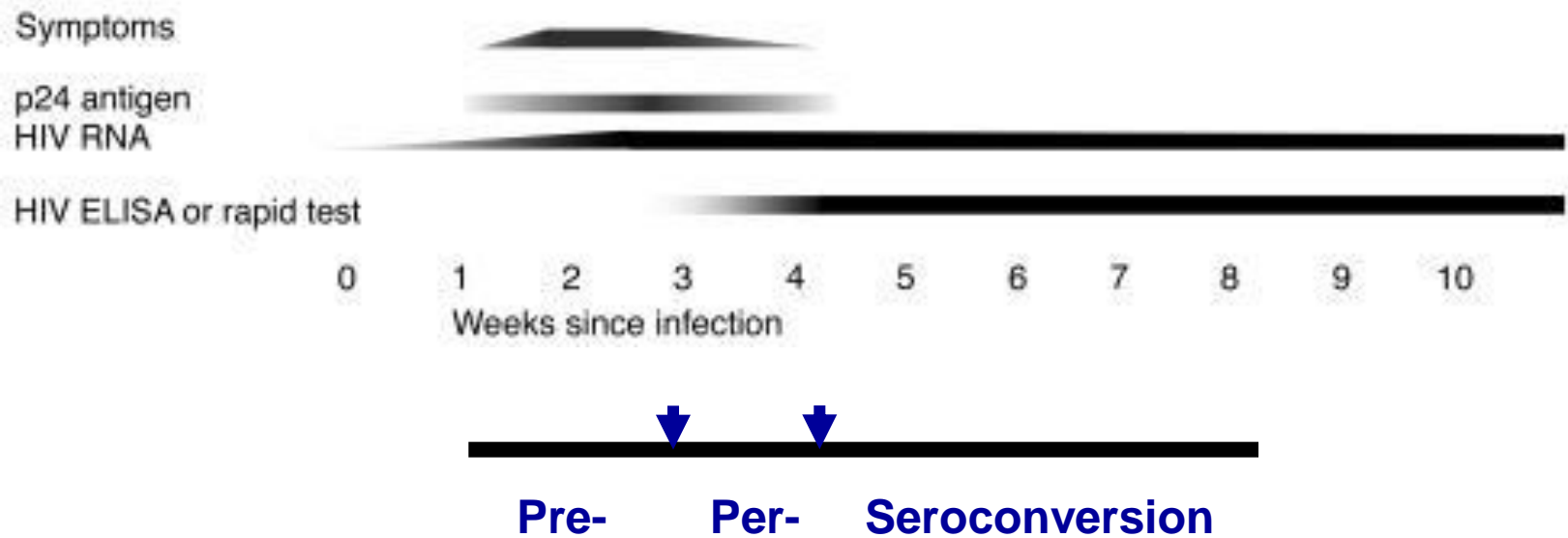




Field-oriented rapid diagnostics for early diagnosis of HIV infection

**Baruch Rivetz PhD
Orgenics LTD, Yavne, Israel**

Acute HIV diagnostic time-line



Adapted from Pilcher et al, 2004

Acute HIV Infection

Definition: Time interval during which HIV can be detected in blood before the formation of antibodies routinely used to diagnose infection.

This interval is called “ Window Period”

Characterized by:

- Lasts weeks to months
- High level of viremia
- Absence of detectable adaptive immune response
- Wide dissemination of virus
- Seeding of lymphoid organs
- Infected patients are highly infectious
- Lack of specific signs of retroviral infection
- Symptomatic phase of acute HIV mimics many common febrile illnesses such as mononucleosis

Strategies for HIV Diagnosis Improvement

- **Application of new markers for early HIV infection to shorten seroconversion window**
- **Simplification of tests and shortening time of assay: development of rapid tests, use of other body fluids rather than serum/plasma (whole blood [DBS], oral, semen and genital fluid, urine); immediate results and counseling; avoiding return visits; addressing point-of-care use and emergency blood testing.**
- **New testing algorithms, utilizing new technologies, low-cost tests and avoiding unnecessary tests.**

Advantages of rapid tests

- **Accuracy.** Rapid tests are as sensitive, specific and reproducible as EIAs
- **Enable decentralization of HIV testing and counselling**
- **Feasible for limited laboratory infrastructure settings**
- **Acceptability of HIV testing to patients and counsellors**
- **Short time to obtain test results**
- **Cost effective**
- **Ease of performance and ease of test results interpretation**
- **Minimal facilities for storage and shelf-life**
- **Flexibility in numbers of tests performed**
- **Reduction in occupational exposure risk**

