
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

Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

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 result.

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.

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Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

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.

Test Worksheet									
Connection Name /	Test Name	Test Code	Result	Units	Result Status	Rerun	Test Dilution	Result Date/Time	Error Name(s)
Cancelled									
Held for Verification									
R02-ISR-02	Hepatitis B Surface Antigen	HBAG1	4.52	S/CO	F	<input type="checkbox"/>	UNDILUTED	10/29/2020 8:48:06	Re-centrifuge and Rerun in Duplicate
Pending									
(none)									
DMS-G STATUS, DMS-R	HEPSPIN	HEPSPIN				<input type="checkbox"/>			
FT801, FT802, R01-ISR-0...	Hepatitis B Surface Antigen	HBAG3				<input type="checkbox"/>			
FT801, FT802, R01-ISR-0...	Hepatitis B Surface Antigen	HBAG2				<input type="checkbox"/>			
FT801, FT802, R02-ISR-0...	Hepatitis B Surface Antigen	HBAGR				<input type="checkbox"/>			
Released									
(none)									
R09-C16-02	Hemolysis	H	0	Index	F	<input type="checkbox"/>	STANDARD	10/29/2020 8:17:39	

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.

Test Worksheet									
Connection Name /	Test Name	Test Code	Result	Units	Result Status	Rerun	Test Dilution	Result Date/Time	Error Name(s)
Cancelled									
(none)									
Held for Verification									
(none)									
R02-ISR-02	Hepatitis B Surface Antigen	HBAG1	4.52	S/CO	F	<input type="checkbox"/>	UNDILUTED	10/29/2020 8:48:06	Re-centrifuge and Rerun in Duplicate
R04-ISR-04	HBAGR	HBAGR	Reactive			<input type="checkbox"/>		10/29/2020 9:51:52	Final Result Reactive
R04-ISR-04	Hepatitis B Surface Antigen	HBAG3	4.30	S/CO		<input type="checkbox"/>		10/29/2020 9:51:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	Hepatitis B Surface Antigen	HBAG2	4.38	S/CO		<input type="checkbox"/>		10/29/2020 9:51:52	OTHER TEST(S) HELD FOR REVIEW
Pending									
(none)									
FT801, FT802, R01-ISR-0...	HBsAg Conf 3N	HBAGN				<input type="checkbox"/>			
FT801, FT802, R01-ISR-0...	HBsAg Conf	HBAGC2				<input type="checkbox"/>			
Released									
(none)									
R04-ISR-04	Duplicate	Duplicate	2			<input type="checkbox"/>		10/29/2020 9:51:52	
R09-C16-02	Hemolysis	H	0	Index	F	<input type="checkbox"/>	STANDARD	10/29/2020 8:17:39	

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

Held for Verification									
(none)									
R02-ISR-02	Hepatitis B Surface Antigen	HBAG1	4.52	S/CO	F	<input type="checkbox"/>	UNDILUTED	10/29/2020 8:48:06	Re-centrifuge and Rerun in Duplicate
R04-ISR-04	HBAGR	HBAGR	Reactive			<input type="checkbox"/>		10/29/2020 9:51:52	Final Result Reactive
R04-ISR-04	Hepatitis B Surface Antigen	HBAG2	4.38	S/CO		<input type="checkbox"/>		10/29/2020 9:51:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	Hepatitis B Surface Antigen	HBAG3	4.30	S/CO		<input type="checkbox"/>		10/29/2020 9:51:52	OTHER TEST(S) HELD FOR REVIEW
R04-ISR-04	HBsAg Conf	HBAGC2	3.79	S/CO	F	<input type="checkbox"/>	PRETREAT 2	10/29/2020 10:38:2	
R04-ISR-04	HBsAg Conf 3N	HBAGN	98		F	<input type="checkbox"/>		10/29/2020 10:39:1	
R04-ISR-04	HBCON	HBCON	Confirmed			<input type="checkbox"/>		10/29/2020 10:42:5	Confirmed REVIEW
Released									
(none)									
R09-C16-02	Hemolysis	H	0	Index	F	<input type="checkbox"/>	STANDARD	10/29/2020 8:17:39	
R04-ISR-04	Duplicate	Duplicate	2			<input type="checkbox"/>		10/29/2020 9:51:52	

