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Multiplex NAT Reactive Donor Specimens Tested Non-Reactive in Discriminatory Assays are Negative for HIV-1 and HCV RNA

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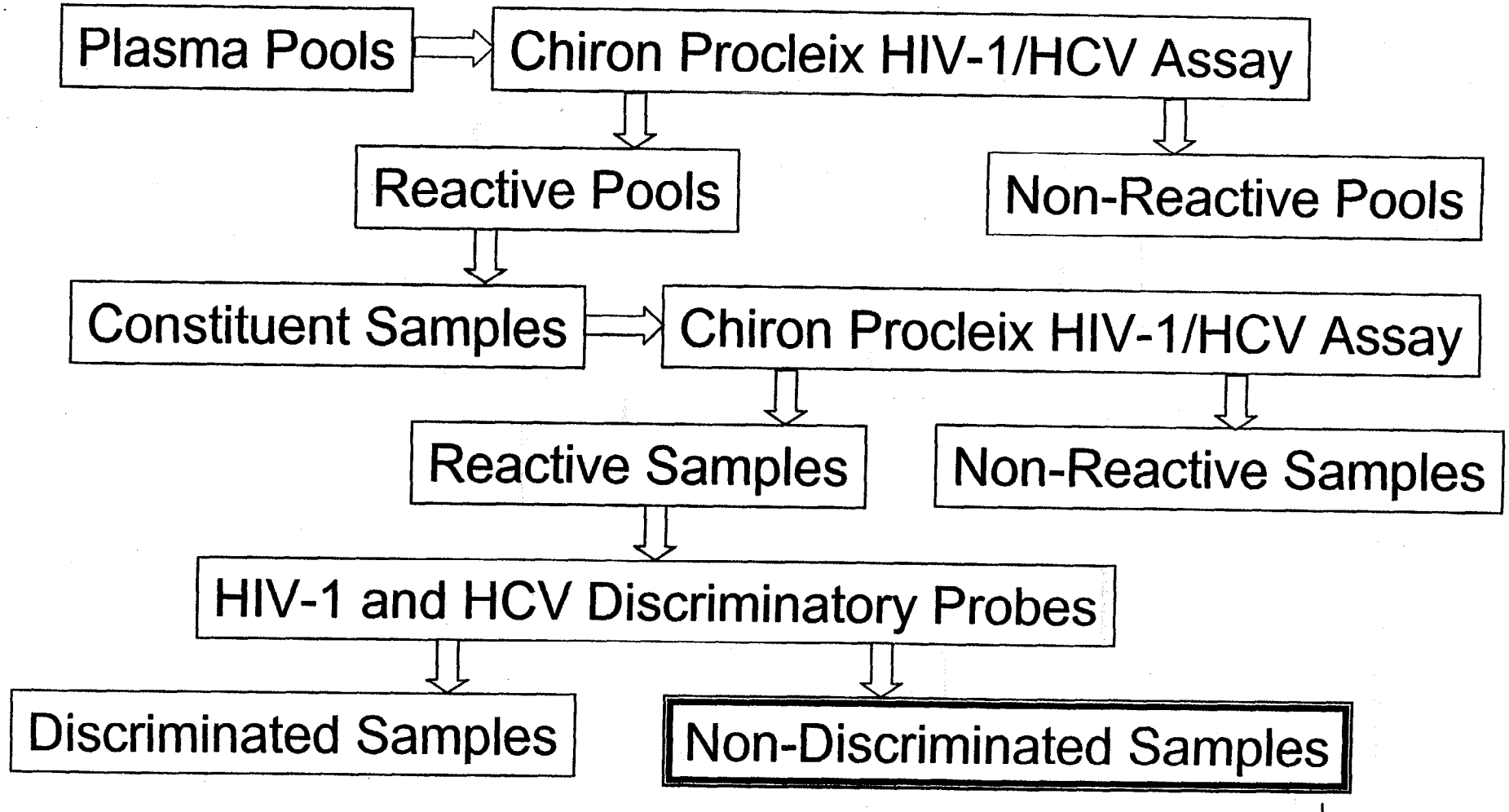
Background

The Chiron Procleix™ HIV-1/HCV Assay has been used to screen more than 70% of U.S. blood supply since March / April 1999 under FDA approved INDs.

The Chiron Procleix HIV-1/HCV Assay is a multiplex nucleic acid amplification testing (NAT) system for simultaneous detection of HIV-1 RNA and HCV RNA in human plasma.

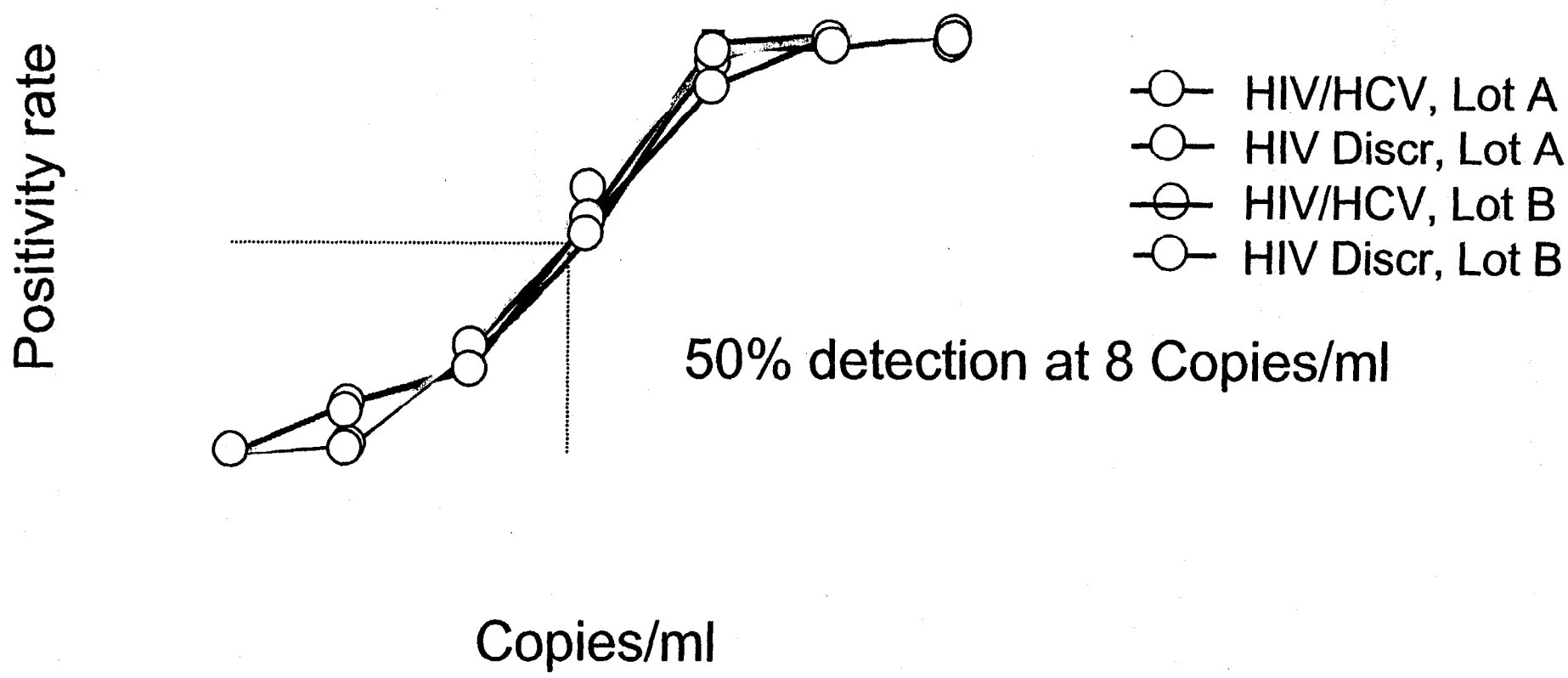
Samples tested reactive in the Chiron Procleix HIV-1/HCV Assay must be further tested using the HIV-1 and HCV specific probe reagents.