Orgenics' HIV test repertoire

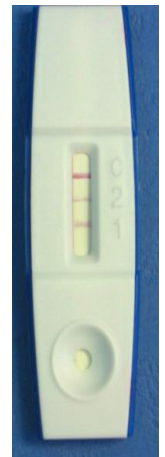
ImmunoComb Platform

- ❖ ImmunoComb HIV 1&2 BiSpot
- ❖ ImmunoComb HIV 1&2 Combfirm
- ❖ ImmunoComb HIV 1&2 TriSpot Ag/Ab

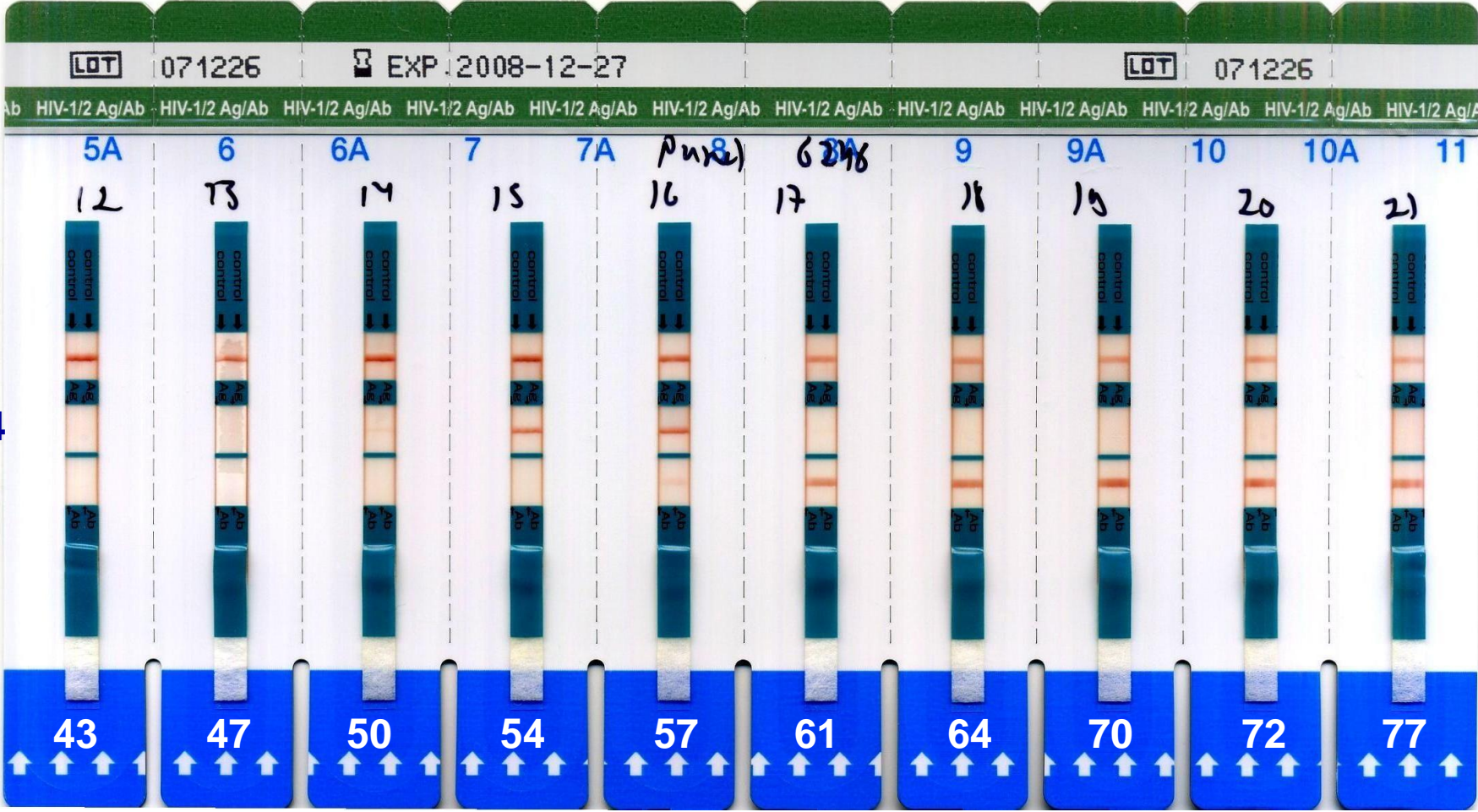


Individual Rapid tests

- ❖ DoubleCheck II HIV 1&2
- ❖ Genie (Developed for Bio-Rad)
- ❖ DoubleCheckGold HIV 1&2
- ❖ DoubleCheckGold HIV 1&2 Ultra
- ❖ Determine® HIV 1/2 Ag/Ab Combo