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Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

4. Results can be released from IM.

	R08 C16-02	Hemolysis	H	0	Index	F	<input type="checkbox"/>	STANDARD	10/29/2020 8:17:39 ...	
	R02 ISR-02	Hepatitis B Surface Antigen	HBAG1	4.52	S/C/D	F	<input checked="" type="checkbox"/>	UNDILUTED	10/29/2020 8:48:06 ...	Re-centrifuge and Rerun in Duplicate
	R04 ISR-04	Hepatitis B Surface Antigen	HBAG2	4.38	S/C/D		<input type="checkbox"/>		10/29/2020 9:51:52 ...	OTHER TEST(S) HELD FOR REVIEW
	R04 ISR-04	Hepatitis B Surface Antigen	HBAG3	4.30	S/C/D		<input type="checkbox"/>		10/29/2020 9:51:52 ...	OTHER TEST(S) HELD FOR REVIEW
	R04 ISR-04	Duplicate		2			<input type="checkbox"/>		10/29/2020 9:51:52 ...	
	R04 ISR-04	HBAGR	HBAGR	Reactive			<input type="checkbox"/>		10/29/2020 9:51:52 ...	Final Result Reactive
	R04 ISR-04	HBsAg Conf	HBAGC2	3.79	S/C/D	F	<input type="checkbox"/>	PRETREAT 2	10/29/2020 10:38:2 ...	
	R04 ISR-04	HBsAg Conf 3N	HBAGN	98		F	<input type="checkbox"/>		10/29/2020 10:39:1 ...	
	R04 ISR-04	HBCON	HBCON	Confirmed			<input type="checkbox"/>		10/29/2020 10:42:5 ...	Confirmed REVIEW

- 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).

Outstanding List - RYO LABORATORY - RYO Chemistry new - 1 out of 5

Views ▾ Comm Log Refresh Results Specimen Update Labels Chart Review Order Inquiry Slide Counts Patient Inquiry

Outstanding
Scanned
Recent
Pinned

11 All 0 new	0 STAT 0 new	0 Overdue 0 new	5 Resulted 0 new
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P	H	TAT Remaining	ID	Name	MRN	Test	A	R
		15h 35m	20RO-303CH0004	Beakerepic, Toxii	9103201	Potassium		
		21h 13m	20RO-303CH0019	Beakerepic, Chemb	9102726	Hepatitis B Surface Antigen (HBsAg)		
		21h 54m	20RO-303CH0028	Beakertest, Chang...	9106733	Creatinine		
		21h 59m	20RO-303CH0029	BeakerOP, Femal...	9107161	Creatinine		
		22h 28m	20RO-303CH0036	Beakerepic, Chemb	9102726	Creatinine		

- 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.

Hepatitis B Surface Antigen (HBsAg) Routine

Holds, Flags, FYIs, & Follow Ups

- Hepatitis B Surface Antigen (HBsAg) Preliminary Auto Verification Failed
Rule BH LAB FACILITY PREVENT RESULT PRELIM AV RULE stopped auto v
- State ELR Reportable on Hepatitis B Surface Antigen (HBsAg)

Res	Component	Value	Units	Index	L	E	R	Ref. Range	Meth
1	HEPATITIS B SURFACE ANTIGEN (INDEX)	4.52						0.00-0.99	RYO i2000 02
1	HEPATITIS B SURFACE ANTIGEN	Reactive						Nonreactive...	RYO i2000 04
1	HEPATITIS B SURFACE AG.CONFIRMATION	Confirmed							RYO i2000 04

Method: RYO i2000SR 04 Last received: 10/29/2020 8:08 AM

Summary Tracking Charges Communication

CSN 100388566

Questions

Collection Question
Is the patient pregnant?
Answer No

Auto Verification History

Hepatitis B Surface Antigen (HBsAg)

