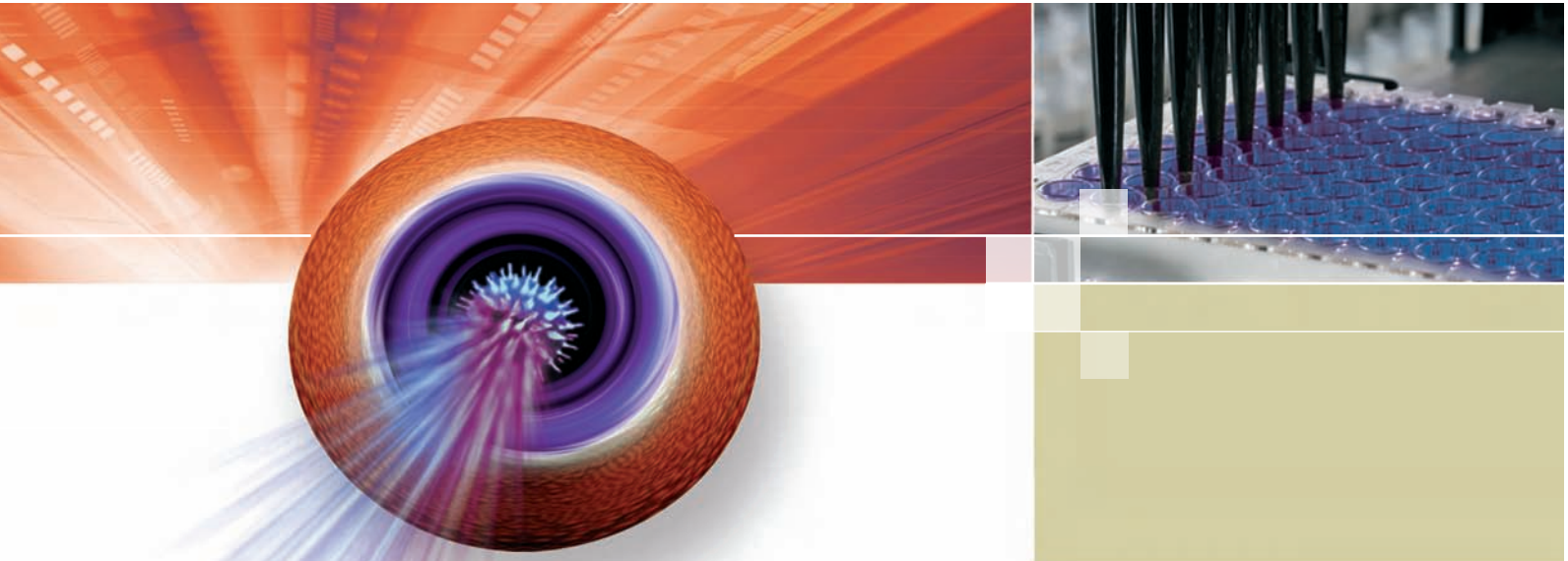


Monolisa™ HCV Ag-Ab ULTRA Assay

Pushing The Limits





Monolisa™ HCV Ag-Ab ULTRA Assay

EIA for Detection of HCV Ag and HCV Ab

Easily Automatable, Robust and Secure

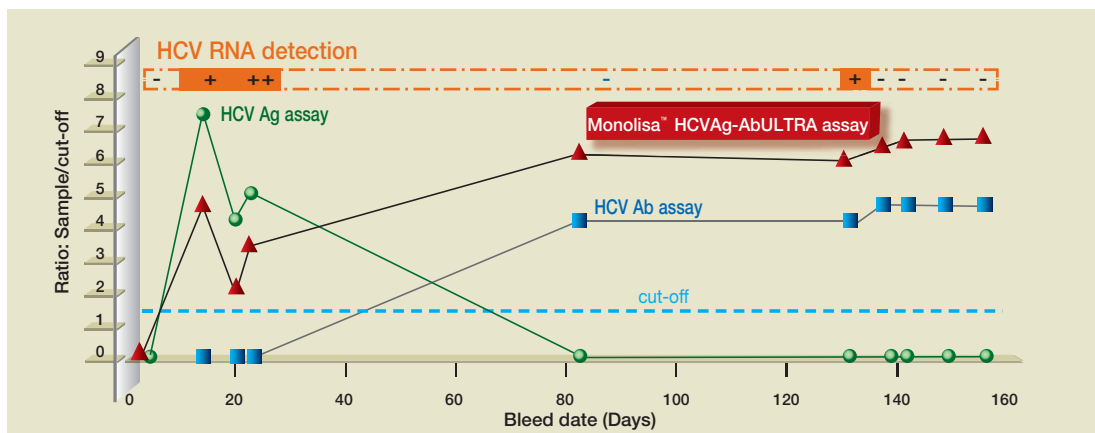
- High sensitivity: early HCV detection
- Dispense monitoring for all steps and OD norms in package insert
- Barcode on reagents
- Quality assurance: CE registered product
- Specific colored packaging for each marker
- Microplate and strip identification

Early HCV Exposure Detection

70% reduction of the serologic HCV Ab negative Window Period

A total of 35 commercially seroconversion panels, including subtype 1a, 1b, 2b, 3a, were tested by Monolisa™ HCV Ag-Ab ULTRA assay and by commercial EIA anti-HCV Ab assays.