Example of seroconversion panel (BCP 6246) in Determine[®] HIV-1/2 Ag/Ab Combo assay



Bleeding day

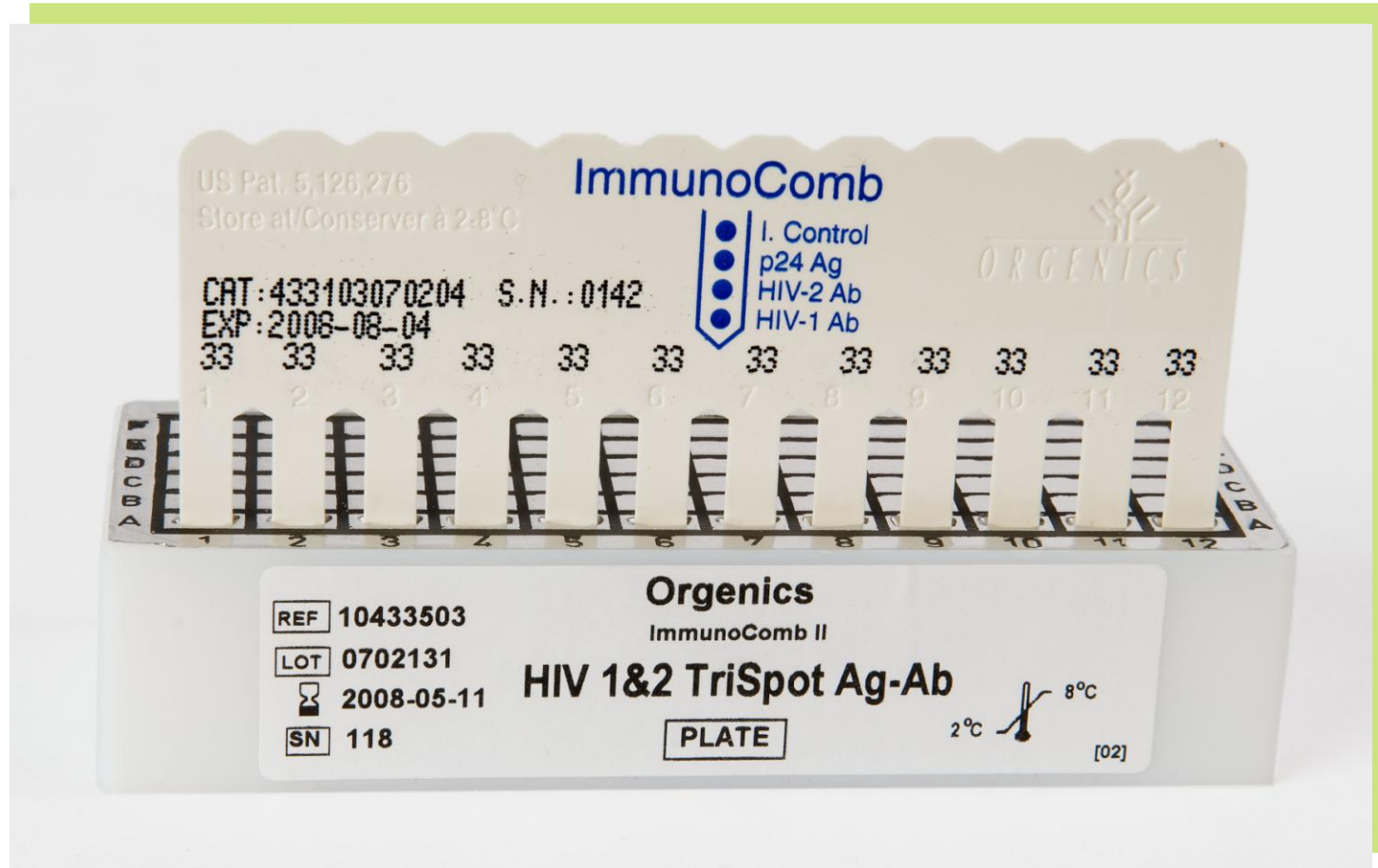
Determine® HIV-1/2 Ag/Ab Combo

Seroconversion Panels: Days of Detection

Panel	Reference p24 Antigen Test	Reference 3 rd Gen EIA	Determine HIV-1/2 Ag/Ab Combo		Gained days Compared to 3 rd Generation EIA
			p24 Ag	HIV Ab	
BBI – J	14	26	14	26	12
BBI - Q	53	60	53	65	7
BBI - W	37	47	47	84	37
BBI - AE	3	7	3	7	4