Action Occurred Rule
Preliminary Auto Verification 10/29/2020 10:55 AM BH LAB FACILITY PREVENT RESULT PRELIM AV RULE Failed
Comment: Rule BH LAB FACILITY PREVENT RESULT PRELIM AV RULE stopped auto verification.
Final Auto Verification Failed 10/29/2020 10:55 AM BH LAB CHEM HBSAG REACTIVE AM
Comment: Rule BH LAB CHEM HBSAG REACTIVE stopped auto verification.
Preliminary Auto Verification 10/29/2020 10:55 AM BH LAB FACILITY PREVENT RESULT Failed
Comment: Rule BH LAB FACILITY PREVENT RESULT PRELIM AV RULE stopped auto verification.
Final Auto Verification Failed 10/29/2020 10:55 AM
Comment: Not all required fields have been filled in.

Previous Values

Component	9/17/2020 7:52 AM	9/15/2020 2:43 PM	9/15/2020 1:47 PM	9/14/2020 12:38 PM
HEPATITIS B SURFACE ANTIGEN	Nonreactive	Nonreactive	Nonreactive	Nonreactive

Alternate Specimen IDs

Internal Specimen	68842
20RO-303CH0019.1	100050450

Linked Orders

None

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Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

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

Rejected										
Released										
R11-C8-01	Hemolysis	H	1	Index	F	<input type="checkbox"/>	STANDARD	10/29/2020 8:25:32		
R02-ISR-02	Hepatitis B Surface Antigen	HBAG1	90.09	S/CO	F	<input type="checkbox"/>	UNDILUTED	10/29/2020 8:48:24	Re-centrifuge and Remun in Duplicate	
R04-ISR-04	HBAGR	HBAGR	Reactive			<input type="checkbox"/>		10/29/2020 9:53:20	Final Result Reactive	
R04-ISR-04	Duplicate	Duplicate	2			<input type="checkbox"/>		10/29/2020 9:53:20		
R04-ISR-04	Hepatitis B Surface Antigen	HBAG3	96.43	S/CO		<input type="checkbox"/>		10/29/2020 9:53:20	OTHER TEST(S) HELD FOR REVIEW	
R04-ISR-04	Hepatitis B Surface Antigen	HBAG2	97.74	S/CO		<input type="checkbox"/>		10/29/2020 9:53:20	OTHER TEST(S) HELD FOR REVIEW	
R04-ISR-04	HBsAg Conf	HBAGC2	0.51	S/CO	F	<input type="checkbox"/>	PRETREAT 2	10/29/2020 11:32:5		
R04-ISR-04	HBsAg Conf	HBAGC1	Not Confirmed			<input type="checkbox"/>		10/29/2020 11:36:5	Review Confirmation	
N BEAKER RES	HBsAg Conf 1N	HBAGN	5			<input type="checkbox"/>		10/29/2020 11:48:1		

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."

Specimens									
20RO-303CH0020									
✓ Hepatitis B Surface Antigen (HBsAg)									
Res	Component	Value	Units	I	A	L	IE	R	Ref. Range
1	HEPATITIS B SURFACE ANTIGEN (INDEX)	90.09	Index						0.00-0.99
1	HEPATITIS B SURFACE ANTIGEN	Nonreactive		✓					Nonreactive...
1	HEPATITIS B SURFACE AG, CONFIRMATION	Not Confirmed							
Method: RYO I2000SR 04									
Last received: 10/29/2020 8:08 AM									
Last verified: 10/29/2020 11:50 AM by Back									

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.

