A: - bias, 60% acceptable (calibrator problem)
2006-B: ok

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Alternative Assessments

- **Participation in any formal PT program (for which enrollment is not required) including educational**
- **Split sample analysis with other laboratories**
- **Testing against an established method**

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Alternative Assessments

- **Testing against a reference sample**
  - **product calibrator**
  - **previously assayed material (*e.g.*, regional pool)**
- **Analysis of patient data**
  - **clinical correlation**
  - **delta checking; moving averages**
- **See NCCLS GP-29A "Assessment of Laboratory Tests When Proficiency Testing is Not Available [2002]"**

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Split-Sample testing: Quantitative

- Determine type of statistical analysis to use
- Determine criteria for acceptability
- Test samples representing AMR
- Test enough samples

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Split-Sample Testing: Qualitative

•If only 2 of 3 match, the sample size must be increased to 6

•5 of the 6 must match to achieve the same level of confidence.

95% confidence

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Continuing education

Formal CME/CE

- Contact individual PT providers for list of opportunities

Informal

- Discuss performance/investigations with all techs
- Review of summaries/critiques at staff meetings
- Pathologist led CE meeting using PT readings

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Objective of PT:

Quality patient care

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Key Points for PT Management

- Spend more time - a lot more time - going over your PT results
- Be sure PT samples are handled as patient samples
- Be certain that every analyte is covered by formal or alternative assessments
  - Establish limits of acceptability if the provider has not

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Additional Tips

- Keep original worksheets and instrument tapes with the PT file
- Make sure every less-than-acceptable result is followed up and documented
- Resolve systematic biases
- Confirm that corrective actions make sense and actually fix the problem

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Technical Assistance

http://www.cap.org

e-mail: accred@cap.org

800-323-4040, ext. 6065

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Thank You

Questions and Answers

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Case Study

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CAP Number: 1176826-14 **Kit #** **Kit ID:** 20133822
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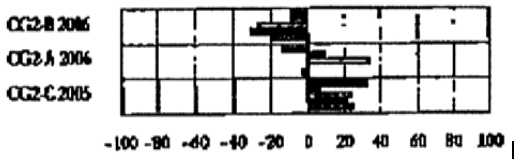
Attention: **Original Evaluation:** 09 / 28 / 20XX
City / State: **Revision Evaluation:** 10 / 13 / 20XX

