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## Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

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### **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 2 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

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

### IV. Confirmatory testing

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

#### A. Invalid

1. Samples are reported as invalid if the sample result percentage is below the cutoff value of the Abbott Architect. 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).

#### B. 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 NCONF (Not confirmed).
  - b. If still no interpretation, it will flag comment "Manual Dil of 1:20000 Required." Interpretation is either Confirmed or NCONF.
  - 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 NCONF (Not confirmed).

#### C. Not Confirmed

1. Samples reported as NConf are HBsAg Negative.

#### D. Confirmed

1. Samples reported as Confirmed are HBsAg Positive.

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### 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 Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Error Name(s)	Test Dilution
* Held for Verification								
HBAG1	Hepatitis B Surface Antigen	1.47	S/CO		<input type="checkbox"/>	7/8/2019 1:21...	Re-centrifuge and Rerun in Duplicate	UNDILUTED
- Pending								
HBAG2	Hepatitis B Surface Antigen				<input type="checkbox"/>			
HBAG3	Hepatitis B Surface Antigen				<input type="checkbox"/>			
HBAGR	Hepatitis B Surface Antigen				<input type="checkbox"/>			
HEPSPIN	HEPSPIN				<input type="checkbox"/>			
- Released								
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 1:29...		
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 12:3...		
QRY	QRY	HBAG1			<input type="checkbox"/>	7/8/2019 12:4...		

2. After running 3X, if 2/3 are  $\geq 1.00$ , confirmation testing will be pending (HBAGC2, HBAGN). Once pending in IM, the confirmation assay will run automatically.

Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Error Name(s)	Test Dilution
* Held for Verification								
HBAG3	Hepatitis B Surface Antigen	4.71	S/CO		<input type="checkbox"/>	7/8/2019 2:10...	OTHER TEST(S) HELD FOR REVIEW	
HBAG2	Hepatitis B Surface Antigen	4.69	S/CO		<input type="checkbox"/>	7/8/2019 2:10...	OTHER TEST(S) HELD FOR REVIEW	
HBAG1	Hepatitis B Surface Antigen	4.61	S/CO		<input type="checkbox"/>	7/8/2019 1:22...	Re-centrifuge and Rerun in Duplicate	UNDILUTED
HBAGR	HBAGR	Positive			<input type="checkbox"/>	7/8/2019 2:10...	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"/>	7/8/2019 12:3...		
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 2:11...		
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 1:29...		
Duplicate	Duplicate	2			<input type="checkbox"/>	7/8/2019 2:10...		
QRY	QRY	HBAG1			<input type="checkbox"/>	7/8/2019 12:5...		
QRY	QRY	HBAG2\HBAG3			<input type="checkbox"/>	7/8/2019 1:33...		
QRY	QRY	HBAGC2\HBAGN			<input type="checkbox"/>	7/8/2019 2:14...		

3. HBCON will populate an interpretation. If “Confirmed” the sample is considered Positive HBsAg and can be released from IM as well as the SOFT Instrument Menu.

Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Error Name(s)	Test Dilution
* Held for Verification								
HBAG3	Hepatitis B Surface Antigen	4.71	S/CO		<input type="checkbox"/>	7/8/2019 2:10...	OTHER TEST(S) HELD FOR REVIEW	
HBAG2	Hepatitis B Surface Antigen	4.69	S/CO		<input type="checkbox"/>	7/8/2019 2:10...	OTHER TEST(S) HELD FOR REVIEW	
HBAG1	Hepatitis B Surface Antigen	4.61	S/CO		<input type="checkbox"/>	7/8/2019 1:22...	Re-centrifuge and Rerun in Duplicate	UNDILUTED
HBAGC2	HBsAg Conf	4.12	S/CO		<input type="checkbox"/>	7/8/2019 2:52...		PRETREAT 2
HBAGN	HBsAg Conf %N	97			<input type="checkbox"/>	7/8/2019 2:52...		
HBAGR	HBAGR	Positive			<input type="checkbox"/>	7/8/2019 2:10...	Final Result Reactive	
HBCON	HBCON	Confirmed			<input type="checkbox"/>	7/8/2019 2:53...	Confirmed REVIEW	
- Released								
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 12:3...		
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 2:11...		
CKIN	CKIN	IOM-R2			<input type="checkbox"/>	7/8/2019 1:29...		
Duplicate	Duplicate	2			<input type="checkbox"/>	7/8/2019 2:10...		
QRY	QRY	HBAG1			<input type="checkbox"/>	7/8/2019 12:5...		
QRY	QRY	HBAG2\HBAG3			<input type="checkbox"/>	7/8/2019 1:33...		
QRY	QRY	HBAGC2\HBAGN			<input type="checkbox"/>	7/8/2019 2:14...		