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Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

Test Worksheet									
	Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Test Dilu...	Error Cod... Error Name(s)
*						<input type="checkbox"/>			
▶	- Held for Verification								
	HBAG3	Hepatitis B Surface Antigen	2690.49	S/CO		<input type="checkbox"/>	7/22/2019 12:...		OTHER TEST(S) HELD FOR ...
	HBAG2	Hepatitis B Surface Antigen	2684.35	S/CO		<input type="checkbox"/>	7/22/2019 12:...		OTHER TEST(S) HELD FOR ...
	HBAG1	Hepatitis B Surface Antigen	2734.62	S/CO		<input type="checkbox"/>	7/22/2019 11:...	UNDILU...	Re-centrifuge and Rerun i...
	HBAGC2	HBsAg Conf	3613.89	S/CO		<input type="checkbox"/>	7/22/2019 1:1...	PRETRE...	MDIL Manual Dil of 1:500 required
	HBAGN	HBsAg Conf %N	46			<input type="checkbox"/>	7/22/2019 1:1...		MDIL Manual Dil of 1:500 required
	HBAGR	HBAGR	Positive			<input type="checkbox"/>	7/22/2019 12:...		Final Result Reactive
▶	- Released								
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 11:...		
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 12:...		
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 12:...		
	Duplicate	Duplicate	2			<input type="checkbox"/>	7/22/2019 12:...		
	QRY	QRY	HBAG1			<input type="checkbox"/>	7/22/2019 11:...		
	QRY	QRY	HBAG2\...			<input type="checkbox"/>	7/22/2019 12:...		
	QRY	QRY	HBAGC...			<input type="checkbox"/>	7/22/2019 12:...		

- 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.

Test Worksheet									
	Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Test Dilution	Error Cod... Error Name(s)
*						<input type="checkbox"/>			
▶	- Held for Verification								
	HBAG2	Hepatitis B Surface Antigen	2684.35	S/CO		<input type="checkbox"/>	7/22/2019 12:...		OTHER TEST(S) HELD FO...
	HBAG3	Hepatitis B Surface Antigen	2690.49	S/CO		<input type="checkbox"/>	7/22/2019 12:...		OTHER TEST(S) HELD FO...
	HBAG1	Hepatitis B Surface Antigen	2734.62	S/CO		<input type="checkbox"/>	7/22/2019 11:...	UNDILUTED	Re-centrifuge and Rerun i...
	HBAGC2	HBsAg Conf	3613.89	S/CO		<input checked="" type="checkbox"/>	7/22/2019 1:1...	PRETREAT 2	MDIL Manual Dil of 1:500 required
	HBAGN	HBsAg Conf %N	46			<input checked="" type="checkbox"/>	7/22/2019 1:1...		MDIL Manual Dil of 1:500 required
	HBAGR	HBAGR	Positive			<input type="checkbox"/>	7/22/2019 12:...		Final Result Reactive
▶	- Pending								
	HBAGC2	HBsAg Conf				<input type="checkbox"/>			
	HBAGN	HBsAg Conf %N				<input type="checkbox"/>			
▶	- Released								
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 2:3...		
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 11:...		
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 12:...		
	CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/22/2019 12:...		
	Duplicate	Duplicate	2			<input type="checkbox"/>	7/22/2019 12:...		
	QRY	QRY	HBAG1			<input type="checkbox"/>	7/22/2019 11:...		
	QRY	QRY	HBAG2\...			<input type="checkbox"/>	7/22/2019 12:...		
	QRY	QRY	HBAGC...			<input type="checkbox"/>	7/22/2019 2:4...		
	QRY	QRY	HBAGC...			<input type="checkbox"/>	7/22/2019 12:...		

- 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.
- 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

- 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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Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

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

HBAGC2	HBsAg Conf	124.06	S/CO		<input checked="" type="checkbox"/>	8/6/2019 2:49...	PRETRE...	MDIL_HOLD
HBAGN	HBsAg Conf %N	-17			<input checked="" type="checkbox"/>	8/6/2019 2:50...		MDIL_HOLD
HBCON	HBCON	Invalid			<input checked="" type="checkbox"/>	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 retested. Perform the retest using the calculated assay (HBsAgQu %N) and both constituent assays HBsAgQu C1 and HBsAgQu 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

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