E V A L U A T I O N
REVISION

CG2-B 2006 Coagulation-Comprehensive Survey

Evaluation and Comparative Method Statistics

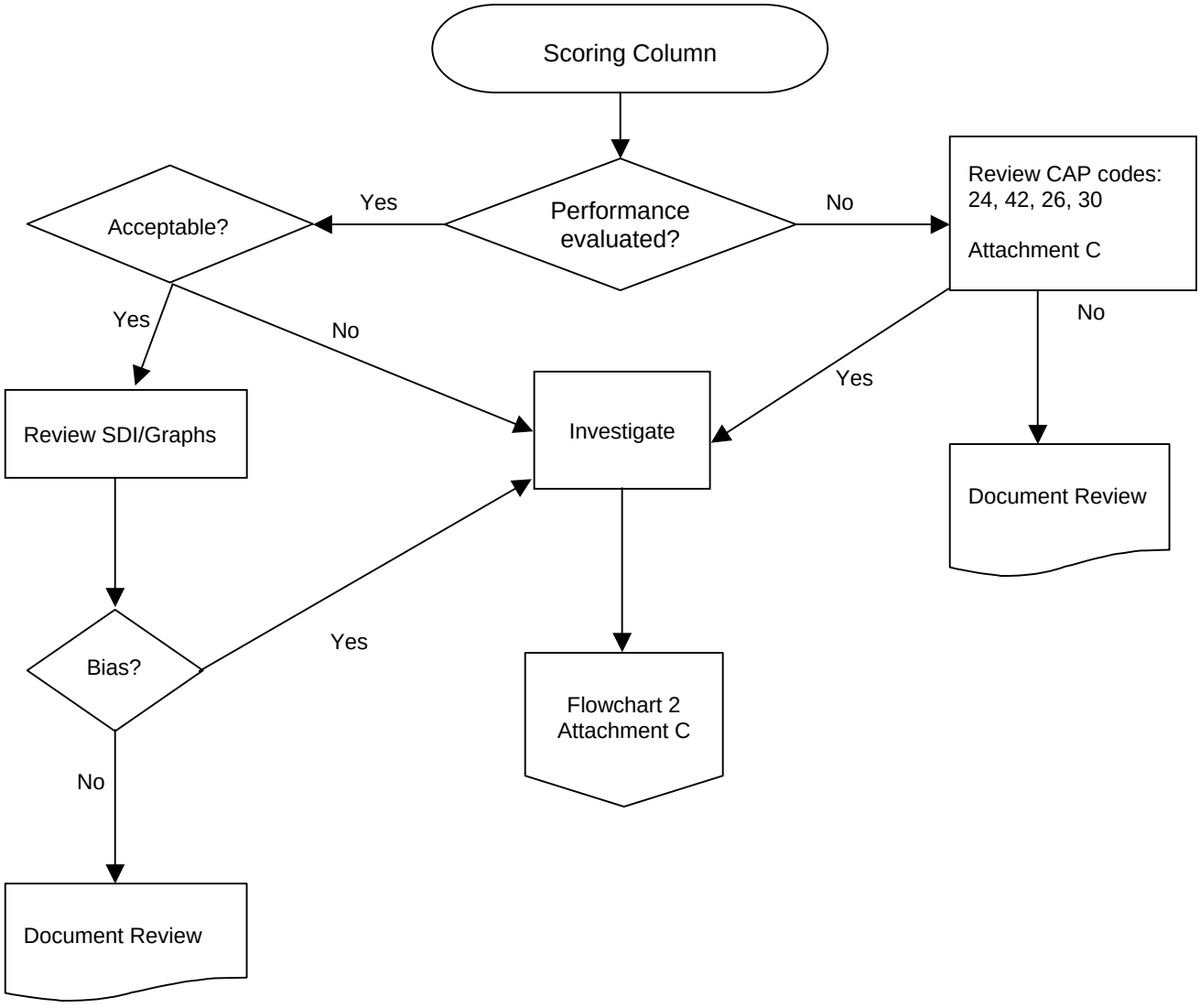
Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation
Fibrinogen	**CG2-07**									Survey -100--------- ---------Mean----------+100
mg/dL	**CG2-08**									
DIAG STAGO	**CG2-09**									
DIAG STAGO STA-R/EVOLU	**CG2-10**									
	CG2-11									
Reagent/Instrument	**CG2-07**	273	278.2	12.2	121	-0.4	222	334	Acceptable	
	CG2-08	288	292.8	13.3	121	-0.4	234	352	Acceptable	
	CG2-09	314	332.5	15.4	123	-1.2	265	399	Acceptable	
	CG2-10	276	294.9	15.1	122	-1.3	235	354	Acceptable	
	CG2-11	159	166.0	7.3	121	-1.0	132	200	Acceptable	
Factor IX	**CG2-09**	13	14.4	2.1	69	-0.7			[26]	
%	**CG2-10**	110	125.82	15.20	68	-1.0			[26]	
DIAG STAGO STA-PTT A	**CG2-11**	60	73.8	11.5	71	-1.2			[26]	
DIAG STAGO STA-R/EVOLU										
Protein S Total,Ag	**CG2-07**	12	13.4	3.8	25	-0.4			[26]	
%	**CG2-08**	98	93.2	14.0	29	+0.3			[26]	
MICROLATES PART MED IA	**CG2-11**	49	50.5	8.4	29	-0.2			[26]	
DIAG STAGO LIATEST										



The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Reading Your PT Evaluation Report

Flowchart 1



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Laboratory Accreditation Program
LAP's Requirements when a PT Result is Linked to an Exception Reason Codes

