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

Reagent L Old Lot #: Date Receive Expiration Da	d:	New Lot #: Date Received: Expiration Date:							
New Kit Inser		Yes No	(If "yes", plea	se attach to	form and info	rm Supervisor)			
Control C		ons							
Control Ide	ntification		Range	Old Rea	gent Result	New Reag	ent Result		
Patient Sa Sample conce		ould span the	AMR as complete	y as possibl	e. New L o		1		
Accession	Data	Old Lo		Doto			Acceptab		
Accession	Date	Result	Interpretation	Date	Result	Interpretation	Acceptab		
			old results and new						
Crithidia. If the	e results are	discrepant, p	nd new results with please notify a Supe should include 1 neg	rvisor.			iin, and Div		
Tech:				Date:					
				Date.					
Approved	ву:				Date:				
			Assay		rence Range				
		AMA		<1:20					
		ANA		<1:160					
		ANCA APA		<1:20 <1:20					
		7.1. / 1		¬ ∪					

<1:20 <1:20

<1:10 <1:5

ASMA DNA Crithidia

Endo

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

New Lot #:

Date Received:

Reagent Lot Information

Old Lot #:

Sm

SSA

SSB

<100 AU/mL

<100 AU/mL

<100 AU/mL

Date Received:

Expiration Dat	e:	Expiration Date:								
New Kit Insert	New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor						upervisor)			
Control Co	omparis	ons								
Control Ide	ntification	1	Ranç	ge	0	ld Reag	ent Resu	llt	New Reag	ent Result
Patient Sa	mnle Co	mnari	eone							
i atient oa				Lot			New	/ Lot		
Accession	Assay	Date	Result		tion	Date	Result		erpretation	Acceptable
The qualitative	interpretati	on shoul	d match be	etween the old	d resu	Its and n	ew results.	If the	e interpretation	ıs are
discrepant, ple	ease notify a	Supervi	sor.						·	
The samples u	used in this a	assessm	ent should	include 1 neg	gative	patient a	ınd 1 positi	ve pa	itient.	
Tech:					[Date:_				
Approved I										
Ass	av		Negative	Range		Fauiyo	cal Range		Positiv	ve Range
Centromere B	~ <i>j</i>	<100	AU/mL	90		120 AU/m	ıL		>120 AU/mL	- Citaligo
DNA			AU/mL			120 AU/m			>120 AU/mL	
Histone			AU/mL		100-	120 AU/m	ıL		>120 AU/mL	
Jo-1	-		AU/mL	<u> </u>		120 AU/m			>120 AU/mL	
RNP			AU/mL			120 AU/m			>120 AU/mL	
Scl-70		<100	AU/mL		100-	120 AU/m	ıL		>120 AU/mL	

100-120 AU/mL

100-120 AU/mL

100-120 AU/mL

>120 AU/mL

>120 AU/mL

>120 AU/mL

Special Chemistry Laboratory Lot to Lot Comparison Worksheet Qualitative DSX Assays

Assay:	
Instrument:	

Reagent L Old Lot #: Date Receive Expiration Da	nation New Lot #: Date Receiv Expiration D		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 Inser	t?	Yes No	(If "yes", plea	se attach to	form and i	nform Supervisor)	
Control C							
Contro	ol Identifica	ition	Ran	ge		New Reagen	t Result
Patient Sa	ample Co	_			New	1.4	
Accession	Date	Old Lo	Interpretation Date Res			Interpretation	Acceptable
						,	
discrepant, plo The samples	ease notify a used in this a ble a positive	Supervisor. assessment s e patient pool	hould include 1 neg	gative patient	t and 2 pos	ts. If the interpretationsitive patients. If pospatients may be utilized	itive patients
Tech:				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	<u><</u> 20				>20
B2GP IgM	<u><</u> 20				>20
CCP	<20		20-39	40-59	<u>></u> 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	<u><</u> 0.89	0.90-1.10			<u>≥</u> 1.11
Parvo IgM	<u><</u> 0.89	0.90-1.10			<u>≥</u> 1.11
tTG	<20		20-30		>30
QuantiFERON	Negative	Indeterminate			Positive

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

Assay:		
Instrun	nent:	

