Institute for Quality Management in Healthcare
Centre for Proficiency Testing

CHEMISTRY & ENDOCRINOLOGY
CHEM 1502 PP Analysis Worksheet

Patterns-of-Practice

SURVEY INSTRUCTIONS

OBJECTIVE

This is a web-based patterns-of-practice survey and only electronic submissions will be accepted. The objective of this survey is to gather data in order to determine current laboratory practices relating to reagent and calibrator lot-to-lot verifications in Ontario laboratories. Findings of this survey will be reviewed by the Chemistry and Endocrinology Committee members and published as Committee Comments.

REPORTING INSTRUCTIONS

It is most likely that staff from multiple laboratory areas will be required to complete this Patterns-of-Practice survey. Please co-ordinate your responses so that only one completed Analysis Worksheet is submitted for each laboratory site.

- General instructions regarding web-based data entry are posted on QView™ in the Documents area in the folder "General – Proficiency Testing \ PT User Information \ Instruction – Submission of Web-based PT Survey Responses."
- Note when completing this form, required fields are highlighted with a **red border.**

PROCESS

1. Does your laboratory perform new reagent and calibrator lot-to-lot verification?

For each test system listed please indicate which tests are covered in the *reagent and calibrator* lot-to-lot verifications:

Test Systems:		Yes, all tests	Yes, some tests	No verification at all	Not Applicable (do not have this test system)
Automated chemistry systems e.g. main analyzer	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Automated immunoassay systems	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Semi-Automated quantitative instruments e.g. blood gas analyzer, POCT	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Semi-quantitative instruments e.g. electrophoresis, antibody titre, urine dipsticks	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Qualitative or POCT Assays e.g. Drugs of Abuse, Pregnancy Test	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Commercial test kits – e.g. RIA, ELISA, Western Blot	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
In-House Developed Assays e.g. HPLC, GC, LC/MS/MS	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○
Other system – please specify system below:	Reagent:	○	○	○	○
	Calibrator:	○	○	○	○

Other system:

If reagent and calibrator comparisons are performed for ALL tests, skip question 2, and go directly to question 3.

2. Are there instances when a new reagent or calibrator lot-to-lot verification is not performed?

If your laboratory does not perform a new reagent or calibrator lot-to-lot verification on a specific test system, choose from the most common reasons below (check all that apply).

Test Systems		**Limited number of tests performed (a)**	**High Cost (b)**	**Difficult to perform in parallel with current testing (c)**	**Insufficient staff time (d)**	**Other* (e)**
Automated chemistry systems e.g. main analyzer	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Automated immunoassay systems	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Semi-Automated quantitative instruments e.g. blood gas analyzer, POCT	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Semi-quantitative instruments e.g. electrophoresis, antibody titre, urine dipsticks	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Qualitative or POCT Assays e.g. Drugs of Abuse, Pregnancy Test	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Commercial test kits – e.g. RIA, ELISA, Western Blot	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
In-House Developed Assays e.g. HPLC, GC, LC/MS/MS	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐
Other System	Reagent:	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐

*Please include all OTHER reasons for not performing a new reagent and calibrator verification:

3. Does your laboratory perform reagent and/or calibrator lot-to-lot verifications on new shipments of the same lot number currently in use?

- ◯ a Yes, for all tests
- ◯ b Yes, for most tests
- ◯ c Yes, for a few tests
- ◯ d No

4. If a full lot-to-lot verification is performed on a new reagent and/or calibrator at one site of a multi-site facility, do affiliated laboratories still perform any lot-to-lot verification?

- ◯ a Yes, with the same full lot-to-lot verification
- ◯ b Yes, with a modified protocol (e.g. QC only)
- ◯ c No
- ◯ d Not applicable – single site facility

5. When are new lot-to-lot verifications performed? (check the best answer below)

- ◯ a Upon receipt of new lot
- ◯ b Before the new lot is put in use
- ◯ c Concurrent with initial use of new lot
- ◯ d Other, please specify: _____

6. How do you differentiate new lot reagent and calibrators from the current ones? (check all that apply)

- ☐ a Using an identification system to alert the users a new lot has been received e.g. stickers
- ☐ b By rotating stock (e.g. store old stock in front to use first)
- ☐ c By storing new lots in a designated area
- ☐ d Other, please specify: _____

7. Please indicate who **most often** performs the actual testing for lot-to-lot verification in your laboratory?

- ◯ a Bench Technologists
- ◯ b Senior/Charge Technologist/Technical Specialist/Supervisor
- ◯ c Manager/Director
- ◯ d Other Personnel, please specify: _____

