Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Indirect Fluorescent Assays
Assay:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

	Old Lot			New Lot			
Accession	**Date**	**Result**	**Interpretation**	**Date**	**Result**	**Interpretation**	**Acceptable**

The results should match between the old results and new results within 1 titer value for Endo and ANA. The results should match between the old results and new results within a 2-fold dilution for ANCA, APA, AMA, ASMA, and DNA Crithidia. If the results are discrepant, please notify a Supervisor.
The samples used in this assessment should include 1 negative patient and 2 positive patients.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range
AMA	<1:20
ANA	<1:160
ANCA	<1:20
APA	<1:20
ASMA	<1:20
DNA Crithidia	<1:10
Endo	<1:5

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Qualitative AtheNA Assays
Assay:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

		Old Lot			New Lot			
Accession	Assay	Date	Result	Interpretation	Date	Result	Interpretation	Acceptable

The qualitative interpretation should match between the old results and new results. If the interpretations are discrepant, please notify a Supervisor.
The samples used in this assessment should include 1 negative patient and 1 positive patient.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Negative Range	Equivocal Range	Positive Range
Centromere B	<100 AU/mL	100-120 AU/mL	>120 AU/mL
DNA	<100 AU/mL	100-120 AU/mL	>120 AU/mL
Histone	<100 AU/mL	100-120 AU/mL	>120 AU/mL
Jo-1	<100 AU/mL	100-120 AU/mL	>120 AU/mL
RNP	<100 AU/mL	100-120 AU/mL	>120 AU/mL
Scl-70	<100 AU/mL	100-120 AU/mL	>120 AU/mL
Sm	<100 AU/mL	100-120 AU/mL	>120 AU/mL
SSA	<100 AU/mL	100-120 AU/mL	>120 AU/mL
SSB	<100 AU/mL	100-120 AU/mL	>120 AU/mL

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Qualitative DSX Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

Lot Specific Data Entry

Mycoplasma IgG DSX A_____ DSX B_____
Mycoplasma IgM DSX A_____ DSX B_____
Parvovirus IgG DSX A_____ DSX B _____
Parvovirus IgM DSX A_____ DSX B_____

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	New Reagent Result

Patient Sample Comparisons

	Old Lot			New Lot			
Accession	Date	Result	Interpretation	Date	Result	Interpretation	Acceptable

The qualitative interpretation should match between the old results and new results. If the interpretations are discrepant, please notify a Supervisor.
The samples used in this assessment should include 1 negative patient and 2 positive patients. If positive patients are not available a positive patient pool control may be substituted or 3 negative patients may be utilized in the absence of positive sample(s).

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Negative/Normal Range	Indeterminate/ Equivocal/ Borderline	Weak Positive Range	Low/Medium Positive Range	Positive/High Positive/Abnormal
ACL IgG	<15	15-20		>20-80	>80
ACL IgA	<12	12-20		>20-80	>80
ACL IgM	<12.5	12.5-20		>20-80	>80
B2GP IgG	≤20				>20
B2GP IgM	≤20				>20
CCP	<20		20-39	40-59	≥60
Gliadin IgG	<20		20-30		>30
Gliadin IgA	<20		20-30		>30
Myco IgG	<0.91	0.91-1.09			>1.09
Myco IgM	<0.91	0.91-1.09			>1.09
Parvo IgG	≤0.89	0.90-1.10			≥1.11
Parvo IgM	≤0.89	0.90-1.10			≥1.11
tTG	<20		20-30		>30
QuantiFERON	Negative	Indeterminate			Positive

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Quantitative DSX Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

QC Data Entry

DSX A_____
DSX B_____

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	New Reagent Result

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	**Date**	**Result (A)**	**Date**	**Result (B)**	B-A=Difference	(B-A)/A X 100=%	

The tolerance for this assay is ±15%. If the result difference falls outside of the tolerance, please notify a Supervisor.

The samples used in this assessment should include 1 negative patient, 1 borderline patient, 1 positive patient.

Tech:_____Date:_____
Approved By:_____ Date:_____

Assay	Normal Range	Borderline Range	Abnormal Range
Calprotectin	<50	50-120	>120

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Beckman DxI Non-Maternal Assays
Assay:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	**Date**	**Result (A)**	**Date**	**Result (B)**	B-A=Difference	(B-A)/A X 100=%	

The tolerance for these assays is ±15%. If the result difference falls outside of the criteria, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	AMR
BAP	3.9-16.8 ug/L (≥25 Year Old Female)	0.1-360.0
EPO	4.5-29.0 mIU/mL	0.6-29.0
sTfR	12.2 – 27.3 nmol/L	3.0 – 1200

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Beckman DxI Maternal Assays
Assay:_____

Reagent Lot Information

Old Lot #:	Date Received:	New Lot #:	Date Received:
Expiration Date:	Substrate Lot:	Expiration Date:	Substrate Lot:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible and should be assayed over 4 to 5 days.
This evaluation must be approved by a Pathologist before the new lot is used to report patient results.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	**Date**	**Result (A)**	**Date**	**Result (B)**	B-A=Difference	(B-A)/A X 100=%	

