Evaluation of Blood Screening Nucleic Acid Tests (NAT) for Detection of Various HCV and HIV Genotypes

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Methods

- NAT Screening Methods:
  - Chiron Procleix™TMA HIV-1/HCV Assay
  - Roche Molecular Systems COBAS AmpliScreen™HCV Test, v.2.0
- Diagnostic NAT Methods:
  - Bayer Quantiplex® HIV RNA 3.0 Assay (bDNA)
  - Organon Teknika NucliSens™ HIV-1 QT Assay
  - Roche AMPLICOR HCV MONITOR® Test, v1.0
  - Roche AMPLICOR HCV MONITOR® Test, v2.0
  - Roche AMPLICOR HIV-1 MONITOR® Test, v1.0
  - Roche AMPLICOR® HCV Test, v2.0

Study Design

- Characterized specimens representing various HCV genotypes and HIV clades were coded and sent to Roche and Chiron for blind testing by the NAT screening methods currently in use for Blood Bank pool testing.
- Specimens were not pooled with other negative specimens, but were tested neat.
- Results were compared with existing BBI data from methods available in diagnostic laboratories.

31 HCV Specimens

- PHV901 HIV Seroconversion Panel
  - genotype 1a, 11 members
- PHV917 HCV Seroconversion Panel
  - genotype 2, 10 members
- PHV909 HCV Seroconversion Panel
  - genotype 3, 3 members
- A405 HCV RNA Reference Control, 100 IU/ml
- PHW802 HCV RNA Sensitivity Panel
  - 16 members, genotypes 1, 2, and 3
  - half log dilutions from 10,000 to 100 IU/ml

36 HIV Specimens

- WWRB302 Worldwide HIV Panel
  - clades A, B, C, D, E, F, G
  - group O and HIV-2
  - 30 members
- PRB954 HIV Seroconversion Panel
  - clade B
  - 6 members

PHV901 HCV Seroconversion Panel

genotype 1a

	bleed day	AMPLICOR, v2.0	TMA	COBAS AmpliScreen
01	0	Negative	Negative	Negative
02	65	Positive	Positive	Positive
03	97	Positive	Positive	Positive
04	99	Positive	Positive	Positive
05	104	Positive	Positive	Positive
06	106	Positive	Positive	Positive
07	131	Negative	Negative	Negative
08	139	Negative	Negative	Negative
09	159	Negative	Negative	Negative
10	166	Positive	Positive	Positive
11	203	Negative	Positive	Positive

PHV909 HCV Seroconversion Panel

genotype 3

	bleed day	AMPLICOR MONITOR, v2.0	TMA	COBAS AmpliScreen
01	0	10,000	Positive	Positive
02	28	40,000	Positive	Positive
03	30	20,000	Positive	Positive

PHV917 HCV Seroconversion Panel

genotype 2b

	bleed day	AMPLICOR MONITOR, v1.0 copies/ml	AMPLICOR, v2.0	TMA	COBAS AmpliScreen
01	0	BLD	Positive	Positive	Positive
02	13	>500,000	Positive	Positive	Positive
03	20	>500,000	Positive	Positive	Positive
04	22	>500,000	Positive	Positive	Positive
05	85	BQR	Positive	Positive	Positive
06	131	BQR	Positive	Positive	Positive
07	135	3000	Positive	Positive	Positive
08	138	BLD	Positive	Positive	Positive
09	146	BLD	Negative	Positive 2/3	Positive
10	152	BQR	Positive	Positive	Positive

	Genotype	IU/ml	AMPLICOR, v2.0	TMA	COBAS AmpliScreen
A405 HCV RNA Reference Control	1b	100	Positive	Positive	Positive

PHW802 HCV RNA Sensitivity Panel

	Genotype	IU/ml	TMA	Ampliscreen
01	1a	6000	Reactive	Reactive
02	1a	2000	Reactive	Reactive
03	1a	600	Reactive	Reactive
04	1a	200	Reactive	Reactive
05	1a	60	Reactive	Reactive
06	2b	8000	Reactive	Reactive
07	2b	3000	Reactive	Reactive
08	2b	800	Reactive	Reactive
09	2b	300	Reactive	Reactive
10	2b	80	Reactive	Reactive
11	2b	20000	Reactive	Reactive
12	3	6000	Reactive	Reactive
13	3	2000	Reactive	Reactive
14	3	400	Reactive	Reactive
15	3	100	Reactive	Reactive
16	neg	0	Nonreactive	Nonreactive

PRB954 HIV-1 Seroconversion Panel BD

	Bleed Day	bDNA Quantiplex 3.0 copies/ml	NucliSens copies/ml	AMPLICOR MONITOR v1.0 copies/ml	TMA
01	0	BLD	BLD	BLD	Negative
02	2	BLD	BLD	BLD	Negative
03	7	BLD	BLD	BLD	Positive
04	10	600	BLD	1000	Positive
05	14	3000	2000	60,000	Positive
06	17	300,000	200,000	600,000	Positive
07	21	>500,000	>1,000,000	>800,000	Positive

WWRB302 Worldwide HIV Performance Panel

	Origin	Clade	bDNA Quantiplex copies/ml	NucliSens copies/ml	AMPLICOR MONITOR copies/ml	TMA
02	Ghana	A	60,000	20,000	500	Reactive
05	Ghana	A	20,000	20,000	600	Reactive
09	Ivory Coast	A	20,000	200	200	Reactive
13	Uganda	A	20,000	40,000	6000	Reactive
21	China	B'	3000	7000	2000	Reactive
26	USA	B	20,000	200,000	20,000	Reactive
27	USA	B/D	600	10,000	5,000	Reactive
29	Argentina	B	300	BLD	900	Reactive
12	Mozambique	C	50,000	20,000	70,000	Reactive
18	Uganda	C	10,000	30,000	20,000	Reactive
19	Zimbabwe	C	200	200	300	Reactive
20	Zimbabwe	C	200	200	700	Reactive

Origin	Clade	bDNA Quantiplex 3.0 copies/ml	NucliSens copies/ml	AMPLICOR MONITOR, v1.0 copies/ml	TMA
Uganda	D	20,000	90,000	50,000	Positive
Uganda	D	800	3000	3000	Positive
Uganda	D	2000	10,000	10,000	Positive
Uganda	D	1000	600	800	Positive
Thailand	E	2000	200	BLD	Positive
Thailand	E	9000	2000	3000	Positive
Thailand	E	900	100	300	Positive
Argentina	F	2000	500	200	Positive
Ghana	G	700	BLD	2000	Positive
Ghana	G	9000	600	6000	Positive
Ivory Coast	G	10,000	BLD	1000	Positive

	Origin	Clade	bDNA Quantiplex	NucliSens	AMPLICOR MONITOR	TMA
01	Spain	Group O	100	BLD	BLD	Reactive
07	Ivory Coast	HIV-2	BLD	BLD	BLD	Nonreactive
11	Mozambique	HIV-2	BLD	BLD	BLD	Nonreactive
25	India	HIV-2	BLD	BLD	BLD	Nonreactive
10	Ivory Coast	Neg	BLD	BLD	BLD	Nonreactive
30	Argentina	Neg	BLD	BLD	BLD	Nonreactive

Conclusion

- Both NAT methods used for blood screening are able to detect less common genotypes of HCV with sensitivity similar to currently available commercial diagnostic test methods.
- TMA is able to detect less common subtypes of HIV with sensitivity similar to currently available commercial diagnostic test methods.