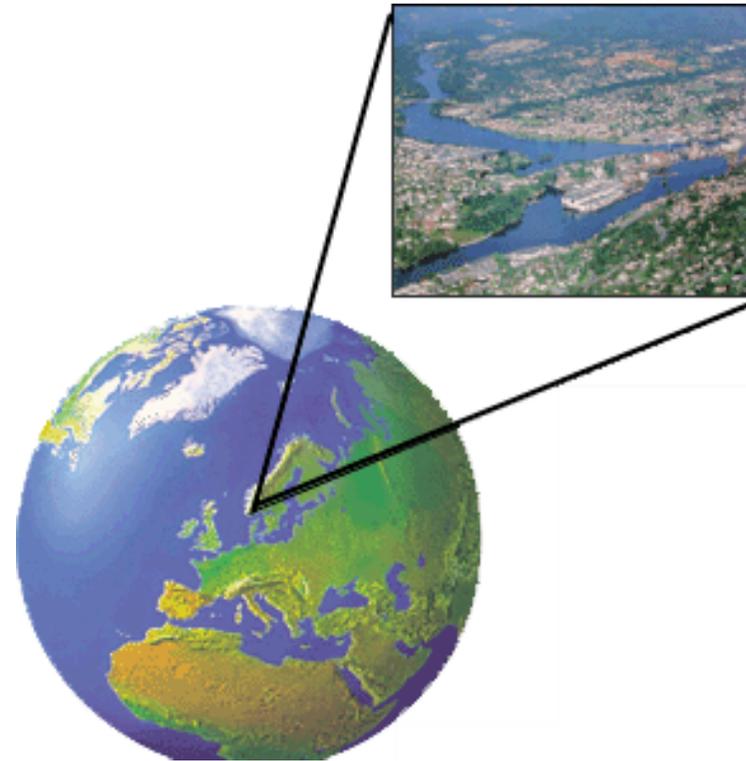
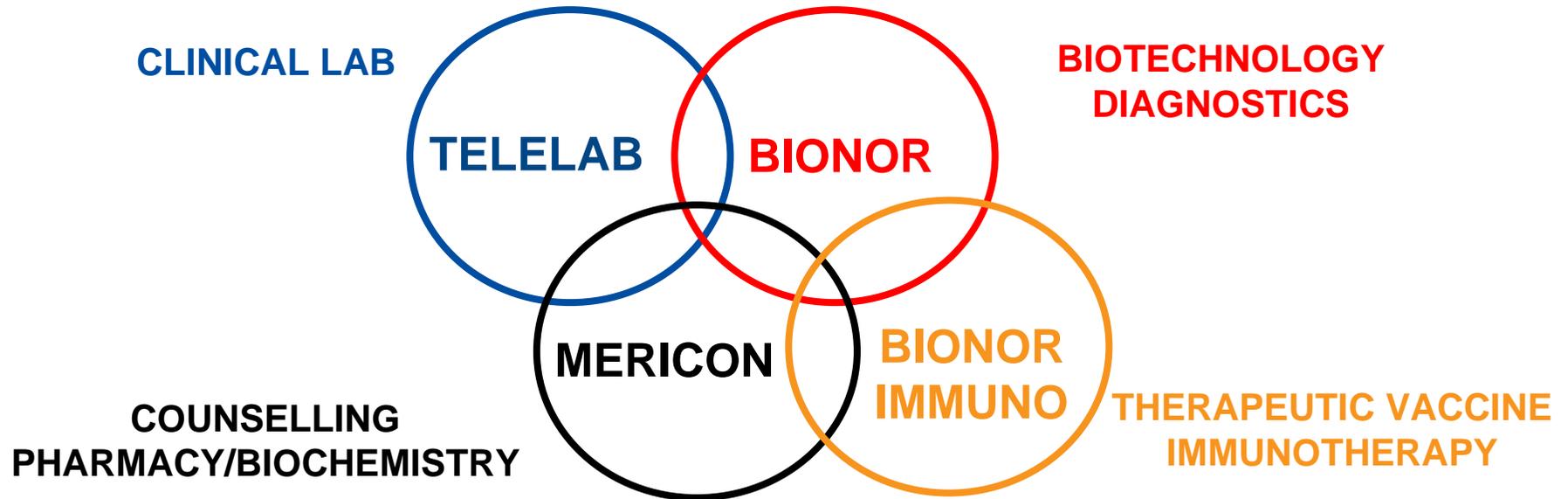




