

This is  
Bio-Rad.



## **Geenius HIV 1/2 Confirmatory assay**

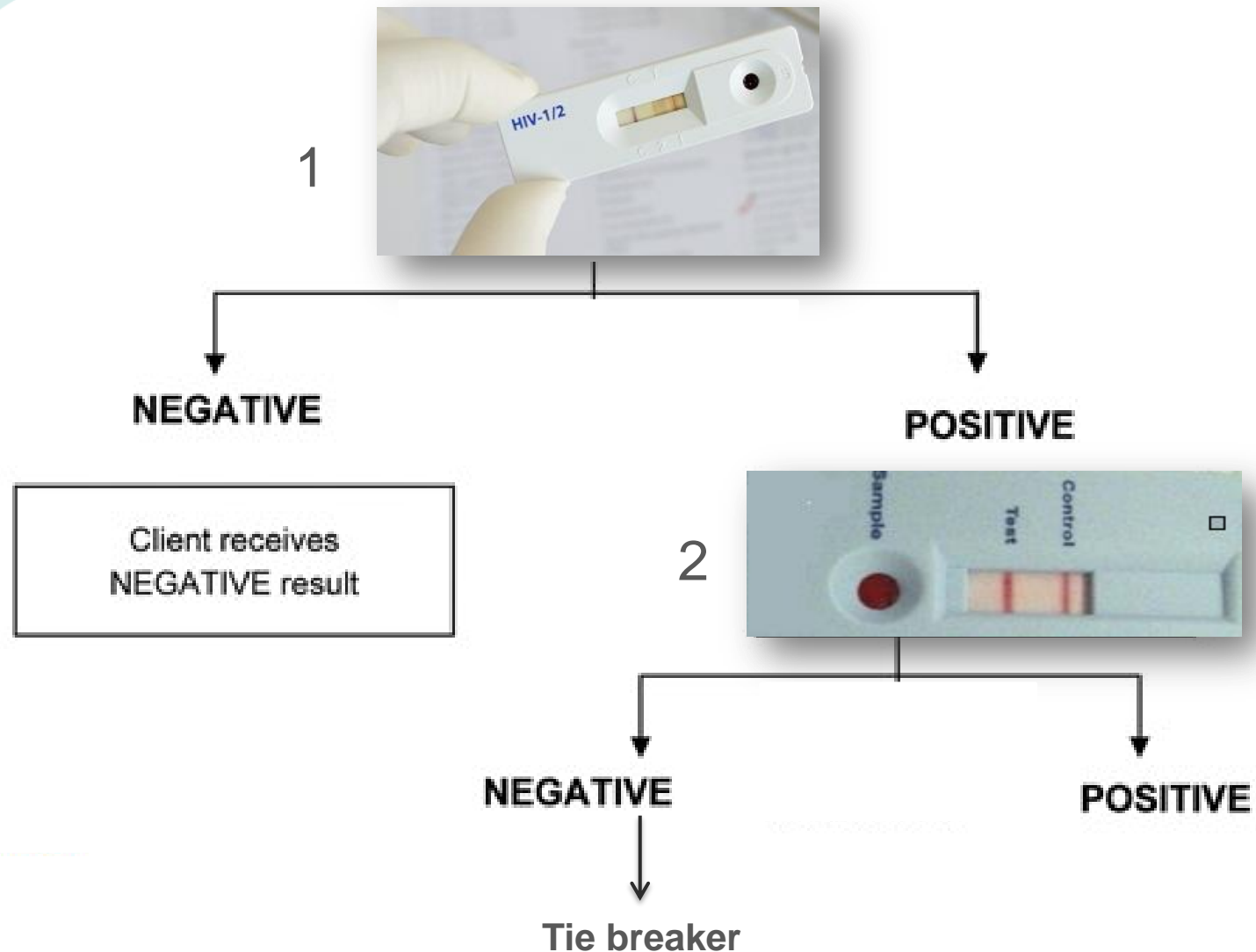
A breakthrough in situations  
facing resource limitations

Cyrille Schreider, PhD  
EMEA Marketing Director,  
Clinical Diagnostics



An ambitious treatment target  
to help end the AIDS epidemic

# Diagnostic Algorithms Using Rapid HIV Tests



# The Difficult Topic with HIV Rapid Tests

- *“False positive HIV tests: the problem no one wants to talk about (and how to solve it)”*

Doctors Without Borders/Médecins Sans Frontières  
(L. Shanks); 2011 ICASA conference in Addis Ababa