Reagent Lot Information Old Lot #: Date Received: Expiration Date:				New Lot #: DSX A Date Received: DSX B Expiration Date:					
New Kit Inser	rt?	Yes	No	(If "yes", ple	ease attach to f	orm a	nd inform	Supervisor)	
Control C	ompariso	ns							
Contro	I Identificati	on		Raı	nge		N	lew Reagent R	esult
	ample Cor			MR as comple	tely as possible				
Campio cono		Lot	11071		Lot		erence	% Difference	Acceptable
Accession	Date	Result	(A)	Date	Result (B)	B-A=	:Difference	(B-A)/A X 100=%	-
								ce, please notify	
						, 1 bo	rderline pa	atient, 1 positive	oatient.
Tech:					Date:_				_
Approved	Ву:					Dat	e:		

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

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

		Beckı	man Dxl No Assay:	on-Materna	-		
Reagent L Old Lot #: Date Received Expiration Date	d:	nation	Da	ew Lot #: ate Received: piration Date:			
New Kit Insert	?	Yes	No (If	"yes", please a	attach to form a	nd inform Superv	isor)
Control Ide			ange	Old Rea	ngent Result	New Reag	ent Result
	entrations sho		MR as complet				
Accession	Old Date	l Lot Result (A)	New Date	Lot Result (B)	Difference B-A=Difference	% Difference (B-A)/A X 100=%	Acceptable
The tolerance	for these ass	says is <u>+</u> 15%.	If the result diffe	erence falls ou	tside of the crite	eria, please notify	a Supervisor.
Tech: Approved	Ву:			Date:_	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 Dxl	
Accay.	

			Assay:				
Reagent	Lot Inforn	nation	•				
_		Date Received	: Nev	New Lot #:		Received:	
Expiration Da	ate:	Substrate Lot:		oiration Date:		rate Lot:	
•			•				
New Kit Inser	rt?	Yes No	(If "yes", plea	ase attach to f	form and inform	Supervisor)	
Control C	ompariso	ons					
Control Identification			ange	Old Rea	gent Result	New Reag	ent Result
		mparisons	MR as complete	elv as possible	and should be	assayed over 4 t	o 5 days.
		pproved by a Pa					o o dayo.
		d Lot	New		Difference	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Difference	(B-A)/A X 100=%	
AFP: 5.5%	uE3: 10	say is listed belo % the tolerance, p	hCG: 8.3%	Inhibin 8 Supervisor.	3.3% PAPF	P-A: 10%	
Tech:				Date:_			_
Approved	Ву:				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

		Quanta	Assay:			ayo	
			Instrument				
Reagent L Old Lot #: Date Received Expiration Date	d:	nation	Date	/ Lot #: e Received: iration Date:			
New Kit Insert	t?	Yes	No (If "y	es", please	attach to form	n and inform Supe	rvisor)
Control C			Range	Old Re	agent Resu	It New Rea	gent Result
	, itilioation		rungo	Old No	agom Rooa	TOW ROA	gont recount
Patient Sa	ample Co	mparisor	าร				
	_	Old Lo			New Lo		
Accession	Date	Result	Interpretation	Date	Result	Interpretation	Acceptable
discrepant, ple	ease notify a	Supervisor.	atch between the old				ons are
Tech:				Date:			
Approved	Ву:				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:					
			Instrumen	ıt:				
Reagent L	_ot Inform	nation			_			
Old Lot #:		-	Ne	w Lot #:				
Date Receive	d:			te Received:				
Expiration Da	te:		Ex	piration Date:				
New Kit Inser	t?	Yes No	(If "yes", ple	ase attach to f	orm and i	nform	Supervisor)	
Control C	ompariso	ns						
	entification		Range	Old Rea	gent Re	Sult	New Read	ent Result
Control lac	Zittiii Cation	•	lange	Old IXC	igent ite	Juit	Hew reag	Citt itesuit
		1		1			1	1
Detient C	ample Co		_					
		mparisons			"			
							d "greater than"	
		ment. Exception	on: 151 results si	nould span the	AIVIR TO	nciuae	e 2 Negative (<0.	10 lu/L) and
3 Positive sar		d Lot	New	Lot	Differer	100	% Difference	Acceptable
Accession	Date	Result (A)	Date	Result (B)	B-A=Diffe			Acceptable
Accession	Date	Result (A)	Date	Result (b)	B-A=DIIIe	rence	(B-A)/A X 100=%	
The tolerance	for these ass	savs is +15%	If the result diffe	erence falls ou	tside of th	e crite	ria, please notify	a Supervisor
1110 1010101100	7101 111000 400	5ayo 10 <u>-</u> 1070.	ii tilo roodit diilo	ronco iano ca	.0.00 0	0 01110	na, prodoc nomy	a Caporricor.
T				D :- (-				
				Date:_				
Approved	By:				Date:_			
	Assay		Adult Re	ference Range			AMR	
ACT			5-46 pg/mL	·····g-		5.0 -1		
ATA			<35 IU/mL			10.0 -		
ATG			<20 IU/mL	(22.24			3000	
BP3			2404-5948 ng/mL		male)		16,000	
GH IGF			<u>0.1-8.0 ng/mL (adu</u> 71-290 ng/mL (<u>></u> 55		2)	0.05 - 25.0 -		
TG			<u>/ 1-290 fig/filL (≥</u> 50 <u><</u> 55 ng/mL	year old leitlalt	-)	0.50		
TSI			<0.10 IU/L			0.10 -		
TIE			<87 IU/mL			1.0 - 2		

