Status Active PolicyStat ID 12900459

Beaumont

Origination	11/8/2021
Last Approved	1/17/2023
Effective	1/17/2023
Last Revised	12/27/2022
Next Review	1/16/2025
Document Contact	Colette Kessler: Mgr, Division Laboratory
Area	Laboratory-Chemistry
Applicability	All Beaumont Hospitals

Reagent Lot-to-Lot Verification

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document is intended to guide the Chemistry staff in performing reagent lot-to-lot comparisons when new lot numbers of reagent or new shipments of the same lot number of reagents are received.

II. POLICY:

A. Per College of American Pathologists' (CAP) Checklist item COM.30450 New Reagent Lot Verification, ***"New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service"***.

B. For quantitative and qualitative non-waived testing, new reagent lots and/or shipments must be tested in parallel with old lots before or concurrently with being placed in service to ensure that the calibration with the new lot of reagent maintains consistent results for patient specimens.

C. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot. A weakly positive sample should also be used in systems where patient results are reported in that fashion.

D. Patient specimens should be used to compare a new lot against the old lot, when possible, since it is patient specimens that are tested.

E. Proficiency testing materials with peer group established means and Quality Control (QC) materials are acceptable alternatives for validating new reagent lots. However, the laboratory should be aware that Proficiency Testing (PT) and QC materials may be affected by matrix interference between different reagent lots. Thus, even if results show no change following a reagent lot change, a calibration inconsistency for patient specimens could exist nonetheless,

masked by matrix interference affecting the PT or QC material. It is for this reason – to confirm the absence of matrix interference- that the use of patient samples is recommended.

F. If QC material is used, the material should have a peer group established mean value based on inter-laboratory comparison that is method specific and includes data from at least 10 different laboratories. If this criteria is not met, patient specimens must be ued to perform a reagent lot-to-lot verification.

G. The use of QC material alone is adequate to check a new shipment of a reagent lot currently in use, as there should be no change in potential matrix interactions between QC material and different shipments of the same lot number of reagents.

H. The Canton Laboratory uses peer group data for reagent verification to meet the CAP standard.

III. SPECIMEN COLLECTION AND HANDLING:

Pull specimens from current day's run and/or from recent archive for comparison testing between current and new lots of reagent.

IV. PROCEDURE:

A. Tag all new reagent lots/shipments as soon as possible after receipt. Evaluate new lots as they are put into use before testing patients.

B. **New Lot, Quantitative Testing**

1. Calibrate the new reagent lot after loading reagent onto respective analyzer/test system.
2. Assay current quality control (QC) materials for each new lot.
3. Select three to five patients who have test results previously reported from the current analyte lot. Perform patient comparisons on the newly calibrated analyte lot and the current analyte lot and record data on a Lot-to-Lot Worksheet.
4. If there is no current lot of reagent available, use the reported patient results.
5. Evaluate QC results for analyte tested. QC results must be within current range.
6. If QC is unacceptable do not begin testing patients with the new lot until approved by MT Lead, Supervisor, or Technical Director. To troubleshoot:
    a. Recalibrate assay.
    b. Run assayed QC if available. The Lot-to-Lot is acceptable for running patients if the assayed QC is within range.
    c. Perform 3-5 additional patients in a range near the failed QC.
    d. If available, load new reagent lot on another instrument, calibrate, QC materials and lot-to-lot patient specimens and compare results from other instrument as a troubleshooting process. This would be used if patient results matched but QC results did not.
    e. Consult Lead Medical Technologist (MT) if QC results are still not in control.

7. Evaluate patient results *individually* for acceptability using Total Error Allowable (TEA) defined by analyte.
8. If patient results do not agree within the TEa, do not begin using the new lot until approved by MT Lead, Supervisor, or Technical Director. To troubleshoot:
    a. Pull additional patients.
    b. Recalibrate assay and repeat QC and patients.
    c. Consult Lead MT, Supervisor, or Technical Director if results still do not match.
    d. Call reagent vendor to begin investigation of a bad lot of reagent or calibrator.
9. If new lot is required for immediate use but failure(s) occur within sample patients, accept new lot based on QC acceptability alone and consult with Technical Director, Lab Manager, Supervisor, or Lead MT for further direction.
10. For new lots that meet the acceptabiity criteria, the MT performing the Lot-to-Lot can begin testing patients. The Supervisor, Lead MT, or Technical Director will final approve the new lot and file it accordingly.
11. All QC is documented electronically.
12. Lot information is tracked in the laboratory.

