

HIV Algorithm LIS reporting Reference Guide

RC.CH.CSL.ARC.RG.002r03

Purpose

This reference guide is to aid in the reporting of discrepant positive HIV test results within SOFT (LIS) and Instrument Manager (IM). If the result is initially positive, the results will be held in IM. Follow the guide below to process positive HIV results for HIV4G, HSPP and HIVOB orders.

1. All reactive HIV results are held in review in Instrument Manager. After the initial result, spin down for 10 mins. Reload the sample and run in duplicate. If 2/3 results are negative, the result is reported as negative. If 2/3 results are positive, confirmatory testing (done at Royal Oak) must be performed.

Test Worksheet									
	Test Code	Test Name /	Result	Units	Reference...	Rerun	Error Name(s)	Result Date/Ti...	Test Dilution
*						☐			
	-	Held for Verification							
	HIV2	HIV Ag/Ab	3.93	S/CO		☐	OTHER TEST(S) HELD FOR REVIEW	8/7/2019 9:48...	
	HIV3	HIV Ag/Ab	3.87	S/CO		☐	OTHER TEST(S) HELD FOR REVIEW	8/7/2019 9:48...	
	HIVAB	HIV Ag/Ab	Reactive			☐	Final Result Reactive	8/7/2019 9:48...	
	HIVRO	HIV Ag/Ab	3.90	S/CO		☐	Re-centrifuge and Rerun in Duplicate	8/7/2019 9:01...	UNDILUTED
	-	Released							
	CKIN	CKIN	IOM-R2			☐		8/7/2019 8:27...	
	CKIN	CKIN	IOM-R2			☐		8/7/2019 9:17...	
	Duplicate	Duplicate	2			☐		8/7/2019 9:48...	
	QRY	QRY	HIVRO			☐		8/7/2019 8:30...	
	QRY	QRY	HIV2\HIV3			☐		8/7/2019 9:20...	

2. **Release**  results from the Instrument Manager. Be sure to only send 1 instance of HIVRO. If there are multiple HIVRO fields you must reject all but the one result you want to send over.

Test Worksheet									
	Test Code	Test Name /	Result	Units	Reference...	Rerun	Error Name(s)	Result Date/Ti...	Test Dilution
*						☐			
	-	Released							
	CKIN	CKIN	IOM-R2			☐		8/7/2019 8:27...	
	CKIN	CKIN	IOM-R2			☐		8/7/2019 9:17...	
	Duplicate	Duplicate	2			☐		8/7/2019 9:48...	
	HIVRO	HIV Ag/Ab	3.90	S/CO		☐	Re-centrifuge and Rerun in Duplicate	8/7/2019 9:01...	UNDILUTED
	HIV2	HIV Ag/Ab	3.93	S/CO		☐	OTHER TEST(S) HELD FOR REVIEW	8/7/2019 9:48...	
	HIV3	HIV Ag/Ab	3.87	S/CO		☐	OTHER TEST(S) HELD FOR REVIEW	8/7/2019 9:48...	
	HIVAB	HIV Ag/Ab	Reactive			☐	Final Result Reactive	8/7/2019 9:48...	
	QRY	QRY	HIVRO			☐		8/7/2019 8:30...	
	QRY	QRY	HIV2\HIV3			☐		8/7/2019 9:20...	

HIV4G Algorithm LIS reporting Reference Guide

- a. **HIV4G:** Results will transmit to Soft but will not populate on the Instrument Menu. They will auto post and not verify. The result will be posted on Royal Oak pending list ROHVC. Sites can verify the result is posted and not verified in Order Entry.

Worklist ROHVC

Patient Info

Name (last, first, middle): **GE, DOUBLE**

MRN: **6001062** Sex: **M** Age: **37** Ward: **ROBUL** Room: More...

Order Info

Order: **B70700016** Prior: **R** Aux#: Collected: **08/07/2019** **08:00**

Tests: **HIV4G**

Comment Verify Verify All Check Canned Msg Def Res Tst Hist Formulary

T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HIV4G	HIVRO	4.76	AB		0.00	08/07/2019	c	LC D P	I/AUT	08/07/2019	09:45	I/AUT
2	HIV4G	HIVAB	Reactive	AB %D		Nonreactive	08/07/2019	c	LC	I/AUT			
3	HIV4G	HIVR1				Nonreactive	08/06/2019	c	LC				
4	HIV4G	HIVR2				Nonreactive	08/06/2019	c	LC				
5	HIV4G	VAL18				Yes	08/06/2019	c	LC				
6	HIV4G	VAL19				Yes	08/06/2019	c	LC				
7	HIV4G	INTHV				@HV11	08/07/2019	c	LC				

Order Entry

General Insurance (1) Specimens (5) Results (13) BBank

Comment Verify Verify All Check Rev Canned Msg Default Res Test History Batch Result