Testing Algorithm for Plasma Pools using Chiron Procleix™ HIV-1/HCV Assay



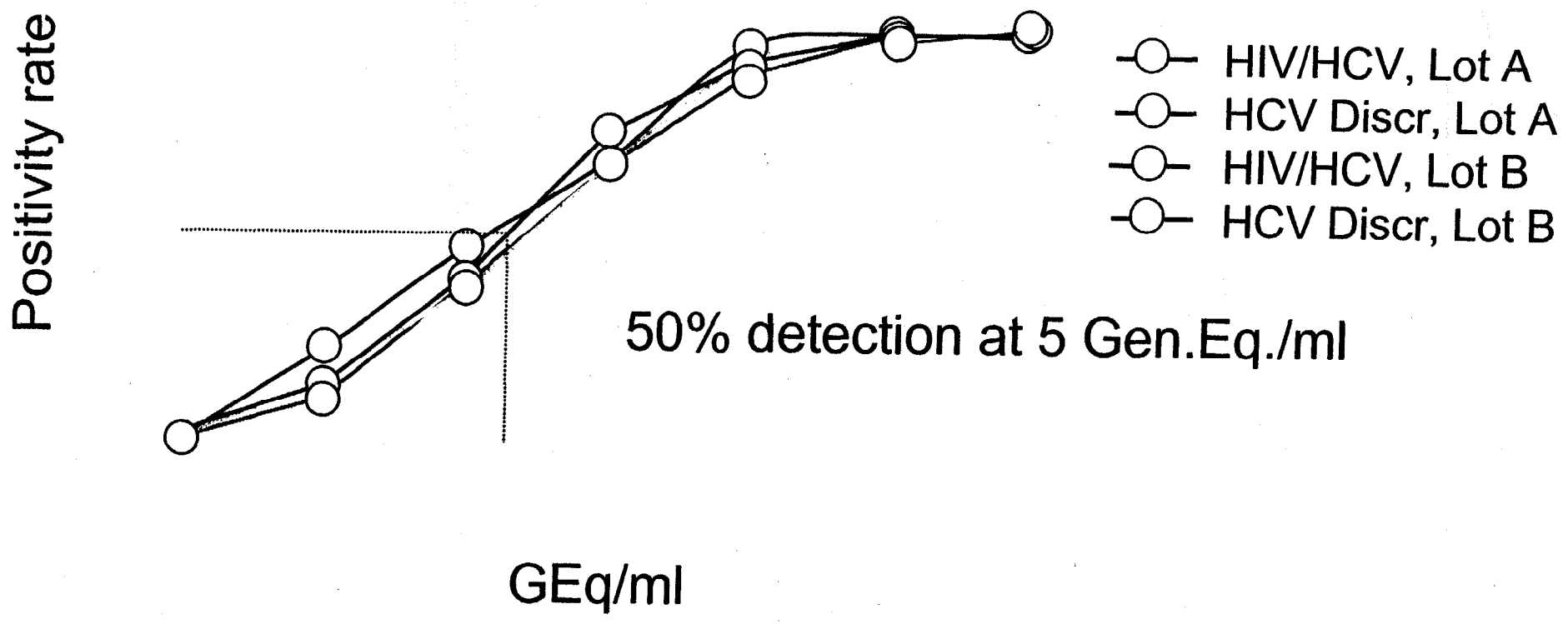
Analytical Sensitivity, HIV-1

Chiron Procleix™ HIV-1/HCV Assay and HIV-1 Discriminatory Assay



Analytical Sensitivity, HCV

Chiron Procleix™ HIV-1/HCV Assay and HCV Discriminatory Assay



Additional Testing on Non-Discriminated Reactive Specimens

Sample Type	Primary Testing		Further Investigation		
	EIA	TMA	EIA	TMA	PCR
Index Donation					
NAT tube		NDR*	✓	✓	✓
Serum tube	NR				
Bag plasma			✓	✓	✓
Follow-Up Sample			✓	✓	✓

*** Non-Discriminated Reactive in Chiron Procleix HIV-1/HCV Assay**

Chiron Procleix™ HIV-1/HCV Assay
Non-Discriminated Reactive Specimens

	ARC	ABC			Total
		BSL	FBS	BCSEW	
	3/99 - 3/00	4/99 - 2/00	4/99 - 3/00	4/99 - 3/00	
Total Donations Tested	5.5 M	--------- 2.2 M ---------			**7.7 M**
No. Non-Discriminated	57 0.001%	262	121	11	451 0.006%
		------- 0.018% --------			
Available for Additional Testing	54	128	22	5	209 46%