C. **New Shipment, Quantitative Testing**

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current QC materials, for each new shipment.
3. Evaluate QC results for analyte tested. QC results must be within current range.
4. If QC is unacceptable, run assayed QC, if available, and perform the procedure used for new lots of reagents.
5. Supervisor or MT Lead can approve new shipment provided the above criteria are met. Otherwise, consult with Technical Director for further direction.
6. All QC is documented electronically.
7. Lot information is tracked within the laboratory.

D. **New Lot, Qualitative Testing - Instrument or Manual Procedure**

1. Calibrate the new lot, if required per instrument operating procedure.
2. Document results on a Lot-to-Lot Worksheet for respective assay.
3. Assay current QC materials.
4. Evaluate QC results for analyte tested. QC results must be within current range.
5. Perform patient comparisons, one known positive and one known negative. Must recover the same qualitative results with new lot.
6. Record the QC and patient results, including the numeric results, if available, on a Lot-to-Lot worksheet.

7. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
8. All QC is documented electronically.
9. Lot information is tracked within the laboratory.

E. **New Shipment, Qualitative Testing - Instrument or Manual Procedure**

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current quality control materials.
3. Evaluate QC results for analyte tested. QC results must be within current range.
4. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. All QC is documented electronically.
6. Lot information is tracked within the laboratory.

F. **New Lot, Exception Analytes, Analyzers**

For some assays, it is difficult to obtain patient specimens for comparison testing (e.g. blood gas specimen integrity for Radiometers, low specimen census for some Drugs of Abuse/ Therapeutic Drug Monitoring assays). For some instruments, only current lot calibration can be held in the analyzer. For such assays, QC materials alone will be utilized to check new reagent lots.

1. Assay all available current quality control materials. QC results must be within current range.
2. Evaluate QC against peer group established mean value (inter-laboratory comparison) if peer group includes data from at least 10 different labs.
3. If less than 10 labs are within the peer group, evaluate the next 5 runs of QC for any QC shifts (preferably complete within 24 hrs).
4. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. All QC is documented electronically.
6. Lot information is tracked within the laboratory.

Attachments

HIV Lot to Lot Worksheet.pdf

Lot to Lot Qualitative Worksheet.pdf

Lot to Lot Worksheet .pdf

Reagent Lot Number Comparison .pdf

Reagent Lot to Lot and Patient Reproducibility .pdf

Reagent Lot_to_Lot .pdf

Total Allowable Error (TEA) Reference Guide .pdf

Approval Signatures

Step Description	Approver	Date
Medical Directors	Vaishali Pansare: Chief, Pathology	1/17/2023
Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	1/9/2023
Medical Directors	John Pui: Chief, Pathology	1/9/2023
Medical Directors	Jeremy Powers: Chief, Pathology	1/6/2023
Medical Directors	Ryan Johnson: OUWB Clinical Faculty	1/5/2023
Medical Directors	Muhammad Arshad: Physician	1/5/2023
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	1/5/2023
Policy and Forms Steering Committee Approval (if needed)	Ilene Hirsch: Project Mgr Policy	1/5/2023
	Caitlin Schein: Staff Physician	1/5/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	1/4/2023
	Qian Sun: Tech Dir, Clin Chemistry, Path	1/4/2023
	Brittnie Berger: Dir, Lab Operations C	1/4/2023
	Elzbieta Wystepek: Dir, Lab Operations B	1/3/2023
	Kimberly Geck: Dir, Lab Operations B	12/30/2022
	Colette Kessler: Mgr, Division Laboratory	12/30/2022

Colette Kessler: Mgr, Division Laboratory	12/30/2022

Beaumont HEALTH

Beaumont Laboratory
Clinical Pathology

Lot Number Patient Comparison HIV

Date Received: _____

Date Expires: _____

Test HIV

Cut off Value _____

Specimen	Current Lot # _____	New Lot # _____	Do qualitative results match between lots? Y or N	Is QC within 2 SD? Y or N
QC Negative (Natural)				
QC Pos 1 (Blue)				
QC Pos 2 (Yellow)				
QC Pos 3 (Purple)				
QC Pos 4 (Orange)				
Positive Sample				
Negative Sample				

