

Beaumont

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Applicability Royal Oak

HIV Algorithm LIS Reporting Reference Guide Royal Oak

Document Type: Guideline

I. PURPOSE AND OBJECTIVE:

- A. This reference guide is to aid in the reporting of Reactive HIV (≥ 1.00) test results within EPIC Beaker Laboratory Information System (LIS) and Instrument Manager (IM). If the initial result (HIVRO) is Reactive, the result will be held in IM. The specimen needs to be centrifuged for 10 minutes and run in duplicate. If 2 of the 3 results are Reactive, the sample will need confirmation testing on the Bio-Rad Geenius. All confirmation testing will be performed at Royal Oak. Follow the guide below to process all HIV results for HIV4G, HSPP and HIVOB orders.

II. DIFFERENCES IN PROCESSING HIVOB/HSPP VS HIV4G FOR REACTIVE RESULTS:

There are some differences in processing HIVOB/HSPP vs HIV4G for the Architect screen which is listed as HIV-1/2 Testing Algorithm in Beaker.

- A. **HIVOB/HSPP** – Results released from IM to Beaker will post as “Unconfirmed Reactive” for the Architect screen. The HIV Antibody confirmation test will be pending. Techs are required to complete the “Results Called?” box by selecting YES and using the comm log to complete the call.

#	Ref Component	Value	Units	Ref Range	Method	Chart
1	HIV 1/2 ANTIBODY (INDEX)	0.00	Index	0.00-0.99	MANUAL METHOD	
2	HIV-1 F24 ANTIGEN/HIV-1/2 ANTIBODY SCREEN	Unconfirmed Reactive		Nonreactive	MANUAL METHOD	

- B. Once the results have been called, the Architect portion of the sample can be SAVED and VERIFIED. Send to Royal Oak core lab for Geenius Confirmation Testing.

Ref	Component	Value	Units	I	A	L	RE	R	Ref Range	Method	Chart
1	HIV 1/2 ANTIBODY (INDEX)	0.00	Index						0.00-0.99	MANUAL METHOD	
1	HIV-1 F24 ANTIGEN/HIV-1/2 ANTIBODY SCREEN	Unconfirmed Reactive		1					Nonreactive	MANUAL METHOD	
	Result called?	Yes								MANUAL METHOD	

- C. **HIV4G** – Results released from IM to Beaker will post as “Reactive” for the Architect screen. The HIV Antibody confirmation test will be pending. Results are not required to be called. The HIV4G screen should NOT be verified until Geenius testing is completed. All HIV4G and Geenius results are to be final verified once Geenius testing is completed.

III. REPORTING HIVS:

A. Nonreactive Architect Result

1. Architect results that are less than 1.0 will not hold in IM. These samples will automatically verify.

B. Reactive Architect Result

1. Architect results will hold in IM. After the sample has completed its 3 runs, and 2 out of 3 results are Reactive, the results can be released from IM.

- a. In IM, the initial result will be held for verification and there will be instructions to Re-centrifuge and Rerun in Duplicate. The sample will sort at IOM2 to the HIVC rack. The sample will need to be spun for 10 minutes and placed back on the track to run HIV 2 more times.

Tests Held										Patient ID: 1
100024672 R BEAKEREPIC.CHEMB										Date of Birth:
Test Worksheet										
Connection Name	Test Name	Test Code	Result	Units	Result	Reference	Reun	Test Dilution	Result Date/Time	Error Name(s)
Held for Verification										
[none]										
R02-ISR-02	HIV Ag/Ab	HIVRO	4.08	S/CO	F	-	☐	UNDILUTED	9/24/2020 8:37:00 AM	Re-centrifuge and Rerun in Duplicate
Pending										
[none]										
DMS-G STATUS, DMS-R	HEPSPIN	HEPSPIN					☐			
FT801, FT802, R4001, R4	HIV Ag/Ab	HIV2					☐			
FT801, FT802, R4001, R4	HIV Ag/Ab	HIV3					☐			
Released										
[none]										
R07-C16-01	Hemolysis	H	2	Index	F		☐	STANDARD	9/24/2020 8:18:33 AM	

- b. Once the sample has been run in duplicate, if 2/3 results are Reactive, the sample will sort at IOM2 in the HIVC rack for Geenius testing. All 3 Reactive results will be Held for Verification. The interpretation in IM (HIVAB) will show as Reactive.

- i. NOTE: If 2/3 results are Nonreactive, the result is Nonreactive and can be released.

- c. These results can be released from IM.