MATERIALS USED FOR LOT-TO-LOT VERIFICATIONS

8. What types of material are used to perform reagent and/or calibrator lot-to-lot verifications? (check all that apply)

		Patient Material			Commercial Material		
Test Systems		**Unmodified Single Patient Samples (a)**	**Modified (Spiked) Single Patient Samples (b)**	**Pooled Patient Samples (c)**	**Proficiency Testing Material (a)**	**Quality Control Material (b)**	**Reference Material (c)**
Automated chemistry systems e.g. main analyzer	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Automated immunoassay systems	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Semi-Automated quantitative instruments e.g. blood gas analyzer, POCT	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Semi-quantitative instruments e.g. electrophoresis, antibody titre, urine dipsticks	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Qualitative or POCT Assays e.g. Drugs of Abuse, Pregnancy Test	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Commercial test kits – e.g. RIA, ELISA, Western Blot	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
In-House Developed Assays e.g. HPLC, GC, LC/MS/MS	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐
Other System	Reagent:	☐	☐	☐	☐	☐	☐
	Calibrator:	☐	☐	☐	☐	☐	☐

Questions 9, 10 & 11 below, apply to *Automated chemistry &*/or *Automated immunoassay* test systems only. Please provide responses as they relate to those test systems only, for the 3 questions on this page.

9. In new lot calibrator verifications, are calibrators analyzed as patient samples during calibrator lot-to-lot verification?

- ◯ a Yes, current calibrator only
- ◯ b Yes, new calibrator only
- ◯ c Yes, both current and new calibrators
- ◯ d No, calibrators are not tested as patients

10. Do you run patient samples and/or QC material in duplicate during new reagent and calibrator lot-to-lot verifications?

- ◯ a Yes, both patient and QC material
- ◯ b Yes, only patient material
- ◯ c Yes, only QC Material
- ◯ d No
- ◯ e Not applicable

11. On average how many patient and/or commercial material samples (as defined in question 8) are tested for each of the material types in the chart below?

Please indicate a quantity for both reagent and calibrator verifications, for both material types:

Patient Material – avg # of samples tested								
Reagent	◯ 0	◯ 2	◯ 3-4	◯ 5-6	◯ 7-10	◯ 11-15	◯ 16-20	◯ >20
Calibrator	◯ 0	◯ 2	◯ 3-4	◯ 5-6	◯ 7-10	◯ 11-15	◯ 16-20	◯ >20

Commercial Material – avg # of samples tested					
Reagent	◯ 0	◯ 2	◯ 3	◯ 4	◯ >4
Calibrator	◯ 0	◯ 2	◯ 3	◯ 4	◯ >4

DATA MANAGEMENT

12. How does your laboratory analyze the lot-to-lot verification data? (check all that apply)

- ☐ a Commercial software product (e.g. EP Evaluator, Analyze-It)
- ☐ b In-house developed spreadsheet (e.g. MS Excel/Word programs)
- ☐ c Manual calculations (paper charts or forms)
- ☐ d Other means, please specify:

13. What test-specific rules or parameters does your laboratory use as acceptance criteria to assess the verification data? (check all that apply)

- ☐ a Total Allowable Error (TEa)
- ☐ b IQMH Allowable performance limits
- ☐ c IQMH Precision goals
- ☐ d Manufacturer limits
- ☐ e A pre-defined percentage (%) change
- ☐ f Regression Equation (including R square)
- ☐ g Reference Change Value
- ☐ h Opinion of Medical Director/Clinical Biochemist/Pathologist
- ☐ i Other criteria used, please specify:

APPROVAL OR REJECTION PROCESS

14. Please indicate who approves the lot-to-lot verifications in your laboratory (check all that apply)?

- ☐ a Bench Technologist
- ☐ b Senior/Charge Technologist/Technical Specialist/Supervisor
- ☐ c Manager/Director
- ☐ d Medical Director /Pathologist/Clinical Biochemist
- ☐ e Other Personnel, please specify:

15. What actions are typically taken if a reagent or calibrator lot number has failed to meet the established acceptance criteria? (check all that apply)

- ☐ a Investigation and corrective action taken e.g. recalibration of current and new lot and re-testing with fresh samples
- ☐ b Lot is rejected and manufacturer is contacted
- ☐ c Lot is accepted with restrictions

16. If a reagent or calibrator lot number is accepted even when it has failed to meet the established acceptance criteria, what restrictions/adjustments are applied? (check all that apply)

- ☐ a Only QC affected – QC target values are updated
- ☐ b Both QC and patient affected - Reference interval is reviewed and adjusted and QC target values are updated
- ☐ c Correction factor is applied - slope and intercept adjusted
- ☐ d Lot is approved - no communication to end users
- ☐ e Lot is approved - differences communicated to end users (e.g. comment on patient report, bulletins or memos)
- ☐ f Other method(s), please specify:

17. Are reagent and/or calibrator trends monitored over several lot changes? ◯ Yes ◯ No

If yes, specify which parameters are monitored? (check all that apply)

- ☐ a Internal QC means
- ☐ b Internal QC SDs
- ☐ c Patient means
- ☐ d Proficiency testing
- ☐ e Other, please specify:

Did you have any additional information you would like to share? Please add comments below.

Comments

Thank you for taking the time to complete this survey!

Contact Person:

Telephone: Extension:

Email: