

Beaumont Laboratory

Royal Oak Effective Date: 10/30/2020 Supersedes: 09/19/2019

Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

RC.CH.CSL.ARC.RG.004.r01

I. Purpose

To provide a systematic process that enables the user to correctly report HBsAg and Confirmatory results when uncommon index/confirmation combinations arise.

II. Specimen Collection and Handling

- **A.** This test is available on a routine status, Monday thru Friday, 24 hours a day and on weekends 6:30 AM to 3:00 PM. Samples that are available in the laboratory will be processed and completed within these hours.
- **B.** STAT testing is available 24/7 ONLY on those patients in Labor and Delivery rooms.
- **C.** Serum, potassium EDTA plasma, and sodium or lithium heparinized plasma are the recommended specimen types for this assay.
 - 1. Follow Universal Precautions when handling specimens and quality control materials.
 - 2. Specimens are processed by centrifugation after allowing adequate amount of time for samples to clot. Keep tubes stoppered and upright at all times.
 - 3. Test specimens as soon as possible after collecting. Store specimens in at 2° to 8°C if not tested within 12 hours after collection.
 - 4. Freeze samples at or below -20°C if sample is not assayed within 7 days.
- **D.** This assay requires 125 uL of specimen for a single determination. This volume includes the unusable volume in the specimen container but does not include the additional volume required when performing duplicates or other tests on the same specimen.
- E. Confirmatory testing requires 146 uL of sample.

III. Procedure

- **A.** Operators must load samples from IOM1 or IOM2.
- **B.** Completed results will automatically upload to Instrument Manager. Results needing operator attention will remain in IM Review and Edit for further investigation.
- C. The system reports HBsAg results in Index Values and as positive or negative.
 - 1. Samples with an index value of less than 1.00 are considered Negative for HBsAg.
 - 2. Samples with an Index Value of greater than or equal to 1.00 are considered initially reactive for HBsAg. Perform repeat testing in duplicate and/or supplemental testing on these samples.
 - 3. After repeat testing, if 2 of the 3 results are negative, the sample is considered negative for HBsAg.
 - 4. After repeat testing, if 2 of the 3 results are reactive, confirmation testing must occur. If a repeatedly reactive result is confirmed by supplemental tests, such as

the Abbott ARCHITECT HBsAg Confirmatory Assay, the sample is positive for HBsAg.

IV. Confirmatory testing

HBsAg Confirmatory testing reports results as Confirmed, Not Confirmed, Invalid or will have an error flag (MDIL) and ask for a manual dilution.

A. Confirmed

1. Samples reported as Confirmed are HBsAg Reactive

B. Not Confirmed

- 1. Samples reported as Not Confirmed are HBsAg Nonreactive
- 2. Note: The percent neutralization (%N) is acceptable for as low as -16%. There may be an exception in IM but if the HBCON has given a status of "Not Confirmed", this is valid and the test can be resulted.

C. Invalid

- 1. Samples are reported as invalid if the sample result percentage is below the cutoff value of the Abbott Architect, -16% with the HBsAg Confirmatory Assay. The assay is invalid and should be repeated. If the interpretation is Invalid after repeat testing, it means a valid result cannot be obtained with this sample and a new sample should be obtained.
 - a. Select HBAGC2, HBAGN and HBCON as reruns in IM and load the sample at the IOM. There is no need to program the dilution on the instrument. Interpretation is either Confirmed or NCONF (Not confirmed).

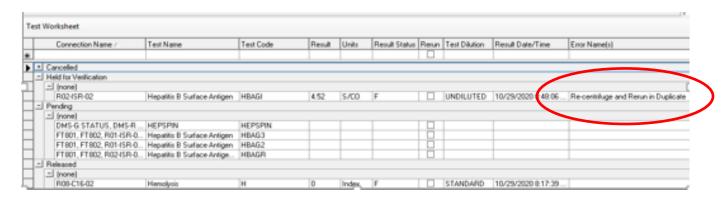
D. Manual Dilution

- 1. Samples without an interpretation will flag comment "Manual Dil of 1:500 Required"
 - a. Select HBAGC2 and HBAGN as reruns in IM and load the sample at the IOM. There is no need to program the dilution on the instrument. Interpretation is either Confirmed or Not Confirmed.
 - b. If still no interpretation, it will flag comment "Manual Dil of 1:20000 Required." Interpretation is either Confirmed or Not Confirmed.
 - c. Again, select HBAGC2 and HBAGN as reruns in IM and load the sample at the IOM. There is no need to program the dilution on the instrument. Interpretation is either Confirmed or Not Confirmed.

