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Section: Serology Manual	Subject Title: AxSym HBsAg Surface Antigen Confirmatory Assay	
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AXSYM HEPATITIS B SURFACE ANTIGEN CONFIRMATORY ASSAY

I. Introduction

AXSYM HBsAg Confirmatory assay is a Microparticle Enzyme Immunoassay (MEIA) used for the detection of HBsAg in human serum or plasma by means of specific antibody neutralization.

II. Specimen Collection and Processing

A minimum of 300 µL of preliminary positive HBs Ag patient sample in a sample cup is required.

III. Procedure

i) Reagents

AxSYM Confirmatory Kit
AxSYM HBs Ag Kit

ii) Method

Use the assigned "H" segment for the confirmatory test.

Using the following chart for the number of samples to be confirmed, add appropriate volume of reagents to the corresponding sample cups at position 1 to position 5. Patient sample starts at position 6 onward.

Segment "H"

S / P	1	=	Reagent A
S / P	2	=	Reagent B
S / P	3	=	Dilution Reagent
S / P	4	=	Index Calibrator 9use cal. Received with reagent kit)

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S / P 5 = HBs Ag Positive Control

S / P 6 = Patient sample

Sample Segment Position	Reagent or Sample	Reagent Color	For Cal/ Control Only	Minimum Volume Required (µL)				
				No. of Patient Samples				
				1	2	3	4	5
1	Reagent A	Violet	100	150	200	250	300	350
2	Reagent B	Yellow	150	200	250	300	350	400
3	Dilution Reagent	Natural	0	500	875	1250	1625	2000
4	Index Calibrator*	Green	270	270	270	270	270	270
5	Positive Control**	Blue	250	250	250	250	250	250
6	Patient Sample			275	275	275	275	275
7	Patient Sample				275	275	275	275
8	Patient Sample					275	275	275
9	Patient Sample						275	275
10	Patient Sample							275

*270 µL = 8 drops

**250 µL = 7 drops

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IV. **Results**

- 1) From the MENU, select "RESULTS"
- 2) Highlight all control and patient results associated with the confirmatory run
- 3) Select "PRINT", choose "Print a formatted result for each displayed test"
- 4) Select "OK" by touch screen

V. **Reporting Results**

HBsAg Confirmatory (8CON) testing results are entered into the LIS using the keypads but do not print on the report. The repeat HBcAb (8HBC2) results also do not print, but are automatically posted to the LIS. These confirmatory and repeat HBcAb (8HBC2) results are used to edit, if necessary, the HBsAg (8HAG) and HBcAb (8HBC) results which will print on the report.

HBsAg Confirmatory Assay

% Neut or % Neut Dil Positive: Confirmed Positive
 % Neut AND % Neut Dil Negative: Not Confirmed

HBcAb (8HBC2) Assay

Reactive: Reactive
 Negative: Negative

Refer to AXSYM portion of manual for guidelines on reporting HBsAg, and HBcAb based on reflex testing.

VI. **Quality Control**

A positive control confirmation should be included on each run.

VII. **Reference**

AXSYM operational manual and manufacturer's package insert. (Abbott Laboratories, Abbott Park, IL 60064, U.S.A.)