The tolerance for each assay is listed below:
AFP: 5.5% uE3: 10% hCG: 8.3% Inhibin 8.3% PAPP-A: 10%
If the result falls outside of the tolerance, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	AMR
AFP	Varies with Gestational Age (ng/mL)	0.5-3000
hCG	N/A (mIU/mL)	0.5-1000
uE3	<0.08 (Adult Female)	0.017-69
Inhibin	1.8-17.3pg/mL (Early Follicular Phase Female)	1-1500
PAPP-A	N/A (ng/mL)	1-5000

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Qualitative EUROLabWorkstation Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If “yes”, please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result

Patient Sample Comparisons

	Old Lot			New Lot			
Accession	Date	Result	Interpretation	Date	Result	Interpretation	Acceptable

The qualitative interpretation should match between the old results and new results. If the interpretations are discrepant, please notify a Supervisor.
The samples used in this assessment should include 2 negative patients and 3 positive patients.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Negative Range	Equivocal Range	Positive Range
COVID-19 IgA	<0.80	0.80-1.09	>1.09
COVID-19 IgG	<0.80	0.80-1.09	>1.09

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Quantitative Immulite Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #: New Lot #:
Date Received: Date Received:
Expiration Date: Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible. "Less than" and "greater than" patients may not be used for this assessment. Exception: TSI results should span the AMR to include 2 Negative (<0.10 IU/L) and 3 Positive samples.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	

The tolerance for these assays is ±15%. If the result difference falls outside of the criteria, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Adult Reference Range	AMR
ACT	5-46 pg/mL	5.0 -1250
ATA	≤35 IU/mL	10.0 -1000
ATG	≤20 IU/mL	20.0 - 3000
BP3	2404-5948 ng/mL (20-24 year old male)	500 -16,000
GH	0.1-8.0 ng/mL (adult female)	0.05 - 40.0
IGF	71-290 ng/mL (≥55 year old female)	25.0 -1600
TG	≤55 ng/mL	0.50 - 300
TSI	<0.10 IU/L	0.10 - 40
TIE	<87 IU/mL	1.0 - 2000

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Qualitative Liaison Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #: New Lot #:
Date Received: Date Received:
Expiration Date: Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

	Old Lot			New Lot			
Accession	**Date**	**Result**	**Interpretation**	**Date**	**Result**	**Interpretation**	**Acceptable**

The qualitative interpretation should match between the old results and new results. If the interpretations are discrepant, please notify a Supervisor.
The samples used in this assessment should include 1 negative patient and 2 positive patients. If positive patients are not available for the Toxoplasma IgM assay, 3 negative patients may be utilized.

Tech:_____Date:_____
Approved By:_____ Date:_____

Assay	Negative Range	Equivocal Range	Positive Range
Measles	≤24.9	25.0-29.9	>30
Mumps	≤8.9	9.0-10.9	≥11.0
Rubella	<0.89	0.90-0.99	>1.0
VZV	≤134	135-165	≥166
Toxoplasma IgG	<5.9	6.0-7.9	≥8.0
Toxoplasma IgM	≤7.9	8.0-9.9	≥10.0
Lyme	≤0.89	0.90-1.09	≥1.10
CMV IgG	≤0.59	0.60-0.69	≥0.70
CMV IgM	≤29.0	30-34.9	≥35.0
EBV EA	<9.0	9.0-10.9	≥11.0
EBNA	<18.0	18-21.9	≥22.0
EBV IgG	<18.0	18.0-21.9	≥22.0
EBV IgM	<36.0	36.0-43.9	≥44.0
HSV-1 IgG	≤0.9	0.91-1.09	≥1.10
HSV-2 IgG	≤0.9	0.91-1.09	≥1.10

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Quantitative Liaison Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible. "Less than" and "greater than" patients may not be used for this assessment.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	

The tolerance for these assays is ±15%. If the result difference falls outside of the criteria, please notify a Supervisor.

For the 1, 25 Vitamin D assay, 2 patients <19.9 pg/mL and 3 patients >19.9 should be assessed.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	AMR
1, 25 Vitamin D	19.9-79.3 pg/mL	5.0-200

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Qualitative Manual Assays
Assay:_____

Reagent Lot Information

Old Lot #:
Date Received:
Expiration Date:

New Lot #:
Date Received:
Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

	Old Lot			New Lot			
Accession	Date	Result	Interpretation	Date	Result	Interpretation	Acceptable

The qualitative interpretation should match between the old results and new results. If the interpretations are discrepant, please notify a Supervisor.
The sample criteria used in this assessment should include:
HPF4 - 1 negative patient and 2 positive patients,
RPR, VDRL, TP-PA - 1 non-reactive patient and 2 reactive patients,
Mono - 1 negative patient and 1 positive patient,

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range
HPF4	<0.400 OD
Mono	Negative
RPR	Non-Reactive
TP-PA	Non-Reactive
VDRL	Non-Reactive

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Quantitative Manual Assays
Assay:_____

Reagent Lot Information

Old Lot #: New Lot #:
Date Received: Date Received:
Expiration Date: Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	**Date**	**Result (A)**	**Date**	**Result (B)**	B-A=Difference	(B-A)/A X 100=%	