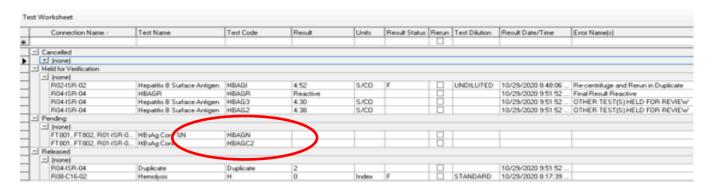
V. Interpreting HBsAg with Confirmation Results

A. Reactive HBsAg Confirmed

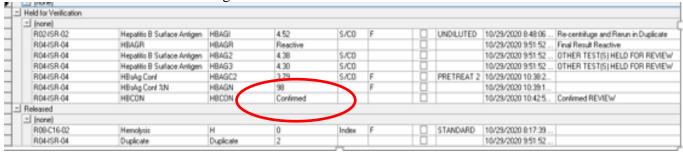
1. In Instrument Manager "Re-Centrifuge and Rerun in Duplicate" will appear. The specimen will be sorted at IOM2 in the HEPSORT/HIVC lane (lane 4). Spin for 10 minutes offline and reload specimen at IOM1 or IOM2. There is no need to program the reruns.



2. After running 3X, if 2 out of the 3 are ≥ 1.00, confirmation testing will be pending (HBAGC2, HBAGN). Once pending in IM, the confirmation assay will run automatically.

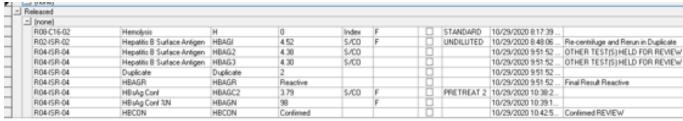


3. HBCON will populate an interpretation. If "Confirmed", the sample is considered Reactive for HBsAg and can be released from IM.

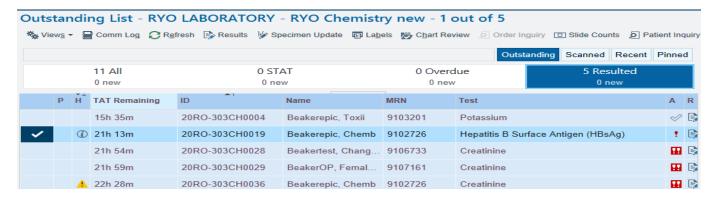


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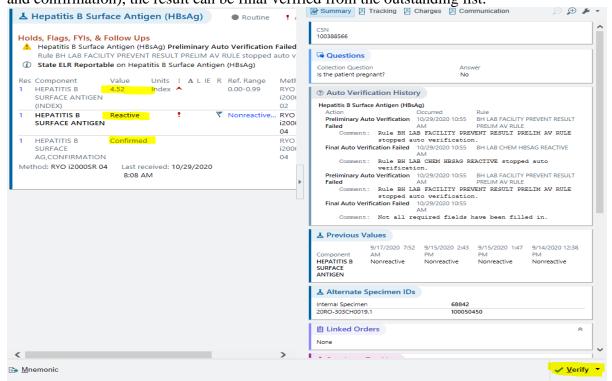
4. Results can be released from IM.



5. The Reactive result will be held on the Beaker outstanding list. Filter the outstanding list by the resulted tab, or filter by test "Hepatitis B Surface Antigen (HBsAg).



6. Click on the test and on the right side of the screen, the sample results can be viewed. On the bottom right, as long as all 3 components of the test are posted (index, interpretation and confirmation), the result can be final verified from the outstanding list.

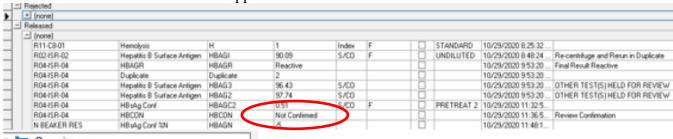


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VI. Interpreting Uncommon HBsAg Confirmation Results

In the event that HBsAg is Reactive, but is Not Confirmed, follow the flow chart below:

- **A.** Abbott Instrument Manager middleware will hold the results for review:
 - 1. Not Confirmed will appear for the tech to review



2. Results should auto verify in Beaker and will be off the outstanding list. The index value will be ≥ 1.00 , but the result will verify as Nonreactive as long as the confirmation states "Not Confirmed."



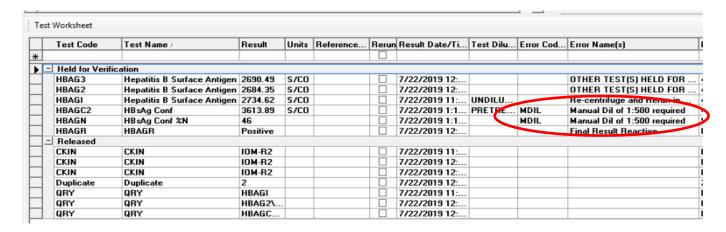
Hepatitis B Surface Antigen (HBsAg) (Final result)

Test Name	Result	Ref. Range Units	Lab
Hepatitis B Surface Antigen	Nonreactive	Nonreactive	BLRYO

Specimen 20RO-303CH0020. Results verified at 10/29/2020 1150.