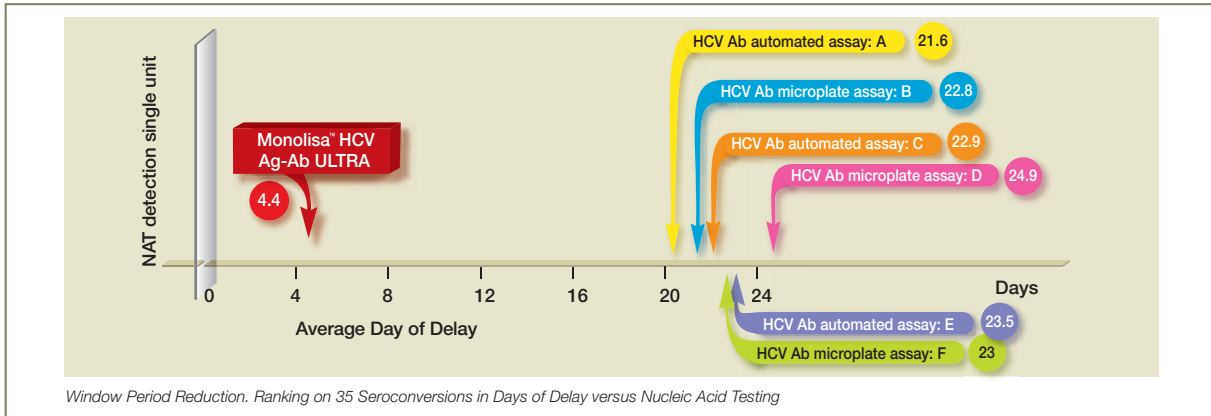
The serological profile for one representative panel is shown below.



Example of serological profile of HCV Seroconversion Panel BBI - 917

Reduction of Anti-HCV Ab Negative Window Period

70% reduction of the serologic HCV Ab negative Window Period



Among these 35 seroconversion panels, Monolisa™ HCV Ag-Ab ULTRA assay detects exposure to HCV at least 17 days earlier than the other anti-HCV Ab assays tested: 70% reduction of the serologic HCV Ab negative Window Period with Nucleic Acid Testing (HCV RNA detection) as reference. Monolisa™ HCV Ag-Ab ULTRA assay is able to detect 126 out of 145 (87%) of HCV RNA positive/anti-HCV negative samples tested.

Genotyped HCV Positive Sample Detection

A total of 405 genotyped samples were tested: 133 genotyped from various origin and 272 genotyped from 2 hospital laboratories.

Genotype	1a	1b	1c	1d	1a/b	2	2a	2b	2c	2i	2a/c	3	3a	3b	TOTAL
Number	53	83	2	3	3	31	7	18	4	1	17	25	77	1	
Genotype	3a/b	4	4a	4c	4d	4h	4k	4f	4c/d	5a	6a	6b	1b 2a/c	1a/b 2a/c	
Number	2	10	21	6	5	2	2	3	1	24	1	1	1	1	

405 genotyped samples tested

All these samples from different genotype were found positive: 100% sensitivity (405/405)

Sensitivity on Samples from Hospital Laboratories

A total of 348 anti-HCV Ab positive samples (confirmed by immunoblot or PCR) mostly from chronically infected people from 2 hospital laboratories were tested.

All of these 348 samples were reactive with Monolisa™ HCV Ag-Ab ULTRA assay giving a sensitivity of 100%