**7% false positive rate**

- *“Are we delivering the wrong results ?”*

*Examining misclassification of HIV status and false positive test results*

WHO, USAID, John Hopkins ; 2014 ASLM South Africa

**4.8-10.5 % false positive rate**

# The Solution



## Geenius™ HIV 1/2 Confirmatory System

A Game Changer

# Geenius™: A New Concept

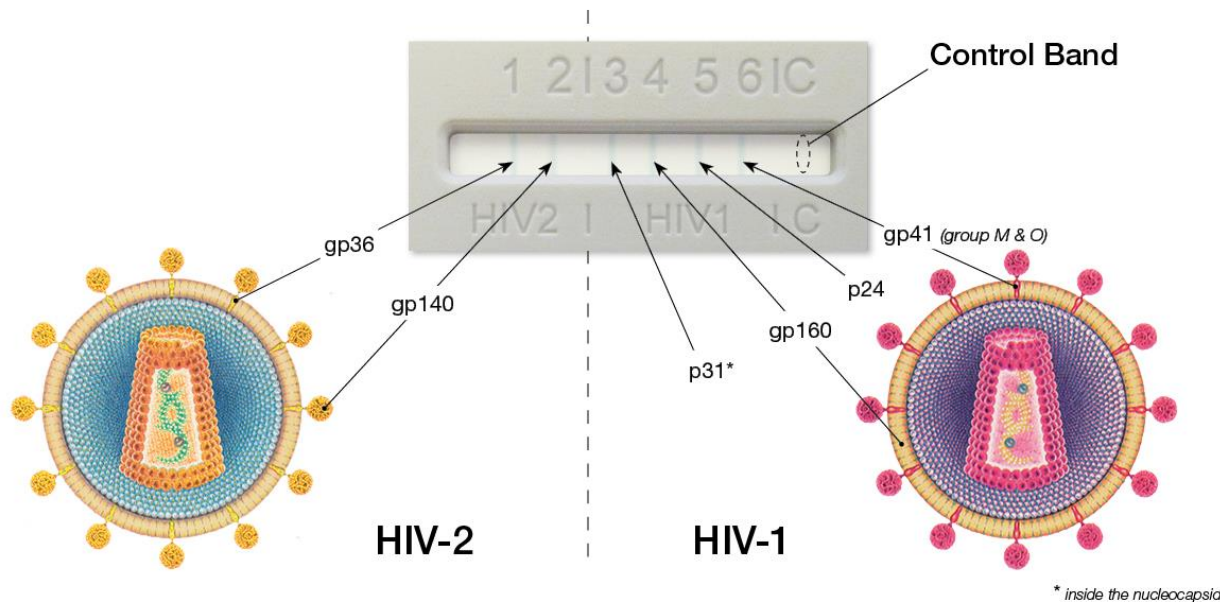


- **Unitary and immediate** testing  
3 sample types: serum, plasma or **whole blood**
- **HIV-1 and HIV-2 confirmation and differentiation**  
**Accurate** results in **less than 30 minutes**

# Geenius Cassette: Biologicals

Geenius HIV 1/2 Confirmatory cassettes utilises the following HIV peptides and recombinant antigens.

**Dual Path Platform (DPP™) technology**



HIV-2		HIV-1				Ctrl Band
GP36 peptide	GP140 peptides	P31 peptide	GP160 recombinant	P24 recombinant	GP41 peptides	Protein A
ENV	ENV	POL	ENV	GAG	ENV	

# Geenius Evaluations



<i>Untersuchungsergebnisse des Austestung des Geenius™ HIV1/2 Confirmatory Assay</i>		August 2013	Pr. Dr. H. Rabenau Pr.Dr. O. Keppler Dr. I. Friedrichs	Inst. of Med. Virology GERMANY	New Lav Blot I & II
<i>Comparative Evaluation of Bio-Rad Geenius HIV 1 and HIV-2 Assay as a Confirmation Assay for Detection of HIV-1 and HIV-2 Antibodies</i>		August 2014	A.H. Hallen & al.	Karolinska University Hospital SWEDEN	RIBA HIV-1/HIV-2 Immunoblot
<i>Discriminatory capacity between HIV-1 and HIV-2 of the new rapid confirmatory assay Geenius</i>		July 2014	N. Herssens K. Fransen	Inst. of Trop. Medicine BELGIUM	INNO-LIA HIV I/II Score (Old & New interpretation criteria)
<i>Evaluation of the Bio-Rad Geenius HIV 1/2 Assay as an alternative to INNO-LIA HIV 1/2 Assay for confirmation of HIV Infection</i>		July 2014	O. Mor F. Mileguir	National HIV Reference Laboratory ISRAEL	INNO-LIA HIV I/II Score (Overnight protocol)
<i>Evaluation in a clinical setting of the performances of a new rapid confirmatory assay for HIV 1/2 serodiagnosis</i>		June 2014	I. Abbate C. Pergola	N.I.I.D. ITALY	New Lav Blot I & II
<i>Comparison of a conventional HIV 1/2 line immunoassay with a rapid confirmatory HIV 1/2 assay</i>		May 2014	C. Tinguely & al.	S.R.C. SWITZERLAND	INNO-LIA HIV I/II Score
<i>Evaluation of the Bio-Rad Geenius HIV-1/2 test as a confirmatory assay</i>		April 2014	I. Montesinos & al.	Erasmus Hospital BELGIUM	MP HIV BLOT 2.2 New Lav Blot II