Tests Held										Patient ID: 9102726
100024672 R BEAKEREPIC.CHEMB										Date of Birth: 3/4/1984
Test Worksheet										
Connection Name	Test Name	Test Code	Result	Units	Result	Reference	Reun	Test Dilution	Result Date/Time	Error Name(s)
Cancelled										
[none]										
Specimen Management	HEPSPIN	HEPSPIN					☐			
Specimen Management	HIV Reactive Sort	HIVC					☐			
Held for Verification										
[none]										
R02-ISR-02	HIV Ag/Ab	HIVRO	4.08	S/CO	F	-	☐	UNDILUTED	9/24/2020 8:37:00 AM	Re-centrifuge and Rerun in Duplicate
R04-ISR-04	HIV Ag/Ab	HIV2	4.04	S/CO			☐		9/24/2020 10:18:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	HIV Ag/Ab	HIV3	4.18	S/CO			☐		9/24/2020 10:18:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	HIV Ag/Ab	HIVAB	Reactive				☐		9/24/2020 10:18:52	Final Result Reactive
Released										
[none]										
R04-ISR-04	Duplicate	Duplicate	2				☐		9/24/2020 10:18:52	
R07-C16-01	Hemolysis	H	2	Index	F		☐	STANDARD	9/24/2020 8:18:33 AM	

Tests Held										Patient ID: 9102726
100024672 R BEAKEREPIC.CHEMB										Date of Birth: 3/4/1984
Test Worksheet										
Connection Name	Test Name	Test Code	Result	Units	Result	Reference	Reun	Test Dilution	Result Date/Time	Error Name(s)
Cancelled										
[none]										
Specimen Management	HIV Reactive Sort	HIVC					☐			
Specimen Management	HEPSPIN	HEPSPIN					☐			
Released										
[none]										
R02-ISR-02	HIV Ag/Ab	HIVRO	4.08	S/CO	F	-	☐	UNDILUTED	9/24/2020 8:37:00 AM	Re-centrifuge and Rerun in Duplicate
R04-ISR-04	Duplicate	Duplicate	2				☐		9/24/2020 10:18:52	
R04-ISR-04	HIV Ag/Ab	HIV2	4.04	S/CO			☐		9/24/2020 10:18:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	HIV Ag/Ab	HIVAB	Reactive				☐		9/24/2020 10:18:52	Final Result Reactive
R04-ISR-04	HIV Ag/Ab	HIV3	4.18	S/CO			☐		9/24/2020 10:18:52	OTHER TEST(S) HELD FOR REVIEW
R07-C16-01	Hemolysis	H	2	Index	F		☐	STANDARD	9/24/2020 8:18:33 AM	

2. Go to Result Entry in Beaker. The Architect Results should be listed but not verified and the confirmation test should be added on.
3. Complete Geenius testing and record results for HIV-1 Antibody Confirmation, HIV-2 Antibody Confirmation, and Is QC Present?

HIV Antibody Confirmation 		● Routine	U On Test	ⓘ
HIV-1 Antibody Confirmation		Manual	➔	
HIV-2 Antibody Confirmation		Manual	➔	
IS QC Present?		Manual	⚡	
HIV Interpretation		HIV Antibody...	Manual	⚡

4. Save and Verify the results for the HIV4G and Geenius Confirmation.
5. An HIV interpretation and comment will automatically populate as necessary. These are determined by the Geenius results.
6. For more information on reporting Geenius results, see the [Geenius HIV 1/2 Supplemental Assay - Royal Oak](#) procedure.
7. This test is complete and should no longer be listed on the outstanding list. 0.5mL of sample should be poured over and frozen if the sample permits.

C. Further MT/MLT actions required

1. Certain combinations of Geenius results require further tech action.
2. Send sample out to Warde for HIV-1 RNA testing
 - a. For these Geenius interpretations, **HIV Antibody Negative, HIV Indeterminate, HIV-1 Indeterminate, or HIV-2 Indeterminate**, an aliquot of the sample should be sent to Warde for HIV-1 RNA testing.
 - b. The results of the HIV 1/2 Architect screen and Geenius Confirmation should be verified.
 - c. See the HIV Geenius Flowchart to send email to the correct individuals.
 - d. An order for HIV-1, Qualitative Real-Time PCR will automatically generate. Use this label to send out an aliquot of 1 mL of EDTA plasma to Warde.
 - e. An order for a Path Review will also generate.
3. For all other Geenius interpretations, **HIV Positive untypable (undifferentiated), HIV-1 Positive, HIV-2 Positive, HIV-2 Positive with HIV-1 cross reactivity**, HIV 1/2 Architect screen and Geenius Confirmation results should be verified.

Attachments

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Approval Signatures

Step Description	Approver	Date
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CLIA Directors	Ann Marie Blenc: System Med Dir, Hematopath	11/29/2023
System Medical Director	Caitlin Schein: Staff Physician	11/29/2023
Medical Director	Subhashree Mallika Krishnan: Staff Physician	11/20/2023
Technical Director	Qian Sun: Tech Dir, Clin Chemistry, Path	11/7/2023
Policy and Forms Steering Committee Approval (if needed)	Kelly Walewski: Supv, Laboratory	11/6/2023
Lab Manager	Leah Korodan: Mgr, Division Laboratory	11/6/2023
	Kelly Walewski: Supv, Laboratory	11/6/2023

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