Special Chemistry Laboratory Lot to Lot Comparison Worksheet Qualitative Liaison Assays

Assay:	
Instrument:_	

_		4	4.
KDDU	ant I	At Inta	rmation
ILCAU	CIIL	.UL IIIIU	THALION

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 Resu		

Patient Sample Comparisons

	-	Old Lot			New Lot			
Accession	Date	Result	Interpretation	Date	e 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	<u><</u> 24.9	25.0-29.9	>30
Mumps	<u><</u> 8.9	9.0-10.9	≥11.0
Rubella	<0.89	0.90-0.99	>1.0
VZV	<u><</u> 134	135-165	<u>></u> 166
Toxoplasma IgG	<5.9	6.0-7.9	≥8.0
Toxoplasma IgM	<u><</u> 7.9	8.0-9.9	≥10.0
Lyme	<u><</u> 0.89	0.90-1.09	≥1.10
CMV IgG	<u><</u> 0.59	0.60-0.69	<u>≥</u> 0.70
CMV IgM	<u><</u> 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	<u><</u> 0.9	0.91-1.09	≥1.10
HSV-2 IgG	<u><</u> 0.9	0.91-1.09	<u>≥</u> 1.10

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

			Instrument	t:				
Reagent Old Lot #: Date Receive Expiration Da		ation	Dat	v Lot #: e Received: iration Date:				
New Kit Inser		Yes	No (If "	yes", please a	attach to form ar	nd inform Superv	isor)	
	ompariso			OLLD		l Non Brown		
Control Id	entification	R	ange	Old Rea	gent Result	New Reag	ent Result	
							-	
							ļ	
							ļ	
Sample conc				ly as possible	e. "Less than" ar	nd "greater than"	patients may	
	Old	Lot	New I	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:								
				Date:			_	
Approved	By:				Date:			

Reference Range

19.9-79.3 pg/mL

AMR

5.0-200

Assay

1, 25 Vitamin D

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

Reagent L	ot Inform	ation							
Old Lot #:			New	Lot #:					
Date Received	d:	Date Received:							
Expiration Dat	e:		Expi	ration Date:					
New Kit Insert	?	Yes	No (If "y	(If "yes", please attach to form and inform Supervisor)					
Control Co		ns	Range Old Reagent Result New Reage			ant Danult			
Control Ide	ntification		Range	Old Rea	agent Resu	Ιτ	New Reag	ent Result	
		•							
Patient Sa	ımple Coı								
		Old Lo			New Lo				
Accession	Date	Result	Interpretation	Date	Result	Inte	erpretation	Acceptabl	
The qualitative	e interpretatio	n should ma	I atch between the old	t results and	l I new results	If the	interpretation	s are	
discrepant, ple							· ····································		
			ment should include) :					
HPF4 - 1 nega									
			itient and 2 reactive	patients,					
Mono - 1 nega	ative patient a	ınd 1 positiv	e patient,						
Tech:				Date:					
Approved					Date:				
, ippiovou	- y∙				D ato				
			Assay	Refer	rence Range				
		HPF4	•	<0.400 OD					
		Mono		Negative					
		RPR		Non-Reactiv					
		TP-PA VDRL		Non-Reactiv					
		VDUL		INUITINGACIIN	1				