BBI - AT	2	14	7	14	7
BBI – BA	8	19	11	19	8
BBI – BE	3	12	7	12	5
BBI - BI	0	9	7	12	2
BBI - AS	12	14	12	19	7
BBI - AM	0	9	0	9	9
BBI - AI	0	7	0	7	7
BBI - AP	7	11	7	11	4
BBI - AU	13	13	13	15	2
BBI – BG	23	28	23	28	5
BCPI-6240	23	28	23	30	5
BCPI-6246	50	57	50	57	7

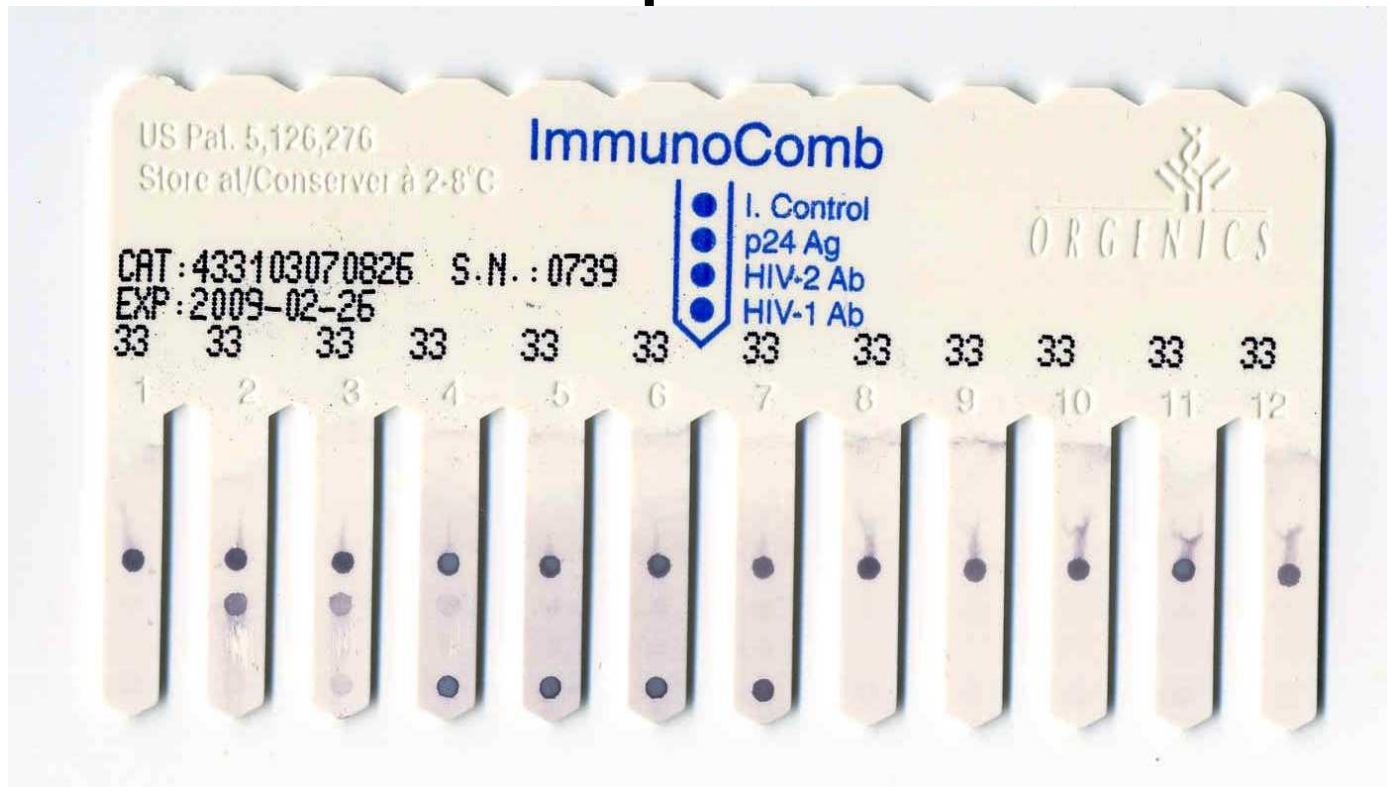
The Determine® HIV-1/2 Ag/Ab Combo detects HIV infection 2-37 days earlier than the HIV 3rd generation antibody test, depending on the panel tested.

