

Berkeley



Diagnostics and Biomarkers Working Group

Presenter

Pedro Goicochea on behalf of
Gavin Cloherty and Ed Marins

HBV Forum 3

October 24th, 2017
Marriott Marquis, Washington DC

www.forumresearch.org



Introduction

- Working group mandate:
 - Map out the markers that might be needed for drug development and approval
 - Review and discuss the regulatory paths to approval



Activities

- Identify the regulatory approval status of the different HBV markers
- Review potential regulatory paths:
 - Prioritize markers that are not CE/FDA approved and discuss what would be the regulatory pathway to get registered and how to expedite their availability



HBV Forum: Diagnostics and Biomarkers Working Group Output

Use the filters on the left side to browse assays by purpose, marker type and approval status
Make a selection to view further details.

Selected Assay Information

US FDA CE
Approved: Approved?

US approval	CE approval
<input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Null
<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	<input checked="" type="checkbox"/> Yes

Number of Assays by Marker ▼

Hold down Command to make multiple selections.

Clicking the selection again will allow you to de-select it.

- Anti Hbc total (10)
- Anti HBs (13)
- Anti-HBc IgG (1)
- Anti-HBc IgM (9)
- Anti-Hbe (18)
- HBeAg qual (18)
- HBeAg quant (1)
- HBS antigen antibody complex (1)
- HBsAg qual (36)
- HBsAg quant (6)
- HBV cccDNA (1)
- HBV core related antigen (1)
- HBV CP/BCP mutations (7)
- HBV DNA (28)
- HBV Genotype (6)
- HBV RNA (3)

Company	Assay	Marker
Abbott	ARCHITECT Anti-Hbe - B6C340	Anti-Hbe
	Architect Core	Anti Hbc total
	Architect Core-M	Anti-HBc IgM
	ARCHITECT HBsAg II Assay	HBsAg qual
	AxSYM Anti-HBe 2.0	Anti-Hbe
	AxSYM AUSAB	Anti HBs
	AxSYM Core 2.0	Anti Hbc total
	AxSYM Core-M 2.0	Anti-HBc IgM
	AxSYM HBsAg	HBsAg qual
	RealTime HBV	HBV DNA
	RealTime HBV sequencing assay	HBV Genotype
ACON Labs	HBcAb	Anti Hbc total
	HBcAb IgG	Anti-HBc IgG
	HBeAb	Anti-Hbe
	HBeAg	HBeAg qual
	HBsAb	Anti HBs
	HBsAb Quantitative	Anti HBs
Alere	Determine™ HBsAg	HBsAg qual
	ImmunoComb HBsAg	HBsAg qual
Bio-Rad	MONOLISA Anti-HBC EIA	Anti Hbc total
	MONOLISA Anti-HBC IgM EIA	Anti-HBc IgM
	MONOLISA Anti-HBS EIA	Anti HBs
	MONOLISA Anti-HBS Plus	Anti HBs
Biomerieux	VIDAS Anti-HBc Total II	Anti Hbc total
	VIDAS Anti-HBs Total II	Anti HBs



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No Null
 Yes No
 Yes

Number of Assays by Marker ▼

Hold down Command to make multiple selections.
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- Anti HBs (1)
- HBs antigen antibody complex (1)
- HBsAg quant (3)
- HBV cccDNA (1)
- HBV core related antigen (1)
- HBV CP/BCP mutations (7)**
- HBV Genotype (3)
- HBV RNA (3)