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

Reagent L	_ot Inform	nation							
Old Lot #: New Lot #:									
Date Received: Date Received: Familiation Potential									
Expiration Da	te:		Exp	iration Date:					
New Kit Insert? Yes No (If "yes", please attach to form and inform Supervisor)									
Control C		ns							
Control Ide	entification	F	Range	Old Rea	igent Re	sult	New Reag	ent Result	
Patient Sa Sample conce	entrations sho	ould span the	AMR as complete				0/ P)//		
Accession	Date	Lot Result (A)	New Date	Lot Result (B)	Differer		% Difference	Acceptable	
Accession	Date	Result (A)	Date	Result (b)	B-A=Diffe	rence	(B-A)/A X 100=%		
			1						
The tolerance Citrate Tolera G6PD Tolera Oxalate Toler	nce: +/-20% once: 20% or 3	or 5 mg/L 3.0 U/g Hb	pelow:						
If the result di	fference falls	outside of the	criteria, please n	otify a Super	visor.				
				Date:					
Approved	Ву:				Date:_				
	Assay		Refere	ence Range			AMR		
Citrate			320-1240 mg/24 hc	ours			0 mg/L		
G6PD Oxalate			5.7-14.7 U/g Hgb 7-44 mg/24 hours (Adult Male)		0.4-2	1.0u/g Hb mg/l		
JAGIGIO			i mg/== nouls (ait ividioj		0 100	g/ ⊏		

Special Chemistry Laboratory Lot to Lot Comparison Worksheet Allergy Assays

Instrument:	

Reagent Lot Information

Old Conjugate Lot #:
Date Received:
Expiration Date:

New Conjugate Lot #:
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.

		0	ld Lot	N	lew 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 $\pm 15\%$. 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
<u><</u> 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: Instrumer	nt:	<u>—</u> —		
Old Lot #: Date Receive Expiration Da New Kit Inser	te: Expiration	t #: eceived: on Date: Yes No	Verified QC Screenshots Print Calibra Verified QC (If "yes", ple	w Lot QC Cert Cert. Manual s Attached to \ ation Curves/N Cert. Manual ase attach to t	Data Entry WorksheetTech: lote Lot # Data Entry form and inform	Tech: 2 nd Tech: Tech: Lead: Supervisor)	
	omparison		ior the SPA m inge		ent lot-specific agent Result		certificate) ent Result
Patient S	ample Con	nparisons					
Sample conc		uld span the AM				0/ 5/4	T
Accession	Old Date	Result (A)	New Date	Result (B)	Difference B-A=Difference	% Difference (B-A)/A X 100=%	Acceptable
CH50: 30% Free Kappa:	e for each assa 20% or 0.3 mg : 20% or 0.3 m		N:	IgG2: 1: IgG3: 1:	5% or 40 mg/dL 5% or 15 mg/dL 5% or 10 mg/dL		
		nual data entry r outside of the to		be done by a t	5% or 10 mg/dL echnologist that ervisor.	is trained on the	SPA Plus.

Assay	Adult Reference Range		pproximate AMR ary 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

Instr	umei	nt:	i i

Reagent	Lot In	formation
---------	--------	-----------

New Kit Insert	?	Υ	′es		No	(If "y	es", please a	attac	h to form ar	nd inform S	Supervi	isor)
	Old		ı	Old A/B		N	New Cartridge		New A/B			Calibrator
	Cartridge			Reag			.		Reage			
Old Lot Number												
New Lot Numb	ber											
Control Co			าร									
Control Ide	ntific	cation		Ran	ge		Old Rea	ıger	nt Result	New	Reag	ent Result
Patient Sa Sample conce change only.		ons shou	ıld span th					e. Lo	t to lot is red	quired at a	nalytic	al cartridge
		Old				ew L		Di	fference	% Difference		Acceptable
Accession	D	ate	Result (A	.)	Date		Result (B)	В-	A=Difference	(B-A)/A X	100=%	
The tolerance	for th	ese assa	ays is +6.0°	% or ().4 (% unit	ts) di	fference.					<u> </u>
					•	•						
If the result dif	feren	ce falls o	utside of th	ne crit	eria, pleas	se no	otify a Super	/isor				
Tech:							Dato					
Tech:							Dale.					
Approved I	Б у							υċ	ate:			
	Δςς	ay			R ₄	efere	nce Range				AMR	
1	1700	. ∽ y		1	110		ioo rango		1		, 11411 /	

4.0-5.6%

3.6-20.0%

Hemoglobin A1c

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 Su	pervisor)
-----------------	-----	----	--	-----------

	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)	N	ew Lot (B)	Dif	fferen	ce	% D	iffere	nce	Acceptable
Accession	A2	F	S	A2	F	S	B-A	=Differe	ence	(B-A))/A X 10	00=%	

The tolerance for Hemoglobin A2 and F is +8% difference or +/-0.4 (% 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

The tolerance for Hemoglobin S is $\pm 6\%$ difference or ± -0.3 (% units) difference.