Chiron Procleix™ HIV-1/HCV Assay
Non-Discriminated Reactive Specimens: ARC

	Phase I* 3/3/99 - 9/7/99	Phase IIA** 9/8/99 - 3/2/00	Total 3/3/99 - 3/2/00
Total Donations Tested	2.34 M	2.66 M	**5.5 M**
No. Non-Discriminated	0 0.00%	57 0.002%	57 0.001%
Available for Additional Testing	0	54	54

*** Pool of 128, with no sero-reactives** **** Pool of 16, with sero-reactives**

Chiron Procleix™ HIV-1/HCV Assay
Non-Discriminated Reactive Specimens: ARC

ARC 3/99 - 3/00 57 / 5.5 million donations (0.001%)

	Alternate Sample			Follow-Up Sample			NAT Tube	
N	Sero.	TMA	PCR[a]	Sero.	TMA	PCR[a]	TMA[b]	PCR[a]
19	Neg	Neg	Neg	Neg	Neg	Neg	----	6N/6[c]
3	Neg	Neg	Neg	Neg	NDR[d]	Neg	Neg	2N/2[c]
20	----	Neg	Neg	----	----	----	----	6N/6[c]
1	----	NDR	Neg	----	----	----	----	----
11	----	----	----	Neg	Neg	Neg	----	3N/3[c]
3	----	----	----	----	----	----	----	1N/1[c]

[a] For HIV-1 and HCV [b] Re-testing [c] No. negatives / No. tested
[d] Non-discriminated reactive in the same assay run

Chiron Procleix™ HIV-1/HCV Assay
Non-Discriminated Reactive Specimens: ARC

Donor	NAT Tube		Alternate Sample			Follow-Up Sample			
Status[a]	TMA	PCR	Sero.	TMA	PCR	Days[b]	Sero.	TMA	PCR
M45R	NDR[c]	Q/NR[d]	NR	NDR[c] NR	NR	(Refused to enroll)			
M39R	NDR[c]	NR	NR	NR	NR	21	NR	NDR[c,f] NR	NR
						130	NR	NR	NR
F22R	NDR[c]	NR	NR	NR	NR	21	NR	R[f]/Q[e]	NR
						62	NR	NR	NR
F22F	NDR[c]	QNS	NR	NR	NR	20	NR	R[f]/Q[e]	NR
						59	NR	NR	NR

a Sex, Age, First-time or Repeat
b Days after the index donation
c Non-discriminated reactive
d HIV-1 PCR QNS, HCV PCR NR
e HIV-1/HCV Assay reactive, Discriminatory Assays QNS
f In the same HIV-1/HCV Assay run

CHIRON Blood Testing

Chiron Procleix™ HIV-1/HCV Assay
Non-Discriminated Reactive Specimens: ABC

ABC 4/99 - 3/00 394 / 2.2 million donations (0.018%)

N	1st Follow-UP Sero.	1st Follow-UP TMA	2nd Follow-Up Sero.	2nd Follow-Up TMA
154	Neg	Neg	---	---
1**	Neg	NDR*	Neg	Neg
239	---	---	---	---

* Non-discriminated reactive

** 1st follow-up 7 days, 2nd follow-up 9 months after the index

Conclusions

A non-discriminated reactive result in the Chiron Procleix HIV-1/HCV Assay is a rare event (0.006%).

None of the 209 donors with non-discriminated reactive results have any evidence of HIV and/or HCV infection.

The original reactive results are due to technical error and/or cross contamination during pooling and/or testing process.

Conclusions

The Chiron Procleix HIV-1 and HCV Discriminatory Assays have been shown to have the same sensitivity as the Chiron Procleix HIV-1/HCV Assay.

Donors with a non-discriminated reactive result in the Chiron Procleix HIV-1/HCV Assay should be re-instated.

The donor should be allowed to donate again and if the next donation is negative in serology and NAT, the donation can be released for transfusion.