Syphilis Line

We always have a Solution that fits your particular Need
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500)

RPR (100 – 500)

TPHA OC 2000 for PK7200-PK7300 systems

Syphilis IgM EIA

Conclusion
Syphilis Worldwide Distribution

Global incidence

The total number of new syphilis cases in adults (ages: 15 – 49)

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.6 million</td>
<td>10.6 million</td>
<td></td>
</tr>
<tr>
<td>0.16% of the worldwide population (6 514 billion)</td>
<td>0.15 % of the worldwide population (6 750 billion)</td>
<td></td>
</tr>
</tbody>
</table>

Global Prevalence

- **36.4 million people living with Syphilis worldwide**
  - (35 million people living with HIV worldwide)
- **0.53 % of the Worldwide population (6 750 billion)**

Syphilis Worldwide Distribution

Prevalence: 36.4 Million adults infected with Syphilis in 2008

- Americas: 6.7 Million
- European Region: 0.3 Million
- Eastern Mediterranean Region: 1.6 Million
- South East Asia: 12.3 Million
- African Region: 14.3 Million
- Pacific Region: 1.2 Million

Causal Agent: Treponema pallidum

Syphilis is a chronic infectious disease caused by the bacteria spirochaete Treponema pallidum

- Spirochete
- Very thin, helicoïdal,
- Exclusive to Human beings
- Can live 24-48 hours in blood (4°C)
- Cannot be cultivated
Transmission

- Sexual contact with an infected person
- Blood Transfusion
- Congenital transmission (mother to child)
## Development

<table>
<thead>
<tr>
<th>Stage</th>
<th>Time</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incubation</td>
<td>2-3 weeks</td>
<td>Silent</td>
</tr>
<tr>
<td><strong>Early Syphilis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Syphilis</td>
<td>1 to 6 months</td>
<td>Ulcer (Chancre), buboes</td>
</tr>
<tr>
<td>Secondary Syphilis</td>
<td>3 months</td>
<td>Skin eruptions, Rash over all the parts of the body, Systemic manifestations</td>
</tr>
<tr>
<td>Early Latent Syphilis</td>
<td>3 to 12 months</td>
<td>Asymptomatic and not contagious</td>
</tr>
<tr>
<td><strong>Late Syphilis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late Latent Syphilis</td>
<td>3 to 12 months</td>
<td>Asymptomatic and not contagious</td>
</tr>
<tr>
<td>Tertiary Syphilis</td>
<td>1 to 4 years &amp; more</td>
<td>Cardiovascular &amp; neurological lesions, Blindness,</td>
</tr>
</tbody>
</table>
Diagnosis

Direct Diagnosis - Not widely used
- Direct microscopic examination (need skilled staff)
- PCR (very expensive method)

Indirect Diagnosis: Serological tests based on antibodies detection

- **Non Treponemal Antibodies** – Non Specific of syphilis because they use cardiolipin antigen.

  Cardiolipin is present in high volumes during destruction of tissues and cells or compromised immune system (Syphilis, Autoimmune disorders Systemic lupus (SLE), any fever inducing infection, drug addicts, Pregnancy …)

- **Treponemal Antibodies** - Specific of syphilis because they use *Treponemal Antigen*. 
Serology Tests Available

**Non-Treponemal Tests (NTT)**  
Detect non Treponemal Ab = Cardiolipin Ab

- **RPR**: Rapid Plasma Reagin*  
- **VDRL test**: Veneral Disease Research Laboratory

**Advantage**  
Early diagnostic marker, widely available, quantitative, treatment monitoring

**Disadvantages**  
Risk of false negative results (prozone effect) in undiluted samples  
Risk of false positive results due to non specific detection

**Treponemal Tests (TT)**  
Detect Total *Pallidum* Ab

- **TPHA**: *T pallidum* Hemagglutination Assay *  
- **Syphilis Total Ab*  
- **Syphilis IgM EIA* 

**Advantage**  
Very specific, sensitive, can be easily automated

**Disadvantages**  
Do not discriminate past/present infection so always used with RPR for proper diagnostic  
No treatment monitoring

* Bio-Rad Offer
Serological reactivity in syphilis patients

Source: Common patterns of serological reactivity in Syphilis patients
Diagnostic tools for preventing and managing maternal and congenital syphilis, Peeling R. et al, 2004
Penicillin, with good results (except for Neurosyphilis)

If established during chancre
  - Serology often remains negative

If established during the first stage, after chancre
  - Non-treponemal tests become negative within 6/8 months
  - Treponemal Test remain positive

If established during second stage
  - Non-treponemal tests become negative within 2/4 years (sometimes a serological scar)
  - Treponemal tests remain positive for years
Serological Syphilis Diagnosis Algorithm