A new approach to
HIV Testing
and
Blood-donor screening



Telemark Biomedical Centre (TBC)



– Total no. of employees: 60+

TBC - Clinical laboratory & Pharma Counselling

■ TELELAB

- Official laboratory for County of Telemark approved by MoH, Norway
- Training of MD's to specialise in clinical microbiology
- Private human medical microbiology laboratory
- Environmental laboratory
- Veterinary laboratory

■ MERICON

- Preclinical studies
- Clinical studies, Data management and Statistics
- Preparing Application for Marketing Authorisation in Norway
- Drug Regulatory Affairs Management
- Writing expert reports

■ Diseases

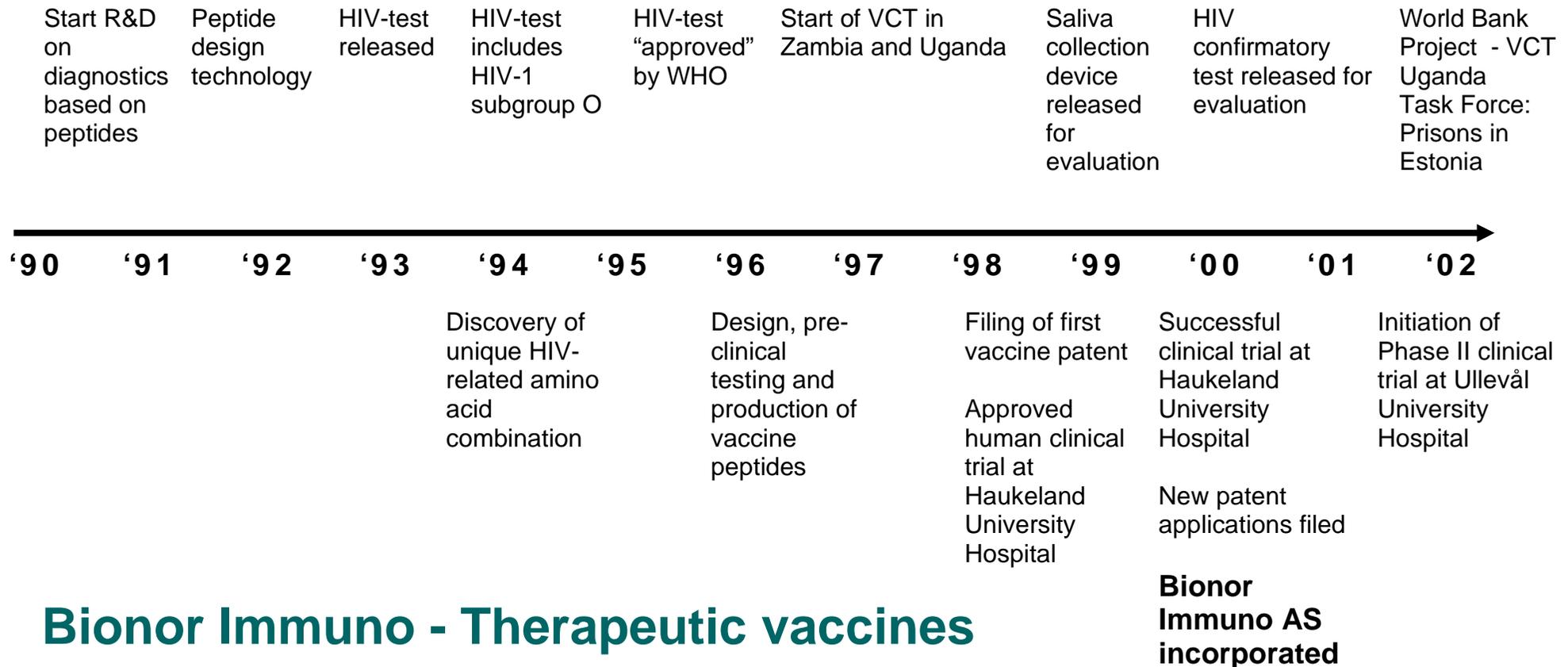
- Human papillomaviruses (HPV),
- Meningococci
- Staphylococci
- Tick-borne diseases (Borrelia and Ehrlichia)