Tech: _____ Date: _____

Approved: _____

Notes: _____

Beaumont HEALTH
Beaumont Laboratory
Clinical Pathology

Lot Number Patient Comparison Qualitative Test

Date Received: _____

Date Expires: _____

Test _____

Cut off Value _____

Specimen	Current Lot # _____	New Lot # _____	Do qualitative results match between lots? Y or N	Is QC within 2 SD? Y or N
QC Level 1				
QC Level 2				
Positive Sample				
Negative Sample				

Tech: _____ Date: _____

Approved: _____

Notes: _____

Beaumont HEALTH

Beaumont Laboratory
Clinical Pathology

Lot Number Patient Comparison Attachment

Date Received: _____

Date Expires: _____

Test _____

Analytical Measuring Range _____

Specimen	Current Lot # _____	New Lot # _____	% Difference Patients (new-old)/old	Is QC within 2 SD? Y or N
QC Level 1				
QC Level 2				
QC Level 3* Or N/A				
Patient sample 1			**	
Patient sample 2			**	
Patient sample 3			**	
Patient sample 4			**	
Patient sample 5			**	
Assayed QC Level 1-if needed				
Assayed QC Level 2-if needed				
Assayed QC Level 3-if needed				

**See TEA Chart for acceptable criteria. All patient specimens must meet the TEA criteria.

Tech: _____ Date: _____

Approved: _____ Notes: _____

Beaumont HEALTH

Beaumont Laboratory

Lot Number Comparison

Date Received: _____

Date Expires: _____

Test _____

Analytical Measuring Range _____

Specimen	Current Lot # _____	New Lot # _____	% Difference Patients (new-old)/old	Is QC within 2SD? Y or N
QC Level 1				
QC Level 2				
QC Level 3 Or N/A				
Patient sample 1				
Patient sample 2				
Patient sample 3				
QC Level 1				
QC Level 2				
QC Level 3 or N/A				
Average% Difference Patient Results**				

**See TEA Chart for acceptable criteria

Tech: _____ Date: _____

Approved: _____ Notes: _____

Lot in use: _____

Beaumont

Beaumont Laboratory
Clinical Pathology

NEW CALIBRATION AND PATIENT REPRODUCIBILITY

Year: _____ Month: _____ Day: _____	Section: Chemistry Instrument: _____ Serial #:	**ASSAY:** _____

	Old Calibration Data	New Calibration Data
Reagent Lot #		
Expiration Date		
Calibrators Lot		
Expiration Date		
Date Run		

New Reagent Lot #: QC Values
QC: L1_____
L2_____
L3_____

Current QC Ranges: Mean and SD
QC: L1_____ **SD**_____
L2_____ **SD**_____
L3_____ **SD**_____

Patient Data

Accession #	Result Date	Old Result (X)	Result w/ New Cal (Y)	Bias (X – Y)	* % Diff = $\frac{\text{Bias}}{X} \times 100$	Correlation Acceptable Y / N

Use Delta % where available. *Acceptable % Diff for this assay

Technologist:	Date:
Supervisor:	Date:

NOTE: Select Low, Normal, High results in mix when possible. Use 3 to 5 patients.
Attach results to new calibration printout.

REAGENT LOT-TO-LOT PATIENT CORRELATIONS

Date: _____ **Analyzer:** _____

Assay: _____

	Current Rgt Lot	New Rgt Lot
Reagent Lot #		
Expiration Date		
Calibrator Lot #		
Expiration Date		

New Reagent Lot # QC values
QC: L1_____
L2_____
L3_____

Current QC ranges: Mean and SD
QC: L1_____ **SD**_____
L2_____ **SD**_____
L3_____ **SD**_____

Patient Data

Accession #	Result Date	Current Lot Result (X)	New Lot Result (Y)	Bias (X - Y)	* % Diff = (Bias/X) x 100	Correlation Acceptable Y or N

* Acceptable % Diff for this Assay: _____

Technologist : _____ Date:_____

Supervisor or Designate: _____ Date:_____

Please Note: Select Low, Normal High patient results when possible.