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Patient Info  
 Name (last, first, middle): **BEAUMONTLABTEST, ROCHEM INTERNAL CHECK MALE2**  
 MRN: 9121341 Sex: M Age: 20 Ward: ROCG Room: More...

Order Info  
 Order: A30808209-S8 Prior: R Seq: 00612 Spec: SHT Collected: 07/08/2019 11:00  
 Tests: HBSAG  Call  Comment(s)  Spec Comm

Comm Post All Part Post Rerun Check Tst Hist

	Wrkst	Itst	Stst	Result	R	D	Flags	M	Error	Status	Prev Res	Prev Date	Prev Order	Tech
1	R2005	HBAGI	<b>HBAGI</b>	4.61			H			O	1.52	07/08/2019	A30804760	
2	R2005	HBAGF	<b>HBAGR</b>	Positive			AB			O	Positive	07/08/2019	A30804760	
3	R2005	HBCON	<b>HBCON</b>	Confirmed						O	Confirmed	06/27/2019	A22705495	

4. Result is released as Positive.

### 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. "NConf" will appear for the tech to review

a. NOTE: "MDIL" will appear if the Confirmation is requesting a manual dilution.

Test Worksheet

Test Code	Test Name /	Result	Units	R...	Rerun	Result ...	Test Dilution	Error Cod...	Error Name(s)
<b>Held for Verification</b>									
HBAG3	Hepatitis B Surface Antigen	1.55	S/CO			7/26/2...			OTHER TEST(S) HELD FOR REVIEW
HBAG2	Hepatitis B Surface Antigen	1.47	S/CO			7/26/2...			OTHER TEST(S) HELD FOR REVIEW
HBAG1	Hepatitis B Surface Antigen	1.43	S/CO			7/26/2...	UNDILUTED		Re-centrifuge and Rerun in Duplicate
HBAGC2	HBsAg Conf	1.76	S/CO			7/26/2...	PRETREAT 2		
HBAGN	HBsAg Conf %N	6				7/26/2...			
HBAGR	HBAGR	Positive				7/26/2...			Final Result Reactive
HBCON	HBCON	NConf				7/26/2...			Review Confirmation
<b>Released</b>									
CKIN	CKIN	IOM-R2				7/26/2...			
CKIN	CKIN	IOM-R2				7/26/2...			
CKIN	CKIN	IOM-R2				7/26/2...			
Duplicate	Duplicate	2				7/26/2...			
QRY	QRY	HBAGI				7/26/2...			
QRY	QRY	HBAG2...				7/26/2...			
QRY	QRY	HBAGC...				7/26/2...			

2. Results will flow into the Instrument Menu. "NConf" will populate the HBCON field indicating that the HBsAg has NOT been confirmed.

Patient Info  
 Name (last, first, middle): **BEAUMONTLABTEST, ROCHEM INTERNAL CHECK MALE2**  
 MRN: 9121341 Sex: M Age: 20 Ward: ROCG Room: More...

Order Info  
 Order: A32606004-S8 Prior: R Seq: 01352 Spec: SHT Collected: 07/26/2019 08:00  
 Tests: HBSAG  Call  Comment(s)  Spec Comm

Comm **Post All** Part Post Rerun Check Tst Hist

	Wrkst	Itst	Stst	Result	R	D	Flags	M	Error	Status	Prev Res	Prev Date	Prev Order
1	R2003	HBAGI	<b>HBAG</b>	1.43			H			O	1.52	07/23/2019	A32307038
2	R2005	HBAGF	<b>HBAG</b>	Positive			AB			O	Negative	07/23/2019	A32307038
3	R2005	HBCON	<b>HBCON</b>	NConf						O	NConf	07/23/2019	A32307038

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3. Post All results from the Instrument Menu
4. **NOTE: HBAGR will still say "Positive" until results are posted. DO NOT CANCEL ANY PARAMETERS IN THE INSTRUMENT MENU BEFORE POSTING**
5. SOFT will change the result from Positive to Negative.