VII. Positive HBsAg requiring Manual Dilution for Confirmation

1. Reactive HBsAg results that require a manual dilution for confirmation testing will be held in Instrument Manager for a tech to review.



2. A manual dilution must be made offline. In Instrument Manager, select the confirmation testing (HBAGC2, HBAGN) for reject/rerun. Once the confirmation is pending in IM, the dilution can be loaded on the track. There is no need to manually program the dilution in IM or at the instrument.

-1	Test Code	Test Name /	Result	Units	Reference	Rerun	Result Date/Ti	Test Dilution	Error Cod	Error Name(s)
ĸ										
١	- Held for Veril	lication								,
4	HBAG2	Hepatitis B Surface Antigen	2684.35	S/CO			7/22/2019 12:			OTHER TEST(S) HELD FO
┪	HBAG3	Hepatitis B Surface Antigen		S/CO		T T	7/22/2019 12:			OTHER TEST(S) HELD FO
┪	HBAGI	Hepatitis B Surface Antigen		S/CO		h	7/22/2019 11:			Re-centrifuge and Rerun i
╛	HBAGC2	HBsAg Conf	3613.89	S/CO		7	7/22/2019 1:1		MDIL	Manual Dil of 1:500 require
╛	HBAGN	HBsAg Conf %N	46	0.00			7/22/2019 1:1		MDIL	Manual Dil of 1:500 require
┪	HBAGR	HBAGR	Positive				7/22/2019 12:		I-I-D-I-E	Final Result Reactive
+	_ Pending	11011011	1 outilo				TTEETEGTO TE			T III O T T T T T T T T T T T T T T T T
۲	HBAGC2	HBsAg Conf								
┪	HBAGN	HBsAg Conf %N				H				
+	□ Released	Tibang com an								1
Π.	CKIN	CKIN	IOM-R2		1		7/22/2019 2:3			
┪	CKIN	CKIN	IOM-R2			in	7/22/2019 11:			
┪	CKIN	CKIN	IOM-R2			l iii	7/22/2019 12:			
┪	CKIN	CKIN	IOM-R2				7/22/2019 12:			
┑	Duplicate	Duplicate	2			I	7/22/2019 12:			
┪	QRY	ORY	HBAGI			Ī	7/22/2019 11:			
┪	QRY	QRY	HBAG2\				7/22/2019 12:			
┪	QRY	QRY	HBAGC				7/22/2019 2:4		1	
Н	ORY	QRY	HBAGC			T T	7/22/2019 12:			

- 3. Interpretation can be Confirmed or Not Confirmed or you will get another Error Name (MDIL2) asking for a 1:20000 manual dilution. Repeat confirmation testing (HBAGC2 and HBAGN) with second manual dilution. Again, there is no need to manually program the dilution in IM or at the instrument. Interpretation will be Confirmed or Not Confirmed.
- **4.** If Confirmed or Not Confirmed, results can be released from IM. If confirmed, the results will hold on the Beaker outstanding list and need to be verified. If Not Confirmed, the results will auto verify in Beaker.

VIII. Reactive HBsAg with Invalid Confirmation

- **A.** Invalid confirmation results will be held in Instrument Manager for a tech to review
 - 1. Invalid HBsAg confirmation must be repeated and then follow dilution protocol for both 1:500 and 1:20000 or until a confirmation can be resulted (HBCON). Reject/rerun HBAGC2, HBAGN and HBCON upon the first invalid result. If the

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repeat confirmation remains invalid after both sets of dilutions, a new sample must be obtained.

HBAGC2	HBsAg Conf	124.06	S/C0	.	8/6/2019 2:49	PRETRE	MDIL,HOLD
HBAGN	HBsAg Conf %N	-17		✓	8/6/2019 2:50		MDIL,HOLD
HBCON	HBCON	Invalid		V	8/6/2019 2:51		
Error Code(s)	Error Name(s)		_				·
MDIL,HOLD	Manual Dil of 1:500 required,						
MDIL,HOLD	Manual Dil of 1:500 required.						
	Invalid results, specimen should be retest	ed. Perform the retest using	the calculated assau (HRsAnQ	u 2N) and both	constituent assaus	HR«ΔαΩιι C1	and HRsAdOu C2

NOTE: DO NOT SEND OUT HBSAG WITHOUT A VALID CONFIRMATION.

IX. References

- **A.** Abbott ARCHITECT System Operation Manual, Abbott Laboratories, Abbott Park, IL. 12-14-2017
- **B.** ARCHITECT System Quick Reference Guide, Abbott Laboratories, Abbott Park, IL 2017

X. Authorized Reviewers

Manager, Chemistry Laboratory

Document Control

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Signature	Date	Revision #		Related Documents Reviewed/ Updated
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Ashley Hurand, MLS(ASCP) ^{cm}	10/29/2020	r01	Updated for Beaker	
Colette Kessler, Mgr Automated Chemistry	10/30/2020			