Selected Assay Information	US FDA Approved?	CE Approved?
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Company	Assay	
Biomerieux	VIDAS HBsAg Ultra	HBsAg quant
DDL Diagnostic Laboratory	HBV DNA genome amplification and sequencing (next gen)	HBV Genotype
	HBV DNA genome amplification and sequencing (Sanger)	HBV Genotype
	HBV Genome amplification from RNA	HBV RNA
Fujirebio	HBV RNA qPCR	HBV RNA
	INNO-LIPA HBV PreCore	HBV CP/BCP mutations
LabCorp	Lumipulse G HBcrAg	HBV core related antigen
	LabCorp HBsAb, Quantitative	Anti HBs
Non Commercial	LabCorp HBV Genotype	HBV Genotype
	Bayliss et al, Deep sequencing shows that HBV basal core promoter and precore variant..	HBV CP/BCP mutations
	Ducancelle et al - Different precore/core mutations of hepatitis B interact with, limit, or fav..	HBV CP/BCP mutations
	Jiang et al, Hepatitis B Virus Core Promoter Double Mutations (A1762T, G1764A) Are As..	HBV CP/BCP mutations
	Puche et al - Genetic diversity of hepatitis B virus and mutations associated to...	HBV CP/BCP mutations
	US20040058314 - detection and quantification of HBV cccDNA by rtPCR	HBV cccDNA
Quest	Zhang et al, Detection of HBV RNA in Serum of Patients	HBV RNA
	Quest Diagnostics Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mut..	HBV CP/BCP mutations
	Quest HBsAg Quant	HBsAg quant
	Quest Hepatitis B Virus Drug Resistance, Genotype, and BCP/Precore Mutations	HBV CP/BCP mutations
Roche	Quest Singapore HBsAg Quant	HBsAg quant
	Roche Immunological multi-parameter chip technology (IMPACT)	HBs antigen antibody complex



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Approved? Approved?

<p>US approval</p> <p><input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</p>	<p>CE approval</p> <p><input type="checkbox"/> Null <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p>
<p>Number of Assays by Marker ▼</p>	
<p>Hold down Command to make multiple selections. Clicking the selection again will allow you to de-select it.</p>	
<ul style="list-style-type: none"> Anti HbC total (4) Anti HBs (5) Anti-HBc IgG (1) Anti-HBc IgM (3) Anti-Hbe (12) HBeAg qual (9) HBeAg quant (1) HBsAg qual (10) HBsAg quant (3) HBV DNA (12) HBV Genotype (3) 	

Company	Assay	
Abbott	ARCHITECT Anti-Hbe - B6C340	Anti-Hbe
	AxSYM Anti-HBe 2.0	Anti-Hbe
	RealTime HBV sequencing assay	HBV Genotype
ACON Labs	HBcAb	Anti HBc total
	HBcAb IgG	Anti-HBc IgG
	HBeAb	Anti-Hbe
	HBeAg	HBeAg qual
	HBsAb	Anti HBs
	HBsAb Quantitative	Anti HBs
Bio-Rad	MONOLISA Anti-HBS Plus	HBsAg qual
		Anti HBs
Biomerieux	VIDAS Anti-HBc Total II	Anti HBc total
	VIDAS Anti-HBs Total II	Anti HBs
	VIDAS HBe IgM II	Anti-HBc IgM
	VIDAS HBe/AntiHBe	Anti-Hbe
	VIKIA HBsAg	HBsAg qual
Bioneer	AccuPower® HBV Quantitative PCR Kit	HBV DNA
Cepheid	SmartCycler Smart HBV(TM)	HBV Genotype
DiaSorin	LIAISON Anti HBc	Anti HBc total
	LIAISON Anti-HBe	Anti-Hbe
	LIAISON HBc IgM	Anti-HBc IgM
	LIAISON HBeAg	HBeAg quant
	LIAISON HBsAg	HBsAg qual
	LIAISON XL Murex HBsAg Quant	HBsAg quant
	Murex HBsAg V3	HBsAg qual
		HBV Genotype
Fujirebio	INNO-LiPA HBV Genotyping	HBV Genotype



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Selected Assay Information

US FDA CE
Approved: Approved?

US approval

- No
 Yes

CE approval

- Null
 No
 Yes

Number of Assays by Marker

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Regulatory Status of HBV Markers

<https://public.tableau.com/profile/maria.ma5849#!/vizhome/HBVDiagnostics/Dashboard1?publish=yes>



Next Steps

- Commentary of the status of HBV biomarkers
- The Diagnostics and Biomarkers working group will be integrated to the Surrogate Endpoints working group as a sub group



Acknowledgements

- Gavin Cloherty
- Ed Marins
- Maria Ma

Berkeley



Thank You!