Use 3 to 5 patients; completed reports with printouts will be attached to calibration printout

Beaumont HEALTH
Beaumont Laboratory

Total Error Allowable (TEA) Reference Guide

Immunoassay Reference

BPT	Test	Proportional	or	Constant	Units
Chemistry	**Homocysteine**	26.4%	or	2.3	µmol/L
Immunochemistry	**AFP**	20.0%	or	3	ng/mL
Immunochemistry	**BNP**	30%	or	30	pg/mL
Immunochemistry	**C-Peptide**	20%	or	0.2	ng/mL
Immunochemistry	**CA 125**	20%	or	7	U/mL
Immunochemistry	**CA 153**	25%	or	7	U/mL
Immunochemistry	**CA 19.9**	25%	or	7.0	U/mL
Immunochemistry	**CEA**	15%	or	1	ng/mL
Immunochemistry	**Cortisol**	20.0%	or	1	µg/dL
Immunochemistry	**DHEAS**	13%	or	9	µg/dL
Immunochemistry	**Estradiol (eE2)**	30%	or	3	pg/mL
Immunochemistry	**Ferritin**	20%	or	9	ng/mL
Immunochemistry	**Folate**	30%	or	1	ng/mL
Immunochemistry	**FSH**	18%	or	2	mIU/mL
Immunochemistry	**hCG**	18%	or	2	mIU/mL
Immunochemistry	**Insulin**	25%	or	0.2	micro U/mL
Immunochemistry	**LH**	20%	or	1.1	mIU/mL
Immunochemistry	**Procalcitonin**	15%	or	0.1	ng/mL
Immunochemistry	**Progesterone**	20%	or	0.6	ng/mL
Immunochemistry	**Prolactin**	20%	or	1.5	ng/mL
Immunochemistry	**PSA, free**	30%	or	0.2	ng/mL
Immunochemistry	**PSA, total**	20%	or	0.2	ng/mL
Immunochemistry	**PTH, intact**	30%	or	10	pg/mL
Immunochemistry	**SHBG**	25%	or	0.2	nmol/L
Immunochemistry	**T3, free**	14%	or	0.32	pg/mL
Immunochemistry	**T4, free**	15%	or	0.3	ng/mL
Immunochemistry	**Testosterone**	30%	or	20	ng/mL
Immunochemistry	**Troponin I**	30%	or	0.2	ng/mL
Immunochemistry	**TSH**	15%	or	0.06	mIU/mL
Immunochemistry	**Vitamin B12**	25%	or	30	pg/mL
Immunochemistry	**Vitamin D 25-OH**	25%	or	3	ng/mL
Special Chemistry	**Hepatitis B Surface (HBsAb)**	30%	or	3.6	mIU/mL
Special Chemistry	**Myoglobin**	30%	or	10	ng/mL

Chemistry Reference

BPT	Test	Proportional	or	Constant	Units
Chemistry	NA	0%	or	4	mmol/L
Chemistry	K	0%	or	0.3	mmol/L
Chemistry	CL	5%	or	4	mmol/L
Chemistry	CO2	20%	or	4	mmol/L
Chemistry	GLU	8%	or	6	mg/dL
Chemistry	BUN	9%	or	2	mg/dL
Chemistry	CREAT	10%	or	0.2	mg/dL
Chemistry	CALCIUM	6%	or	0.5	mg/dL
Chemistry	CALCIUM, IONIZED	4%	or	0.4	mg/dL
Chemistry	T PROT	8%	or	0.4	g/dL
Chemistry	ALB	8%	or	0.4	g/dL
Chemistry	ALK	20%	or	10	IU/L
Chemistry	AST	15%	or	6	IU/L
Chemistry	ALT	15%	or	6	IU/L
Chemistry	TBIL	20%	or	0.4	mg/dL
Chemistry	CHOL	10%	or	6	mg/dL
Chemistry	TRIG	15%	or	8	mg/dL
Chemistry	HDL	20%	or	6	mg/dL
Chemistry	PHOS	10%	or	0.3	mg/dL
Chemistry	MG	15%	or	0.3	mg/dL
Chemistry	UA	10%	or	0.5	mg/dL
Chemistry	CK	20%	or	10	IU/L
Chemistry	LD	15%	or	10	IU/L
Chemistry	GGT	15%	or	5	IU/L
Chemistry	D BILI	20%	or	0.15	mg/dL
Chemistry	IRON	15%	or	10	µg/dL
Chemistry	AMY	20%	or	10	IU/L
Chemistry	LIP	30%	or	10	IU/L
Chemistry	dLDL	16%	or	10	mg/dL
Chemistry	P HGB	15%	or	10	mg/dL
Chemistry	Amylase U	30%	or	10	U/L
Chemistry	NA U	26%	or	6	mmol/L
Chemistry	K U	29%	or	4	mmol/L
Chemistry	CL U	25%	or	6	mmol/L
Chemistry	GLUC U	20%	or	6	mg/dL
Chemistry	UUN	21%	or	20	mg/dL
Chemistry	UCREAT	17%	or	4	mg/dL
Chemistry	UCA	30%	or	4	mg/dL
Chemistry	UPO4	23%	or	4	mg/dL
Chemistry	UMG	25%	or	4	mg/dL
Chemistry	U URIC	24%	or	4	mg/dL
Chemistry	UPROT	25%	or	1	mg/dL
Chemistry	uALB	20%	or	0.4	mg/dL
Chemistry	Lactic Acid	7%	or	0.4	mmol/L
Chemistry	Ammonia	18%	or	12	mcmol/L
Chemistry	Beta-hydroxybutyrate	18%	or	0.2	mmol/L
Clinical Toxicology	Ethanol	20%	or	9	mg/dL