■ Technology

- Molecular epidemiology and PCR-based diagnostics
- Chromosomal DNA fingerprinting
- RFLP techniques
- PFGE and PCR

TBC - Bionor & Bionor Immuno

BIONOR - Diagnostics



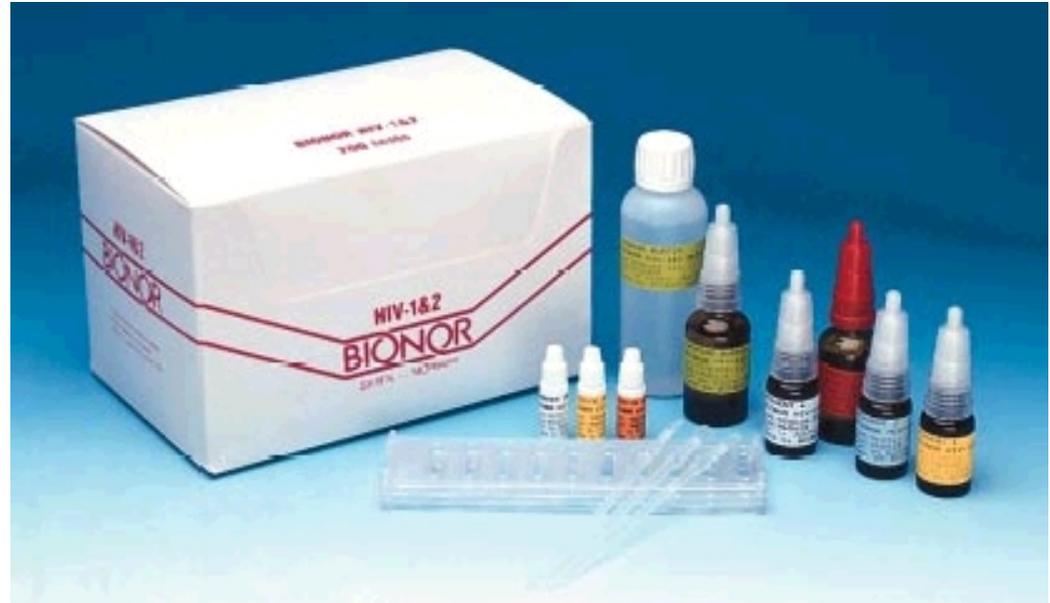
Bionor Immuno - Therapeutic vaccines

Magnetic Particle Rapid ELISA test kits

A Common Assay Technology Platform

■ Robust and easy to use

- In ready to use in droppers
- Visual reading
 - Highly reproducible results also under tropical conditions
- One year shelf life
 - No reduction after opening of kit



■ Available kits

- HIV-1&2
- HIV Confirmatory
- Syphilis
- HCV
- HBsAg (in development)

Magnetic Particle Rapid ELISA Testing Station

A multipurpose testing station designed for :

- **Bionor MP ELISA test kits**
- **Agglutination tests**
- **Blood grouping**

- **Easy to use**
- **Powered by**
 - 220V AC
 - 12V (solar power and/or car battery if power cut is likely to occur)