**FDA approved, CE-IVD, Global Fund list,  
WHO prequalification on going**

**BIO-RAD**



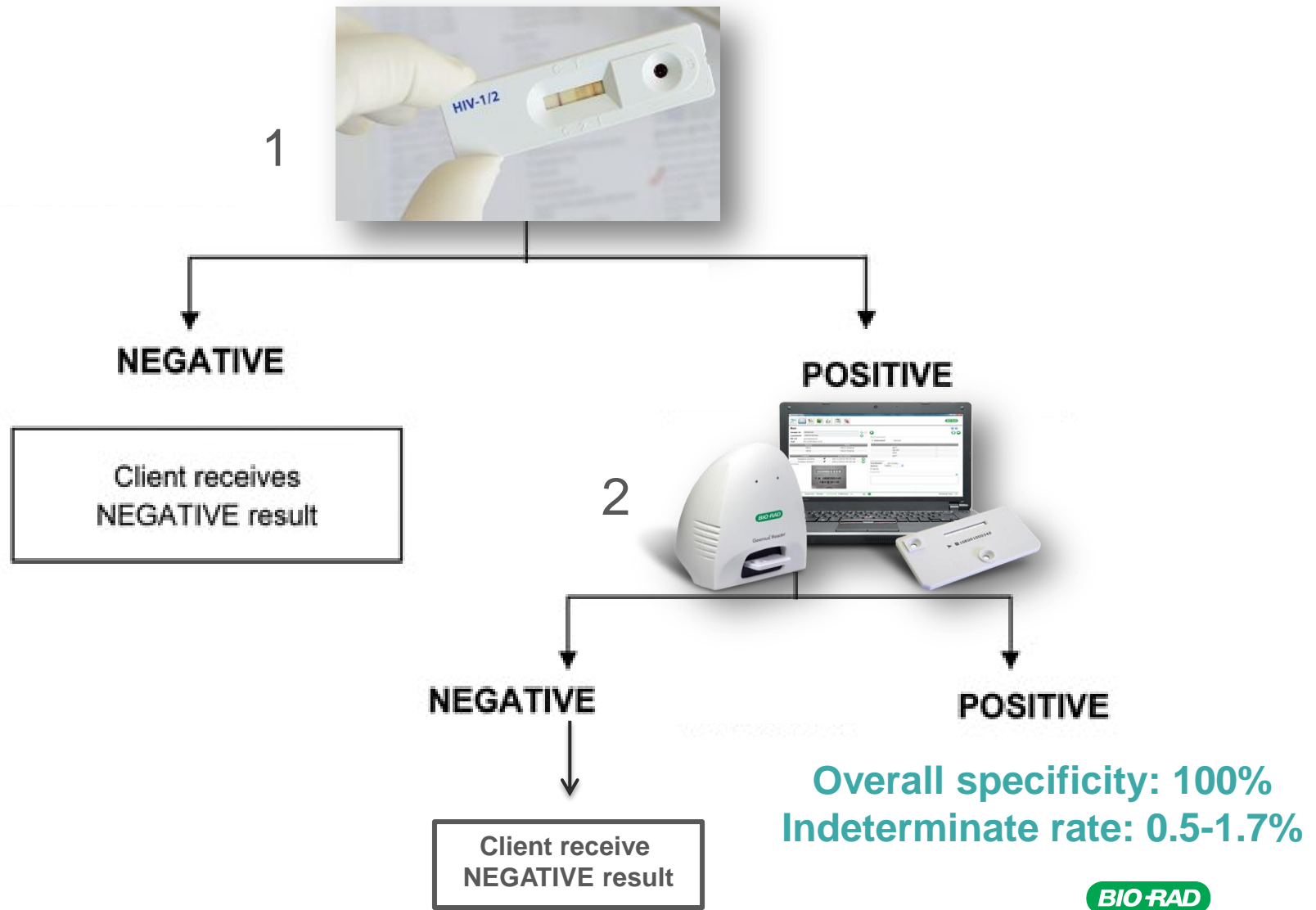
# Geenius™: A New Concept



- **Unitary and immediate** testing  
3 sample types: serum, plasma or **whole blood**
- **HIV-1 and HIV-2 confirmation and differentiation**  
**Accurate** results in **less than 30 minutes**
- **Expert and simple software** using validated algorithm  
Full **automation** and complete **traceability**

**A Breakthrough in the Field of HIV Confirmation!**

# New Algorithm Proposal



# What does Geenius Bring to Your Patients ?

- Highly **reliable** results ensure the **right HIV diagnosis**
  - **Focus resources & deliver care for true HIV patients**
  - **Avoid misclassification of patients**
- **Fast** results for people in situations where the resources are limited  
(who cannot afford to come back to the **reference lab**)

## HIV 4<sup>th</sup> generation assay



**Highest sensitivity HIV assay**

Genscreen™ ULTRA HIV Ag-Ab  
confirmatory assay

Every Test  
Bio-Rad expertise in HIV diagnosis

Thank you for your attention

**BIO-RAD**