BPT	Test	Proportional	or	Constant	Units
Special Chemistry	a1AT	20%	or	10	mg/dL
Special Chemistry	ACE	30%	or	15	U/L
Special Chemistry	ASO	15%	or	35	IU/mL
Special Chemistry	Beta2microglobulin	20%	or	0.3	mg/L
Special Chemistry	C3	15%	or	8	mg/dL
Special Chemistry	C4	20%	or	5	mg/dL
Special Chemistry	CRP	30%	or	0.4	mg/dL
Special Chemistry	Ceruloplasmin	15%	or	2	mg/dL
Special Chemistry	Haptoglobin	24%	or	40	mg/dL
Special Chemistry	IGA	11%	or	13	mg/dL
Special Chemistry	IGG	20%	or	130	mg/dL
Special Chemistry	IGM	10%	or	6	mg/dL
Special Chemistry	Lipoprotein(a)	20%	or	6	mg/dL
Special Chemistry	Prealbumin	25%	or	5	mg/dL
Special Chemistry	RF	10%	or	5.3	U/mL
Special Chemistry	TRF	20%	or	10	mg/dL
Special Chemistry	*hs* CRP	30%	or	0.4	mg/dL
Clinical Toxicology	Acetaminophen	15%	or	3	ug/mL
Clinical Toxicology	Amakacin	25%	or	1	ug/mL
Clinical Toxicology	Carbamazepine	20%	or	1	ug/mL
Clinical Toxicology	Digoxin	15%	or	0.2	ng/mL
Clinical Toxicology	Gentamicin	25%	or	0.4	ug/mL
Clinical Toxicology	Lithium	15%	or	0.3	mmol/L
Clinical Toxicology	Methotrexate	15%	or	0.05	umol/L
Clinical Toxicology	Phenobarbital	15%	or	2	ug/mL
Clinical Toxicology	Phenytoin	15%	or	2	ug/mL
Clinical Toxicology	Salicylate	15%	or	2	mg/dL
Clinical Toxicology	Theophylline	20%	or	1	ug/mL
Clinical Toxicology	Tobramycin	20%	or	0.4	ug/mL
Clinical Toxicology	Valproic Acid	20%	or	4	ug/mL
Clinical Toxicology	Vancomycin	15%	or	2	ug/mL
Clinical Toxicology	Amphetamine	20%	or	0	ng/mL
Clinical Toxicology	Barbiturate	20%	or	0	ng/mL
Clinical Toxicology	Benzodiazepine	20%	or	0	ng/mL
Clinical Toxicology	Cannabinoids	25%	or	0	ng/mL
Clinical Toxicology	Cocaine	20%	or	0	ng/mL
Clinical Toxicology	Fentanyl	20%	or	0	ng/mL
Clinical Toxicology	Methadone	20%	or	0	ng/mL
Clinical Toxicology	Opiates	20%	or	0	ng/mL
Clinical Toxicology	Oxycodone	20%	or	0	ng/mL
Clinical Toxicology	Phencyclidine	20%	or	0	ng/mL
Special Chemistry	Osmolality	5%	or	2	mOsm/kg
Special Chemistry	Osmolality, Urine	5%	or	10	mOsm/kg