The tolerance for these assays is listed below:
Citrate Tolerance: +/-20% or 5 mg/L
G6PD Tolerance: 20% or 3.0 U/g Hb
Oxalate Tolerance: 20% or 5 mg/L

If the result difference falls outside of the criteria, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	AMR
Citrate	320-1240 mg/24 hours	30-290 mg/L
G6PD	5.7-14.7 U/g Hgb	0.4-21.0u/g Hb
Oxalate	7-44 mg/24 hours (Adult Male)	0-180 mg/L

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Allergy Assays
Instrument:_____

Reagent Lot Information

Old Conjugate Lot #: New Conjugate Lot #:
Date Received: Date Received:
Expiration Date: Expiration Date:

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

		Old Lot		New Lot		Difference	% Difference	
Accession	Allergen	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	Acceptable

The tolerance for these assays is ±15%. If the result difference falls outside of the criteria, please notify a Supervisor. Two specimens from each class designation (0-5) should be used to span the 0.35-100 kU/L range for this assessment.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	AMR
Allergen	<0.35 kU/L	0.35-100

Range (kU/L)	Class
≤0.34	0
0.35-0.69	1
0.70-3.49	2
3.50-17.49	3
17.50-49.99	4
50.0-100.0	5
>100	6

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
SPA Assays
Assay:_____
Instrument:_____

Reagent Lot Information

Old Lot #: New Lot #:
Date Received: Date Received:
Expiration Date: Expiration Date:

New Kit Insert? Yes No

Data Entry

	SPA A	SPA B
Entered New Lot QC Certificate Data Tech:	_____	_____
Verified QC Cert. Manual Data Entry 2nd Tech:	_____	_____
Screenshots Attached to Worksheet Tech:	_____	_____
Print Calibration Curves/Note Lot # Tech:	_____	_____
Verified QC Cert. Manual Data Entry Lead:	_____	_____

(If "yes", please attach to form and inform Supervisor)

Control Comparisons **(Controls for the SPA may have reagent lot-specific ranges; see QC certificate)**

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	

The tolerance for each assay is listed below:

CH50: 30%
Free Kappa: 20% or 0.3 mg/dL
Free Lambda: 20% or 0.3 mg/dL

IgG1: 15% or 40 mg/dL
IgG2: 15% or 15 mg/dL
IgG3: 15% or 10 mg/dL
IgG4: 15% or 10 mg/dL

2nd Tech QC certificate manual data entry review should be done by a technologist that is trained on the SPA Plus. If the result difference falls outside of the tolerance, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Adult Reference Range	Dilution and Approximate AMR (SPA AMRs Vary with Each Lot)	
CH50	≥ 41.7 U/mL	None	12.7-95.0
Free Kappa	0.33-1.94 mg/dL	1/10	0.40-18.00
Free Lambda	0.57-2.63 mg/dL	1/10	0.45-16.50
IgG 1	341-894 mg/dL	1/10	150-360
IgG 2	171-632 mg/dL	1/10	20-700
IgG 3	18.4-106 mg/dL	1/10	5.5-100.0
IgG 4	2.4-121.0 mg/dL	1/10	3.0-85.0

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
D100 A1c Assay
Instrument:_____

Reagent Lot Information

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

	Old Cartridge	Old A/B Reagents	New Cartridge	New A/B Reagents	Calibrator
Old Lot Number					
New Lot Number					

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible. Lot to lot is required at analytical cartridge change only.

	Old Lot		New Lot		Difference	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	

The tolerance for these assays is ±6.0% or 0.4 (% units) difference.

If the result difference falls outside of the criteria, please notify a Supervisor.

Tech:_____ Date:_____

Approved By:_____ Date:_____

Assay	Reference Range	AMR
Hemoglobin A1c	4.0-5.6%	3.6-20.0%

Special Chemistry Laboratory
Lot to Lot Comparison Worksheet
Variant Beta Thalassemia Assay

Reagent Lot Information

New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)

	Cartridge	Buffer 1	Buffer 2	Wash	Calibrator
Old Lot Number					
New Lot Number					

Control Comparisons

Control Identification	Range	Old Reagent Result	New Reagent Result	

Patient Sample Comparisons

Sample concentrations should span the AMR as completely as possible. At least one sample must include a significant amount of Hemoglobin F and one must include a significant amount of Hemoglobin S.

	Old Lot (A)			New Lot (B)			Difference			% Difference			Acceptable
Accession	A2	F	S	A2	F	S	B-A=Difference			(B-A)/A X 100=%			

The tolerance for Hemoglobin A2 and F is ±8% difference or +/-0.4 (% units) difference.
The tolerance for Hemoglobin S is ±6% difference or +/-0.3 (% units) difference.

If either difference falls outside of the criteria, please notify a Supervisor.

Tech:_____ Date:_____
Approved By:_____ Date:_____

Assay	Reference Range	BioRad Linear Range
Hemoglobin A2	2.0-3.3%	1-13
Hemoglobin F	0.0-2.0%	1-40
Hemoglobin S	0.0-0.0%	N/A