The College uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded (PT Providers other than the College use a coding process that is similar). The exception reason code is located on the evaluation report in brackets to the right of the result. The laboratory must identify all of the analytes with an exception reason code* and investigate the acceptability of its performance with the same rigor as if it were an unacceptable performance. When an exception reason code is present on the laboratory's evaluation, the laboratory must review the all-participant statistics for any explanatory information. The actions required for the following codes include but are not limited to:

Codes	***Exception Reason Code Description***	***Action Required***
11	Unable to analyze	Document why the specimens were not analyzed (e.g., instrument not functioning or reagents not available). Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	No appropriate target/response; cannot be graded	Document that the laboratory compared its results to the modal (most common) result. Perform and document the corrective action if required.
21	Specimen Problem	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider. Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
22	Result is outside the method/ instrument reportable range	Document the comparison of results to the proper peer group statistics and peer group information supplied by the PT Provider. Perform and document the corrective action if required.
24	Incorrect response due to failure to provide a valid response code	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial	Document the investigation of the result as if they were unacceptable and review the proper peer group statistics to gain knowledge of the reason your response is not appropriate.
26	Educational Challenge	Response to the CAP is not required. Laboratory should document its review.
27	Lack of participant or referee consensus	Document that the laboratory compared its results to the modal (most common) result. Perform and document corrective action if required
28	Response qualified with a greater than or less than sign; unable to quantitate	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Perform and document corrective action, if appropriate.
30	Scientific Committee Decision	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider.
33	Specimen determined to be unsatisfactory after contacting the CAP	Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
40	Results for this kit were not received	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper peer group statistics supplied by the PT Provider.
41	Results for this kit were received past the evaluation cut-off date	
42	No credit assigned due to absence of response.	The Participant Summary booklet mailed with the proficiency testing evaluation indicates which tests are graded (see evaluation criteria) and which tests are Not Evaluated/Educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is **not** a penalty.

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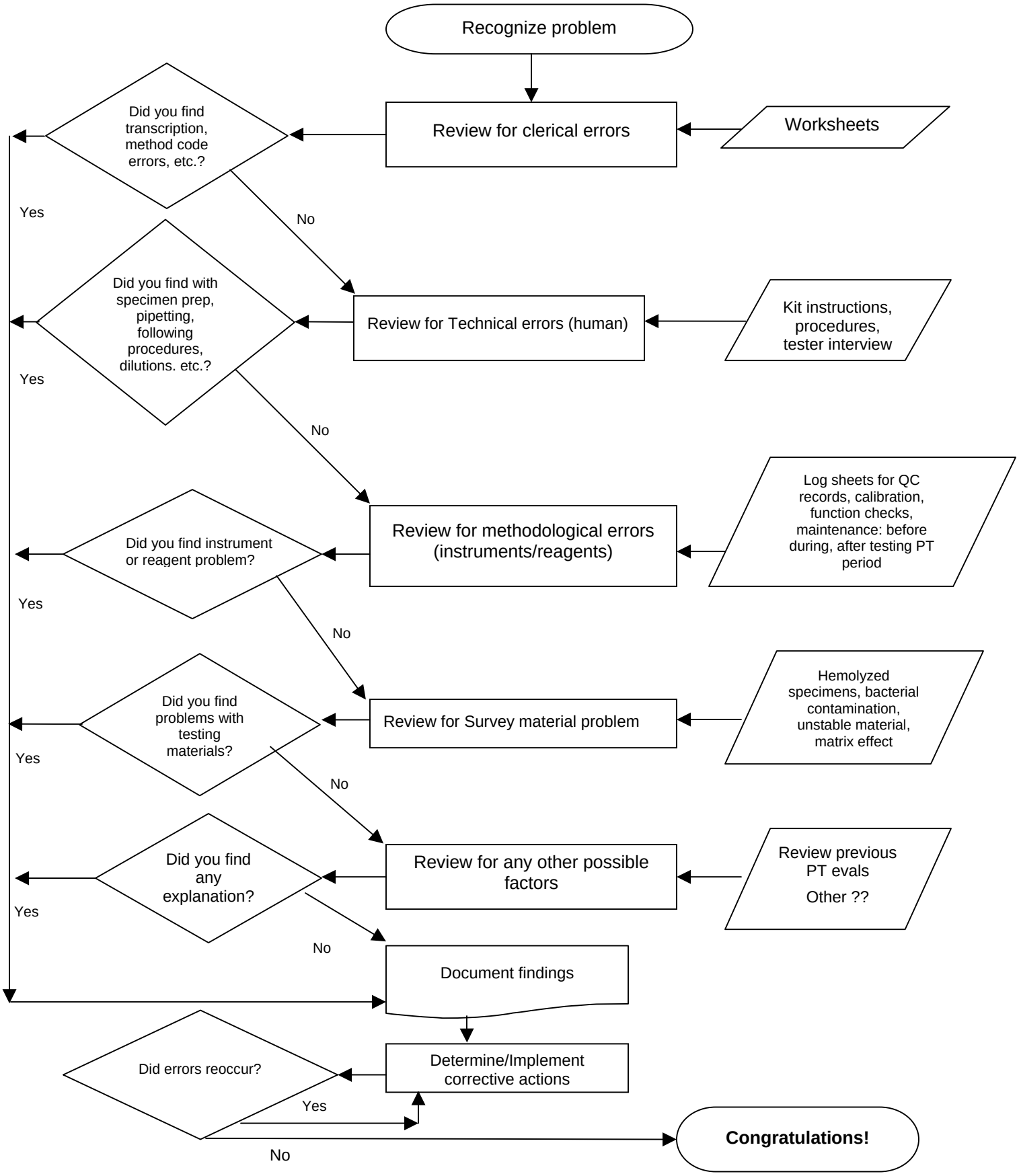
Laboratory Accreditation Program
LAP's Requirements when a PT Result is Linked to an Exception Reason Codes

