

Berkeley

 School of
Public Health



Forum for
Collaborative HIV Research

HBV Forum 1
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Boston

www.hivforum.org

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WG Update: Diagnostics & Biomarkers

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development and health policy*

Introduction

Working Group Charge:

- Map out the markers that might be needed for drug development and approval
- Review and discuss potential regulatory paths for these



Activities

- Identify what is the current regulatory approval status of the following tests, if any:
 - Anti-HBc, Anti-HBs, qHBsAg, qHBeAg, HBcrAg, HBsAb/Ag complex, HBsAg Epitope Mapping, HBV DNA, HBV cccDNA, HBV RNA, HBV Genotype, HBV Resistance, HBV CP/BCP, Markers of inflammation and HCC
- Perform a systematic review of the literature supporting performance and utility of potential tests
- Identify if there are similar markers in other diseases e.g. HIV, CMV and the pathways used for their registration



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Outcomes and Products

- Markers Assessment Spreadsheet
- Review Article(s)
- Recommendations
 - Registration path(s) for key identified markers pending registration



Timelines

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- Markers Assessment Spreadsheet
- Review Article(s)
 - HBsAg quant
 - Other key markers identified in the Spreadsheet
 - Recommendations

	A	B	C	D	E	F	G	H	I	J
1	Assay	Marker	Regulatory Status	Commercial status	Intended use	Current utility	Potential Future Utility	Necessity for Future Utility		
2	COBAS Ampliscreen HBV Test	HBV DNA	Canada-IVD, CE-IVD, US-IVD		Qualitative in vitro	Blood and plasma donation screening				
3	ARCHITECT HBsAg Assay - PO60007	HBsAg quant								
4	Elecsys HBsAg II quantitative	HBsAg quant								
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Fill out relevant information, and select the marker type from the drop down menu. If there is no drop down menu, please click and drag the data from the cell above it.

Clicking on the drop down menu by "Marker" will allow you to filter by marker types.

If your assay marker type is missing, please add it into the tab below labelled "Marker List"



Other activities

- On-going activities
 - Markers Assessment Spreadsheet under completion
- Next steps
 - Start HBsAg quant literature review
 - Identify Lead author
 - Complete Marker Assessment Spreadsheet and start prioritization
 - Align prioritization with Surrogate Endpoints Working Group
- Additional members?



Questions

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