T Ord	T Ind	Result	FI	Flags	M	Prev Res	Prev Date	C	Status	Tech	DateV	TimeV	TechV
1	HBSAG	HBAGI 1.43		H		1.52	07/23/2019		LC D PV	AHUF	07/26/2019	11:49	AHURA
2	HBSAG	HBAGR Negative				Negative	07/23/2019	c	LC D PV	AHUF	07/26/2019	11:49	AHURA
3	HBSAG	HBCON NConf				NConf	07/23/2019		LC D PVR	AHUF	07/26/2019	11:49	AHURA
4	HBSAG	302MS						c	LC E VR	AHUF	07/26/2019	11:49	AHURA

6. Verify on the instant report the result went out as Negative.

### Beaumont Laboratory

Patient: **BEAUMONTLABTEST, ROCHEM INTERNAL CHECK MALE2**      DOB: 06/05/1999 (20 Y)      Gender: M  
 MRN: 9121341      HAR/CSN:9121341      REQ:

Physician: ELIZABETH SYKES, MD

NPI: 1144280207

Location: RO Control Group Location NO BILL

Loc ID: ROCG

Date Visit Created: 12/04/18

Laboratory Key for Results: L - LOW, H - HIGH, AB - ABNORMAL, LL - CRITICAL LOW, HH - CRITICAL HIGH, C - CRITICAL

Microbiology Key for Results: \* - NEW RESULTS      \*\* - RESULT WAS MODIFIED AFTER FINAL STATUS SET

Blood Bank Key for Results: NEG - NEGATIVE, POS - POSITIVE

Order #: A32606004      Collected: 07/26/2019 08:00

Test Name	Result	ABN	Ref-Ranges	Units	Site
<b>Hepatitis B Surface Antigen (HBsAg)</b>	Negative		Negative		R

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## Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

### VII. Positive HBsAg requiring Manual Dilution for Confirmation

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

Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Test Dilu...	Error Cod...	Error Name(s)
* 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:...			

2. A manual dilution must be made offline. In Instrument Manager, select the confirmation testing (HBAGC2, HBAGN) for reject/rerun.

Test Code	Test Name /	Result	Units	Reference...	Rerun	Result Date/Ti...	Test Dilution	Error Cod...	Error Name(s)
* 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:...			

3. Interpretation can be Confirmed or NConf or you will get another Error code MDIL2 asking for a 1:20000 manual dilution. Repeat confirmation testing (HBAGC2 and HBAGN) with second manual dilution. There is no need to manually program the dilution in IM or at the instrument. Interpretation will be Confirmed or NConf.
4. If Confirmed or Nconf, results can be released from IM and posted from the Instrument Menu. (follow steps above).

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## Hepatitis B Surface Antigen Resulting (HBsAg) Workflow

### 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. Reject/rerun HBAGC2, HBAGN and HBCON. If the 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							

- B. If an Invalid HBsAg confirmation result is released to SOFT, the HBAGR will say Positive, but no result will populate into the HBCON field.
1. F4 (cancel) all HBsAg results and Save
  2. **NOTE: DO NOT SEND OUT HBSAG WITHOUT A VALID CONFIRMATION**

Patient Info  
 Name (last, first, middle): **SOFTTEST, PUPPY**  
 MRN: 6001080 Sex: F Age: 27 Ward: RHEON Room: More...  
 Order Info  
 Order: 921300007-S8 Prior: R Seq: 0004 Spec: SHT Collected: 07/13/2017 00:00  
 Tests: HBSAG, 153M2  
 Call Comment(s) Spec Comm  
 Comm Post All Part Post Rerun Check Tst Hist

Wrkst	Itst	Stst	Result	R	D	Flags	M	Error	Status	Prev Res
1	RCENE	HBsAg-INDX	HBAGI	>1000.0		H	M	*	O	23.21
2	RCENE	HBsAg-INTR	HBAGR	Positive		AB			O	Positive
3	RCENE	Conf-INTR	HBCON						O	Conf

**DO NOT POST**

### IX. References

- A. Abbott Architect 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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