		*If a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for **all** challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document corrective actions to prevent future failures.*
44	This drug is not included in our test menu. Use of this code counts as a correct response.	Verification that the drug is not tested on patient samples and document to ensure proper future reporting.
77	Improper use of the exception code for this mailing	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
* 35, 43, 88, 92	Various codes	No action required by the LAP.

Attachment D

Flowchart #2 - Investigation



Case Study

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Institution: **Kit Mailed:** 08/ 28 / 20XX
Attention: **Original Evaluation:** 09 / 28 / 20XX
City / State: **Revision Evaluation:** 10 / 13 / 20XX

E V A L U A T I O N
ORIGINAL

Z-B 2006 Therapeutic Drug Monitoring

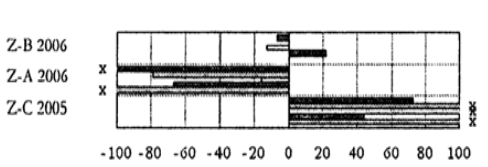
Test
Unit of Measure
Peer Group

Phenytoin
ug/ml
ROCHE COBAS INTEGRA

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Z-06	7.3	7.45	0.29	229	-0.5	5.5	9.4	Acceptable
Z-07	25.2	25.26	1.26	228	-0.1	18.9	31.6	Acceptable
Z-08	16.7	17.31	0.69	225	-0.9	12.9	21.7	Acceptable
Z-09	10.5	9.93	0.40	229	+1.4	7.4	12.5	Acceptable
Z-10	14.8	14.83	0.63	226	0.0	11.1	18.6	Acceptable