T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HIV4G	HIVRO	2.00	AB		0.00	08/14/2019	c	C D P	I/AUT	08/14/2019	10:54	I/AUT
2	HIV4G	HIVAB	Reactive	AB %		Nonreactive	08/14/2019	c	C	I/AUT			
3	HIV4G	HIVEE	Reactive			Nonreactive	08/14/2019	c	C	I/AUT			
4	HIV4G	HIVE1	Cancel			Cancel	08/14/2019	c	C V	AHUF	08/14/2019	10:53	AHURA
5	HIV4G	HIVR1				Nonreactive	08/14/2019	c	C				
6	HIV4G	HIVR2				Nonreactive	08/14/2019	c	C				
7	HIV4G	VAL18				Yes	08/14/2019	c	C				
8	HIV4G	VAL19				Yes	08/14/2019	c	C				
9	HIV4G	XH1RN						c	C VR		08/14/2019	10:53	V/AUT
10	HIV4G	XH2DN						c	C VR		08/14/2019	10:53	V/AUT
11	HIV4G	INTHV				@HV11	08/14/2019	c	C				
12	HIV4G	MD0HV				E Sykes, MD	08/14/2019	c	C				
13	HIV4G	315MS	Unknown			Unknown	08/14/2019	c	C V	AHUF	08/14/2019	10:53	V/AUT

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.

HIV4G Algorithm LIS reporting Reference Guide

- b. **HSP/HIVOB**: Results will transmit to SOFT and will be listed on the Instrument Menu. Use the Lab Results Tab [Lab Results](#) at the bottom to complete the CALTO box. Save and Verify All – results will be released as Uncon Reactive. The results will be posted and verified on Royal Oak pending list ROHVC. Sites can verify results are posted and confirmed in Order Entry.

Instrument Menu

Patient Info
Name (last, first, middle): **BEAN, POLE**

MRN: 6000783 Sex: F Age: 18 Ward: RRONC Room: More...

Order Info
Order: B71300266-SI Prior: R Seq: 00002 Spec: SIT Collected: 08/13/2019 08:00

Tests: HIVOB

Comm Post All Part Post Rerun Check Tst Hist

Wkst	Itst	Stst	Result	FI	D	Flags	M	Error	Status	Prev Res	Prev Date	Prev Order	T
1	R4001	HIVRO	HIVRO	2.00		AB			O	1.10	08/13/2019	B71300003	

Lab Results Tab from Instrument Menu

Patient Info
Name (last, first, middle): **BEAN, POLE**

MRN: 6000783 Sex: F Age: 18 Ward: RRONC Room: More...

Order Info
Order: B71300266-SI Prior: R Seq: 00002 Spec: SIT Collected: 08/13/2019 08:00

Tests: HIVOB

Save Comm Coll/Rec Ver Ver All Check Rev Cnd Msg Def Res Tst Hist Batch R

T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV	
1	HIVOB	VAL11						c	C	VR	AHURA	08/13/2019	15:31	AHURA
2	HIVOB	HVRP2						c	C	VR	AHURA	08/13/2019	15:31	AHURA
3	HIVOB	HVRP1						c	C	VR	AHURA	08/13/2019	15:31	AHURA
4	HIVOB	HVRP3						c	C	VR	AHURA	08/13/2019	15:31	AHURA
5	HIVOB	CALTO	Yes			Yes	08/13/2019	c	C	V	AHURA	08/13/2019	15:35	AHURA
6	HIVOB	TAKE4						c	C	VR		08/13/2019	15:31	V/AUT
7	HIVOB	HVRP						c	C	VR		08/13/2019	15:31	V/AUT
8	HIVOB	TAKE1						c	C	VR		08/13/2019	15:31	V/AUT
9	HIVOB	HIVRO				1.10	08/13/2019	c	C	D				
10	HIVOB	HIVAB				Uncon Reac	08/13/2019	c	C					
11	HIVOB	HIVEE				Uncon Reac	08/13/2019	c	C					
12	HIVOB	HIVE1	Cancel			Cancel	08/13/2019	c	C	V	AHURA	08/13/2019	15:31	AHURA
13	HIVOB	HIVR1				Reactive	08/13/2019	c	C					
14	HIVOB	HIVR2				Nonreactive	08/13/2019	c	C					
15	HIVOB	VAL18				Yes	08/13/2019	c	C					
16	HIVOB	VAL19				Yes	08/13/2019	c	C					
17	HIVOB	XH1RN						c	C	VR		08/13/2019	15:31	V/AUT
18	HIVOB	XH2DN						c	C	VR		08/13/2019	15:31	V/AUT
19	HIVOB	INTHV				@HV12	08/13/2019	c	C					
20	HIVOB	MDQHV				E Sykes, MD	08/06/2019	c	C					
21	HIVOB	315MS	Unknown			Unknown	08/13/2019	c	C	V	AHURA	08/13/2019	15:31	V/AUT

[Lab Results](#)

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.