ImmunoComb



ImmunoComb HIV Ag/Ab TriSpot Performance

Seroconversion panel BBI BI



0 7 9 14 19 21 26

Days since 1st bleeding

ImmunoComb HIV Ag/Ab TriSpot Performance

Seroconversion panels: Days of Detection

Panel	Reference p24 Antigen Test	Reference 3rd Gen EIA	ImmunoComb TriSpot		Gained days Compared to 3rd Generation EIA
			HIV-1 p24 Ag	HIV-1 Ab	
BBI - J	14	26	14	26	12
BBI - Q	53	60	53	60	7
BBI - R	0	2	0	2	2
BBI - V	0	4	0	4	4
BBI - W	37	47	37	47	10
BBI - AB	28	33	28	33	5
BBI - AE	0	7	0	7	7
BBI - AF	15	28	15	28	13
BBI - AT	2	14	7	14	7
BBI - BA	8	19	11	19	8
BBI - BB	10	17	19	14	7
BBI - BE	3	12	3	12	9
BBI - BF	47	50	47	50	3
BBI - BI	0	9	7	9	2

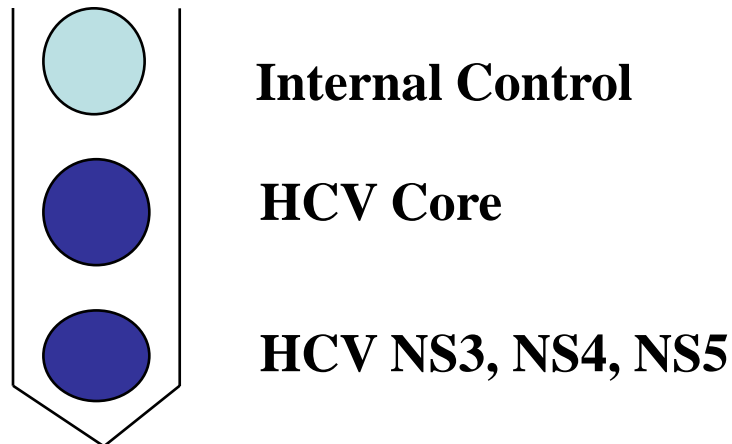
The ImmunoComb HIV TriSpot detects HIV infection 2 to 13 days earlier than 3rd-generation EIA

ImmunoComb® II HCV

A third-generation test for qualitative detection of anti HCV IgG antibodies in human serum or plasma.

Simultaneous and differential detection of antibodies to Core and non-structural Antigens (NS3, NS4, NS5)

Test duration – 36 minutes at room temperature



ImmunoComb® II HBs Ag

A test for the qualitative detection of hepatitis B virus surface antigen (HBsAg) in human serum or plasma.

Performance:

Sensitivity = 99%

Specificity = 100%

Test Duration: 90 minutes at 37C

Threshold = 0.5 ng /mL



Determine[®] HBs Ag

Features:

Specimen: Whole blood (EDTA), plasma and serum

Specimen volume: 50 µl

Running time: 20 minutes

Analytical sensitivity:

Current: 4 ng/ml

Feasibility: 0.5 ng/ml

Specificity (In-house studies): 100%



Conclusions

The sequential use of the Determine[®] HIV 1/2 Ag/Ab Combo as an initial screening test and ImmunoComb HIV 1&2 TriSpot Ag/Ab as a confirmatory test provides a field-oriented, rapid, economical and complete high performance diagnostic system that may suit Blood Banks and transfusion centers in out-of-hospital emergencies during disasters or any other blood crisis. Field-oriented diagnosis for HBV and HCV that can be used in the same circumstances is available as well.

Thanks

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- Dorit
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- Gani *et al**

* Part time

IMJ:

- Karasawa-san*
- Tamanoue-san*
- Tanaka-san*
- Asahina-san*
- Miwa-san*

Abbott:

R&D scientists of
greater Abbott who
developed the
Determine[®] platform