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



x: Result is outside the acceptable limits

E V A L U A T I O N
ORIGINAL

Z-A 2006 Therapeutic Drug Monitoring

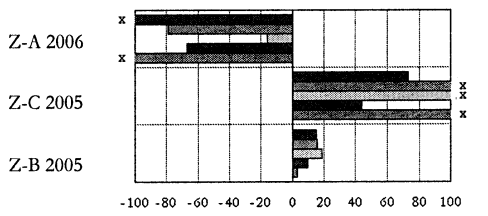
Test
Unit of Measure
Peer Group

Phenytoin
ug/ml
ROCHE COBAS INTEGRA

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Z-01	20.4	27.91	1.40	245	-5.3	20.9	34.9	Unacceptable
Z-02	10.7	13.46	0.60	247	-4.6	10.0	16.9	Acceptable
Z-03	4.7	4.92	0.18	246	-1.2	3.6	6.2	Acceptable
Z-04	8.2	9.88	0.41	245	-4.1	7.4	12.4	Acceptable
Z-05	21.4	30.41	1.60	246	-5.6	22.8	38.1	Unacceptable

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



x: Result is outside the acceptable limits

Case Study

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E V A L U A T I O N
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Z-C 2005 Therapeutic Drug Monitoring

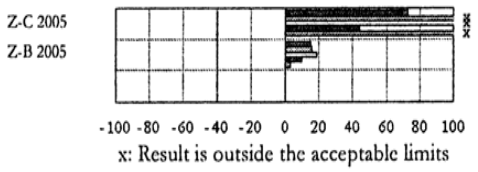
Test
Unit of Measure
Peer Group

Phenytoin
ug/ml
ROCHE COBAS INTEGRA

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Z-11	8.7	7.31	0.33	347	+4.2	5.4	9.2	Acceptable
Z-12	37.80	27.80	1.28	341	+7.8	20.8	34.8	Unacceptable
Z-13	39.0	30.37	1.37	338	+6.3	22.7	38.0	Unacceptable
Z-14	5.4	4.83	0.17	339	+3.4	3.6	6.1	Acceptable
Z-15	19.1	14.95	0.63	340	+6.6	11.2	18.7	Unacceptable

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



E V A L U A T I O N
ORIGINAL

Z-B 2005 Therapeutic Drug Monitoring

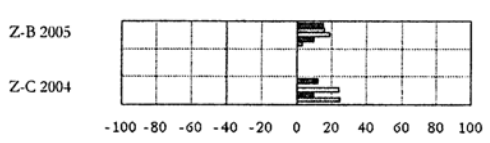
Test
Unit of Measure
Peer Group

Phenytoin
ug/ml
ROCHE COBAS INTEGRA

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Z-06	26.0	25.00	1.18	360	+0.9	18.7	31.3	Acceptable
Z-07	18.2	17.46	0.73	358	+1.0	13.0	21.9	Acceptable
Z-08	26.3	25.06	1.26	360	+1.0	18.7	31.4	Acceptable
Z-09	12.6	12.28	0.47	359	+0.7	9.2	15.4	Acceptable
Z-10	7.4	7.34	0.26	359	+0.2	5.5	9.2	Acceptable

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



Case Study

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E V A L U A T I O N
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Z-A 2005 Therapeutic Drug Monitoring

Laboratory failed to submit results.

E V A L U A T I O N
ORIGINAL

Z-C 2004 Therapeutic Drug Monitoring

Test
Unit of Measure
Peer Group

Phenytoin
ug/ml
ROCHE COBAS INTEGRA

Evaluation and Comparative Method Statistics

Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I.	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Z-11	25.4	24.65	1.29	311	+0.6	18.4	30.9	Acceptable
Z-12	4.8	4.80	0.16	306	0.0	3.6	6.1	Acceptable
Z-13	17.9	16.86	0.72	306	+1.4	12.6	21.1	Acceptable
Z-14	12.3	11.98	0.51	305	+0.6	8.9	15.0	Acceptable
Z-15	31.6	29.69	1.45	346	+1.3	22.2	37.2	Acceptable

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

Survey	-100-	-- --50-	---0--	--50-	+100
	:	:	:	:	:
	:	:	:	:	:
Z-C 2004	:	:	12-2	:	:
	:	:	:	:	:
	:	:	:	:	:
Z-B 2004	:	:	4-1	:	:
	:	:	:	:	:
Z-A 2004	:	21-1-1	:	:	:

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.