HIV4G Algorithm LIS reporting Reference Guide

Order Entry

General Insurance (1) Specimens (7) Results (25) BBank													
Comment Verify Verify All Check Rev Canned Msg Default Res Test History Batch Result													
T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HIVOB	VAL11	.					c	C E VR	AHUF	08/13/2019	15:35	AHURA
2	HIVOB	HVRP2	.					c	C E VR	AHUF	08/13/2019	15:35	AHURA
3	HIVOB	HVRP1	.					c	C E VR	AHUF	08/13/2019	15:35	AHURA
4	HIVOB	HVRP3	.					c	C E VR	AHUF	08/13/2019	15:35	AHURA
5	HIVOB	CALTO	Yes			Yes	08/13/2019	c	C V	AHUF	08/13/2019	15:35	AHURA
6	HIVOB	TAKE4	.					c	C VR		08/13/2019	15:31	V/AUT
7	HIVOB	HIVRP	.					c	C VR		08/13/2019	15:31	V/AUT
8	HIVOB	TAKE1	.					c	C VR		08/13/2019	15:31	V/AUT
9	HIVOB	HIVRO	2.00	AB		0.00	08/13/2019	c	C D PV	AHUF	08/13/2019	15:35	AHURA
10	HIVOB	HIVAB	Uncon Reactive	AB		Nonreactive	08/13/2019	c	C V	AHUF	08/13/2019	15:35	AHURA
11	HIVOB	HIVEE	Uncon Reactive			Nonreactive	08/13/2019	c	C V	AHUF	08/13/2019	15:35	AHURA
12	HIVOB	HIVE1	Cancel			Cancel	08/13/2019	c	C V	AHUF	08/13/2019	15:31	AHURA

3. *****Important work around for 2/3 negative results.** If a sample is positive initially and negative after the 10 min spin, the HIVRO result in IM must be manually changed to a negative result. SOFT can only accept HIVRO (not HIV2 or HIV3).

Test Worksheet									
Test Code	Test Name /	Result	Units	Reference...	Rerun	Error Name(s)	Result Date/Ti...	Test Dilution	
* Held for Verification									
HIVRO	HIV Ag/Ab	3.71	S/CO		☐	Re-centrifuge and Rerun in Duplicate	8/7/2019 9:00...	UNDILUTED	
- Released									
CKIN	CKIN	IOM-R2			☐		8/7/2019 9:01...		
CKIN	CKIN	IOM-R2			☐		8/7/2019 9:18...		
CKIN	CKIN	IOM-R2			☐		8/7/2019 8:27...		
Duplicate	Duplicate	2			☐		8/7/2019 9:49...		
HIV2	HIV Ag/Ab	0.08	S/CO		☐		8/7/2019 9:49...		
HIV3	HIV Ag/Ab	0.09	S/CO		☐		8/7/2019 9:49...		
HIVAB	HIV Ag/Ab	Nonreactive			☐	Final Result NONREACTIVE	8/7/2019 9:49...		
QRY	QRY	HIVRO			☐		8/7/2019 8:30...		
QRY	QRY	HIV2\HIV3			☐		8/7/2019 9:21...		

HIV2 and HIV3 will auto release. It will hold HIVRO. This result must be manually changed and then released from IM. Be sure to save  before releasing  the HIVRO result.

Test Worksheet									
Test Code	Test Name /	Result	Units	Reference...	Rerun	Error Name(s)	Result Date/Ti...	Test Dilution	Er
* Held for Verification									
HIVRO	HIV Ag/Ab	0.08	S/CO		☐	Re-centrifuge and Rerun in Duplicate	8/7/2019 9:00...	UNDILUTED	
- Released									
CKIN	CKIN	IOM-R2			☐		8/7/2019 9:01...		
CKIN	CKIN	IOM-R2			☐		8/7/2019 9:18...		
CKIN	CKIN	IOM-R2			☐		8/7/2019 8:27...		
Duplicate	Duplicate	2			☐		8/7/2019 9:49...		
HIV2	HIV Ag/Ab	0.08	S/CO		☐		8/7/2019 9:49...		
HIV3	HIV Ag/Ab	0.09	S/CO		☐		8/7/2019 9:49...		
HIVAB	HIV Ag/Ab	Nonreactive			☐	Final Result NONREACTIVE	8/7/2019 9:49...		
QRY	QRY	HIVRO			☐		8/7/2019 8:30...		
QRY	QRY	HIV2\HIV3			☐		8/7/2019 9:21...		

The negative result will autoverify.

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.

HIV4G Algorithm LIS reporting Reference Guide

4. ****All confirmation testing is performed at Royal Oak****

All sites will send over HIV sample with at least 1.5 mL serum for Geenius testing.
Please send additional tubes to complete 1.5mL requirement.