Blood Bank Specificity

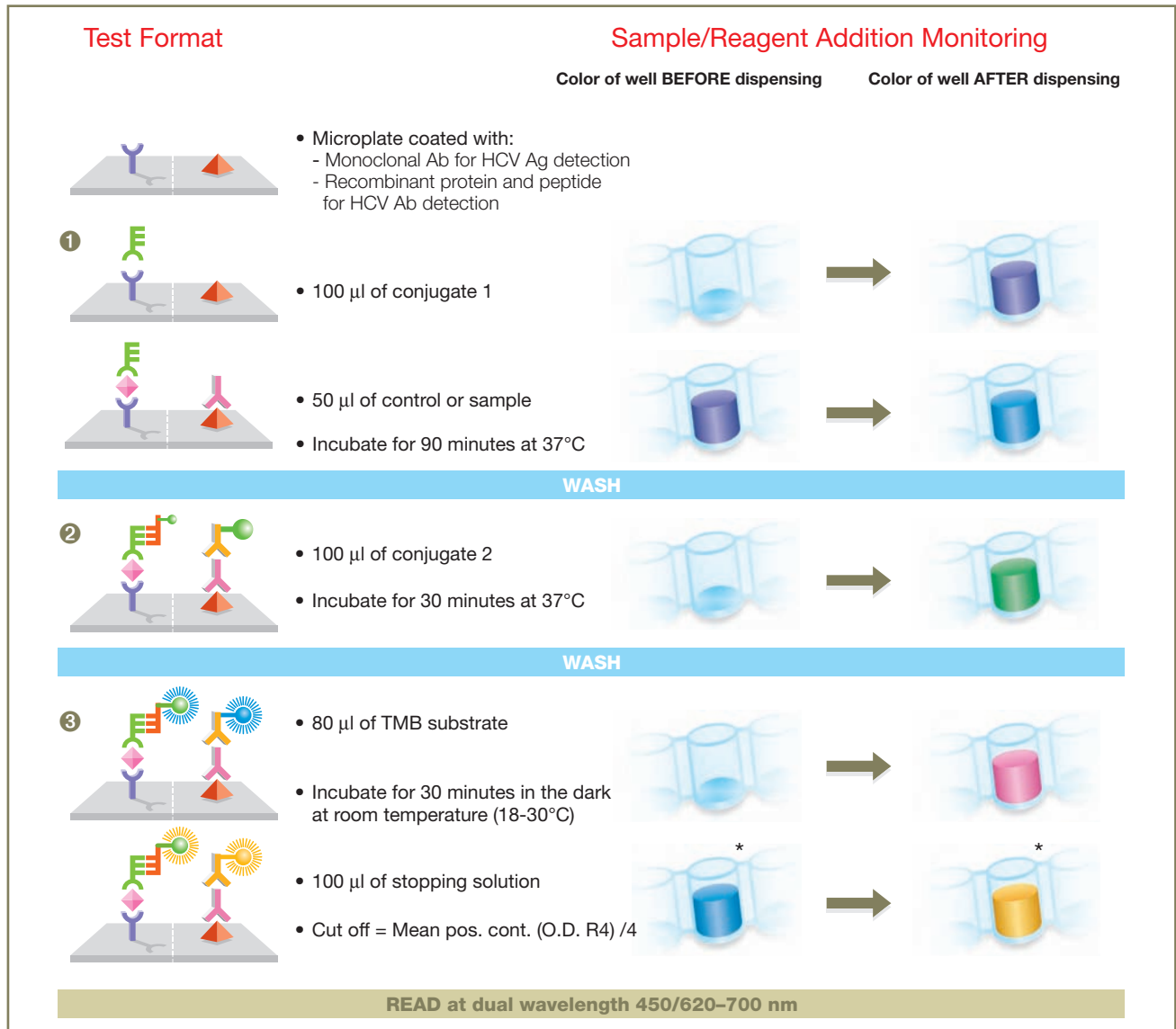
	Blood Bank Sites	Matrix	Number tested	Reactive samples	Specificity (%)	95% confidence interval
Initial Reactive	Site 1	EDTA Plasma	2,144	3	99.86	(99.70-100)
	Site 2	Serum	4,263	7	99.84	(99.71-99.96)
	Site 3	Serum	2,430	6*	99.75	(99.55-99.95)
	Site 4	Serum	3,564	7*	99.80	(99.66-99.95)
	Total		12,401	23	99.81	(99.74-99.89)
Repeat Reactive	Total		12,399	19	99.85	(99.78-99.92)

Example of serological profile of HCV Seroconversion Panel BBI - 917

Very low rate of repeat reactive samples. Specificity: 99.85%

Monolisa™ HCV Ag-Ab ULTRA Assay
4th Generation Assay

Monolisa™ HCV Ag-Ab ULTRA Assay



Anti-HCV capsid monoclonal antibodies
 Mutated capsid peptide, recombinant protein NS3 genotype 1 and 3, recombinant protein NS4
 Biotinylated anti-HCV capsid monoclonal antibodies
 Peroxidase labeled streptavidine
 Peroxidase labeled antibodies to human IgG

* Reactive samples after 30 minutes incubation

Ordering Information

Catalog No.	Description	
72556	Monolisa™ HCV Ag-Ab ULTRA Assay	96 tests
72558	Monolisa™ HCV Ag-Ab ULTRA Assay	480 tests



Bio-Rad Laboratories

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics

Clinical Diagnostics Group

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