QUIX™ HIV-1 (M&O) AND HIV-2 RAPID BLOOD TEST

A Rapid Whole Blood/Serum/Plasma Test for Detection of Antibodies to HIV-1 (M&O) & HIV-2

Presented By:

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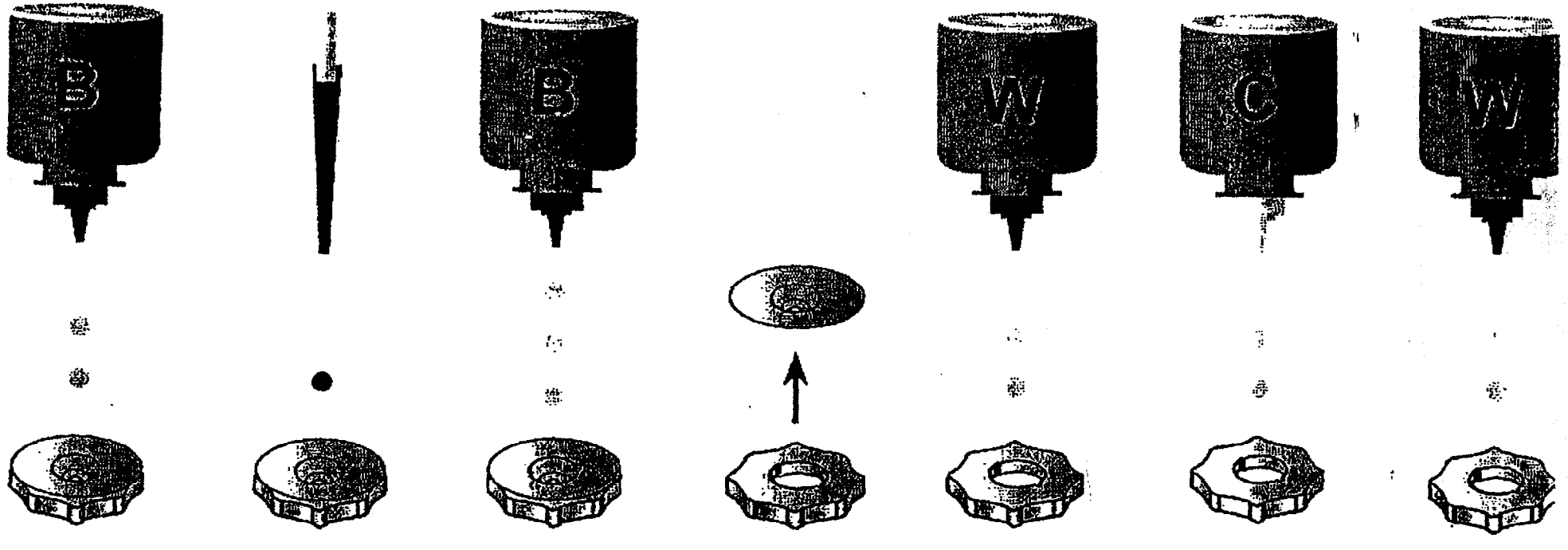
Quix™ HIV-1 (M&O) and HIV-2 Rapid Blood Test:

Sample Preparation **Test Procedure**



The Whole Process Requires Less Than 6 Minutes

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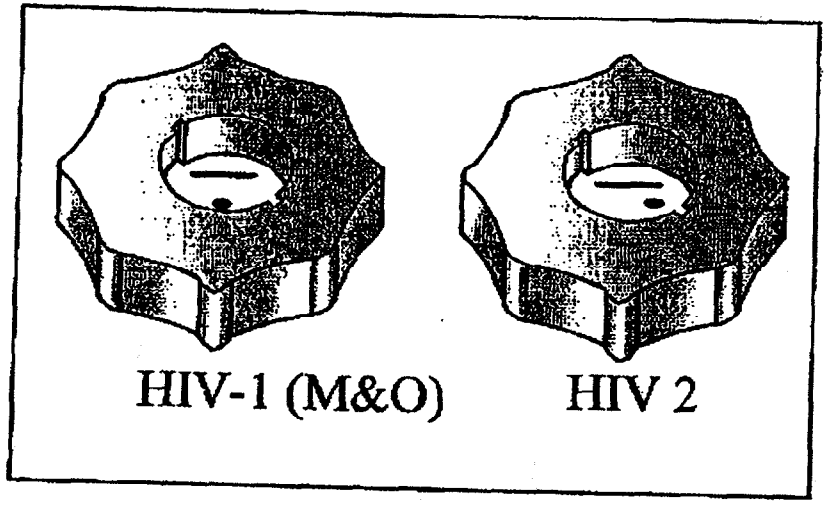
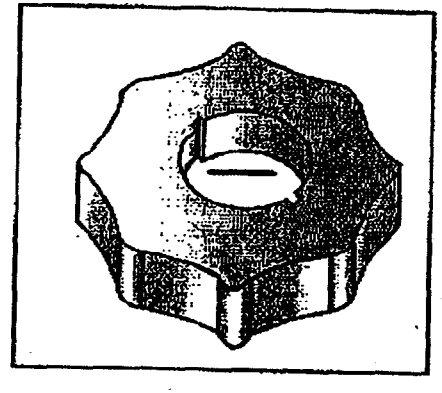
Quix™ HIV-1 (M&O) and HIV-2 Rapid Blood Test - Interpretation:



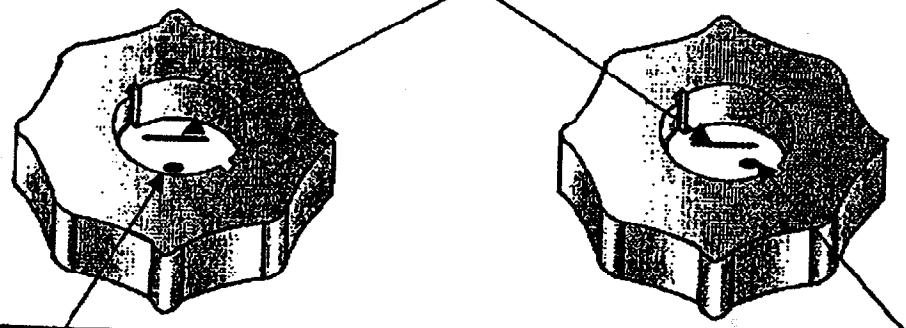
Reactive



Non-reactive

Quix™ HIV-1 (M&O) and HIV-2 Rapid Blood Test
Biological Principle of the Procedure:

Procedural Control:
Line Containing Anti-human IgG



Test Spot HIV-1 (M&O):
Dot Containing A Mixture of Proprietary Synthetic Peptide Antigens That Bind Antibodies to HIV-1 Group M & O gp41 IDR

Test Spot HIV-2:
Dot Containing Proprietary Synthetic Peptide Antigen That Binds Antibodies to HIV-2 gp36 IDR

Feasibility Study on HIV-1 (M&O) & HIV-2 Peptides in Quix™ Rapid Test and ELISA Formats:

Test For:	Sample Type, n =	Correctly Identified, n =
HIV-1 (M&O)	HIV-1 (Group M) Subtypes: Antibody Positive, n = 92	92
	HIV-1 (Group O) Variants: Antibody Positive, n = 39	39
HIV-2	HIV-2: Antibody Positive, n = 74	74
Both	Panel of Problematic Negatives, n = 14	14
Total	n = 219	219

Conclusion: Peptide antigens identified all samples correctly.

Further In-House Pre-clinical Studies on Quix™ HIV-1 (M&O) & HIV-2 Rapid Blood Test:

Samples Originating From:

United States, Uganda, Gabon, Ivory Coast, Thailand, India, Mali, Peru, Cameroon, Egypt, Ghana, South Africa, Zimbabwe, China, Canada, and Argentina.

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Samples Include:

HIV-1 Group M:

BBI World Wide HIV-1 Performance Panel; Subtypes Including 'A' Through 'G', Recombinant types B/D, E/F, C/E, and E/C; BBI HIV-1 Seroconversion Panels.

HIV-1 Group O:

Variants Including ANT70, MVP5180, LA 'O' and MD 'O'.

HIV-2:

BBI HIV-2 Performance Panel, Prospectively and Retrospectively Collected Samples From Ivory Coast.

HIV Negative:

Samples Including Icteric, Lipemic, Hemolyzed and Samples Positive for RF, HCV, HSV, CMV, ANA, Syphilis, and HBV.

Samples:

Finger-stick	10
Whole Blood	50
Plasma	380
Serum	1,118
Total Samples Tested	1,558

Quix™ HIV-1 (M&O) & HIV-2 Rapid Blood Test

Summarized In-house Pre-clinical Studies:

Test Spot:	Sample Type, n =	Correctly Identified, n =
HIV-1 (M&O)	HIV-1 (Group M) Subtypes: Antibody Positive, n = 723	723
	HIV-1 (Group O) Variants: Antibody Positive, n = 39	39
HIV-2	HIV-2: Antibody Positive, n = 169	169
Both	HIV Negative, n = 627	627
Total	n = 1,558	1,558

Conclusions of In-House Pre-clinical Studies:

- Quix™ HIV-1 (M&O) & HIV-2 Rapid Blood Test Correctly Identified All HIV Antibody Positive & Negative Samples.
- No False Positive or False Negative.
- There were 28 Unlinked WB Indeterminate Samples Originated in Uganda Remained Unresolved.

Pre-clinical Study Done at Institute of Human Virology
By Dr. Niel T. Constantine

Study:	Total:
HIV-1 Group M (75 Positives)	270
HIV-1 Group O (20 Positives)	20
HIV-2 (160 Positives)	200
(Ivory Coast)	
Non-US Origin (98 Positives)	100
(Trinidad, Thailand, Mali, Peru, Gabon, India)	

Conclusions: No False Positive & No False Negative.

Results of Clinical Trial: 1st Generation Recombinant-based Quix™ HIV 1-2-O Rapid Whole Blood Test:

- No. of blood samples: 9,758
- No. of sites tested: 33†
- Sensitivity: 100%§
- Specificity: 99.8%‡

† Included CDC, American Red Cross, Ryan White Foundation *etc.*

§ No false negative

‡ Compared to Abbott HIV EIA Specificity of 99.1%

Equivalence Study Done at WRAIR:

1st Generation: Quix™ HIV-1-2-O Rapid Whole Blood Test

Vs.

2nd Generation: Quix™ HIV-1 (M&O) & HIV-2 Rapid Blood Test

Total Samples:	**1,679**
Positive Samples:	**485**
Negative samples:	**1,194**

Conclusions:

2nd Generation Peptide-Based and 1st Generation Recombinant-Based Quix™ HIV Tests are in 100% Concordance.