Royal Oak Only: Workflow for all Geenius testing:

1. Follow the HIV flow chart to determine if the positive sample needs to be sent out to LabCorp or Quest.
 - a. If the Architect results are positive and the Geenius is Positive for HIVR1, all results can be verified from the ROHVC worklist. A comment should auto populate and all results can be verified.

Worklist ROHVC

Comment Verify Verify All Check Canned Msg Def Res Tst Hist Formulary													
T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HIV4G	HIVR0	4.76	AB		0.00	08/07/2019	c	LC D P	I/AUT	08/07/2019	09:45	I/AUT
2	HIV4G	HIVAB	Reactive	AB %D		Nonreactive	08/07/2019	c	LC	I/AUT			
3	HIV4G	HIVR1	Reactive	AB		Nonreactive	08/06/2019	c	LC	AHURA			
4	HIV4G	HIVR2	Nonreactive			Nonreactive	08/06/2019	c	LC	AHURA			
5	HIV4G	VAL18	Yes			Yes	08/06/2019	c	LC	AHURA			
6	HIV4G	VAL19	Yes			Yes	08/06/2019	c	LC	AHURA			
7	HIV4G	INTHV	@HV12			@HV11	08/07/2019	c	LC	AHURA			

Order #: B70700016 Collected: 08/07/2019 08:00

Test Name	Result	ABN	Ref-Ranges	Units	Site
HIV-1/2 Testing Algorithm					
HIV-1 p24 Antigen/HIV-1/2 Antibody Screen	Reactive	AB	Nonreactive		R
HIV-1 Antibody Confirmation	Reactive	AB	Nonreactive		R
HIV-2 Antibody Confirmation	Nonreactive		Nonreactive		R
Interpretation	see below				R
Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present. NOTE: HIV vaccine recipients may develop antibodies to HIV, but may and or may not be infected with HIV.					

- b. If the Architect results are Positive and the Geenius is negative or indeterminate (refer to flow chart for all possible scenarios), the results

must be SAVED and NOT VERIFIED from the ROHVC worklist. The INTHV field will remain open.

- i. Be sure to fill out the HIV send out Log for samples sent out.
- ii. These orders will remain on the pending list until the results come back from LabCorp/Quest and the pathologist has time to review.

Worklist ROHVC

Comment Verify Verify All Check Canned Msg Def Res Tst Hist Formulary													
T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HIV4G	HIVR0	3.90	AB		4.76	08/07/2019	c	LC D P	I/AUT	08/07/2019	09:56	I/AUT
2	HIV4G	HIVAB	Reactive	AB		Reactive	08/07/2019	c	LC	I/AUT			
3	HIV4G	HIVR1	Nonreactive			Reactive	08/07/2019	c	LC	AHURA			
4	HIV4G	HIVR2	Nonreactive			Nonreactive	08/07/2019	c	LC	AHURA			
5	HIV4G	VAL18	Yes			Yes	08/07/2019	c	LC	AHURA			
6	HIV4G	VAL19	Yes			Yes	08/07/2019	c	LC	AHURA			
7	HIV4G	INTHV				@HV12	08/07/2019	c	LC				

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.

Entering Bio-Rad Geenius results:

Reporting fields' descriptions:

HIVR1 HIV-1 Confirmation	Options: Reactive, Non-Reactive, or Indeterminate
HIVR2 HIV-2 Confirmation	Options: Reactive, Non-Reactive, or Indeterminate
VAL18 QC, Is QC spot present?	Options: Yes
VAL19 QC, Is background clear?	Options: Yes

If the sample allows, save one labeled 0.5 mL aliquot for Beaumont in the HIV rack in the silver freezer.

If the result is reactive on the Architect and Negative or Indeterminate on the Bio-Rad Geenius, email Patient Name, MRN, Date Drawn and the Date Specimen was Placed in Send-out refrigerator to:

Dr. Sykes (Elizabeth.Sykes@beaumont.org)

Dr. Kennedy (timothy.kennedy2@beaumont.org)

Joel Waddington (joel.waddington@beaumont.org)

Ashley Hurand(ashley.hurand@beaumont.org)

Refer to the BioRad Geenius procedure for additional details. RC.CH.CSL.MT.PR.014

Authorized Reviewers

Section Supervisor or MT II

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.

HIV4G Algorithm LIS reporting Reference Guide

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:\Automated Chemistry\Document Control Library\start) INDEX and TEMPLATE\CSL Chemistry Stat Lab\ARC- Architect\Master

Master printed document stored in the Architect Master Binder.

Number of circulating Controlled Copies: 0

Location of circulating Controlled Copies: n/a

Document History

[illegible]

Printed copies of this document are not considered up-to-date. Please verify current version date with online document.