BIONOR HIV-1&2 Rapid ELISA

- **Magnetic Particle Rapid ELISA - Reading of results**
 - Visual reading
 - Red colour indicates reactivity to the antigen
 - Easy and clear cut



Interpretation of results:

+ - - - + - + - - -

BIONOR HIV Confirmatory

- HIV-1

- Core

- Transmembrane 1

- Envelope

- HIV-2

- Transmembrane 2

1 2 3 4 5 6 7 8 9 0

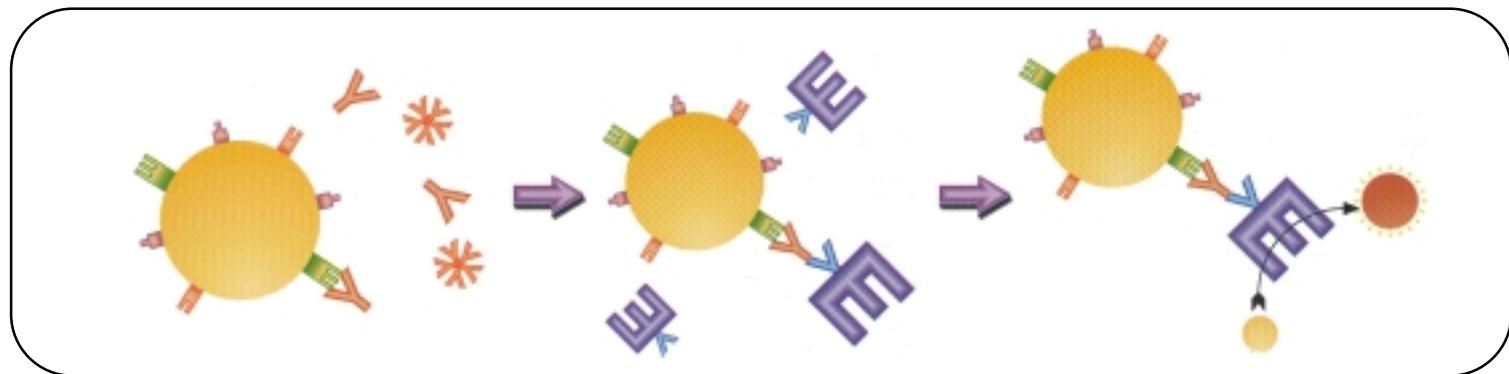


Interpretation of results: + - - | + - + - - -

(+) = Pos result, (-) = neg result, (I) = indeterminate result. Ref: (ASTPHL/CDC)

BIONOR HIV-1&2 Rapid ELISA

- Robust test
- All reagents supplied in dropper bottles
- All reagents in ready-to-use form
- 1 year shelf life
- No reduction in kit shelf life after opening of kit



STEP 1:
Sample incubation

STEP 2:
Conjugate incubation

STEP 3:
Colour development

BIONOR HIV test kits - Evaluations

■ BIONOR HIV-1&2 Rapid ELISA:

– WHO evaluation:

- Sensitivity 100% (n=262)
- Specificity 98,8% (n=332)

Published in January 1999:

WHO/UNAIDS - Operational characteristics of commercially available assays to determine antibodies to HIV-1 and/or HIV-2 in human sera

CONCLUSION:

- Very easy to perform *and*
- Suitable for use *in small laboratories*

■ Bionor HIV Confirmatory

– University of Maryland, USA, Niel Constantine, PhD, Sep 2000

- Sensitivity 100% (n=532)
- Specificity 100% (n=71)

– Swedish Institute for Infectious Disease Control (SMI), Stockholm

- In preparation

A complete HIV testing solution

Same technology platform for both screening and confirmation:

- **Bionor HIV-1&2 Rapid ELISA**

- screening test kit

- **Bionor HIV Confirmatory**

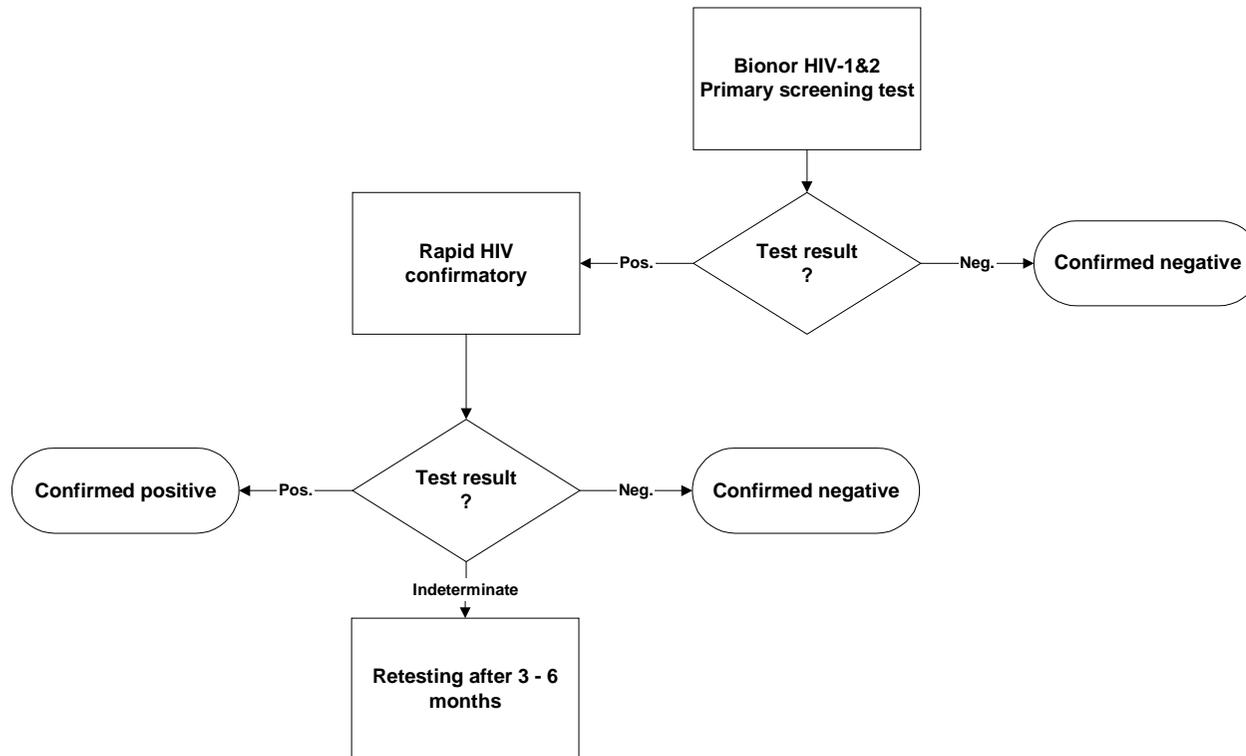
- a Western Blot like rapid test kit

- **Samples:**

- Blood (serum, plasma or whole-blood)
- Saliva (in preparation)

A complete HIV testing solution

TESTING ALGORITHM



QUALITY CONTROL

Second HIV-test
Every 10th sample to ref.lab

Q.C. samples sent to sites

A complete testing solution for blood banks

■ Robust and Reliable

- **Efficient testing procedure**
 - less than 2 minute per test when a batch of 30 tests or more are tested.
- **Testing capacity**
 - In a normal a laboratory setting, up to 120 tests (per testing station per day) and easily be done
- **Reading of results**
 - Visual reading - gives highly reproducible results also under tropical conditions
 - OD reading can also be applied
- **One year shelf life**
 - No reduction after opening of kit

■ Available kits

- HIV-1&2
- HIV Confirmatory
- Syphilis (in evaluation)
- HCV
- HBsAg (in development)

Blood donor screening and VCT Service