Three examples of Syphilis algorithm according to the country, prevalence and needs:

- **USA**: Trend from traditional Algorithm (RPR as first test) to reverse screening Algorithm (EIA or CIA as first test)

- **France**: Diagnostic Model with both Treponemal and Non Treponemal Tests as first line test

- **WHO recommendations for blood screening algorithm**: One test only (Treponemal test in low prevalence countries or non-Treponemal test in high prevalence countries)

☞ Each country has its own syphilis decisional algorithm
Syphilis Serologic screening algorithm : USA - MMWR Feb 2011

Traditional Syphilis Screening
(Low volume activity)

Reverse Syphilis Screening
(Large volume activity)

First-line Test

EIA or CIA

EIA/CIA +

EIA/CIA -

Quantitative RPR

RPR +

RPR -

TPHA or other trep. test

TPHA +

TPHA - Syphilis (past or present)

TPHA -

Syphilis unlikely

Quantitative RPR

RPR +

RPR -

TPHA or other trep. test

TPHA +

TPHA - Syphilis (past or present)

TPHA -

Syphilis unlikely

EIA/CIA +

EIA/CIA -

Traditional Syphilis Screening (Low volume activity)

Reverse Syphilis Screening (Large volume activity)

1st Confirmation

2nd Confirmation

Syphilis unlikely

Syphilis (past or present)
Difference between traditional and reverse algorithms

**Traditional algorithm**
- NTT is used as first test
- The number of confirmation and retest is lower than the reverse algorithm because a non-Treponemal tests can differentiate between recently infected and treated.

**Reverse algorithm**
- TT is used as a first line test
- TT gives an advantage in term of automation. Syphilis Total Ab is suitable to be used as first line test
- Two confirmatory steps are needed. However treatment is given at the first steps

- **Both algorithms are used in Diagnostic labs but pricing or automatisation can drive the choice from one algorithm to another**
France: Decision syphilis algorithm for patients

From HAS Report

**First Line test:**
**TT and NTT Together**

- **TT + / NTT +**
  - *A risk case*
  - Serology +
  - **2nd TT**
    - +
      - Serology +
      - WB IgG
    - -
      - Serology +
      - Serology -

- **TT + / NTT -**
  - 2nd TT
  - +
    - Serology +
    - WB IgG
  - -
    - Serology +
    - Serology -

- **TT - / NTT +**
  - IgM and/or Subsequent serological control***

**TT:** Treponemal tests (TPHA, TPPA, FTA-ABS) and Elisa (IgG or IgG/IgM)

**NTT:** Non treponemal tests (VDRL, RPR)

**WB:** Western-blot

Remark: all tests were carried out on sera except for the case « subsequent serological control »

* No titration from TT if screening with Elisa

** Elisa if screening with TT, TT if screening with Elisa

*** If primary Syphilis infection is suspected (option)
WHO: Syphilis algorithm for Blood screening

First-line Test
One test ONLY

Perform initial screening test (A)

Non reactive (A-)
Release donation and derived blood components

Initial reactive (A+)

Option 1
(No/limited quality system)
Discard donation and derived blood components

Option 2
(Effective quality system)
Repeat test in duplicate using same sample and same assay

Reactive in one or both repeat tests (A+, A+, A+) or (A+, A+, A+)
Discard donation and derived blood components
Send for confirmatory testing

Negative in both repeat tests (A+, A-, A-)
Release donation and derived blood components

A = Assay
A+ = Reactive result in A
A- = Non-reactive result in A

World Health Organization 2009 recommendation
Take - Home Messages : Algorithms

- Each country has its own syphilis decisional algorithm generating multiple syphilis testing procedures

- Two major trends :
  - Move from Non Treponemal Test algorithm (Manual RPR) to Treponemal Test (TPHA, EIA, CIA)
  - EIA replace TPHA for automation benefit

- Bio-Rad has a complete syphilis menu with excellent products that fit all the algorithms.
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Syphilis IgM EIA

Conclusion
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• Objective of the release
• Product Description
• Performance
• System Integration
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• Competitors and Key selling Arguments
• Selling Strategy
  • Positioning
  • Targeted customers
  • Complete Syphilis Menu
  • Selling Tools
Objective of the release

- To protect our main business with Lab21/Trinity products by a vertical integration of Syphilis Total Ab from raw material to release

- To be flexible for any upcoming large opportunity for Syphilis Total Ab, part of our screening offer in blood bank
Syphilis Total Ab

One product with 4 catalog numbers will be impacted

Manufactured by Lab21/ Trinity and distributed by Bio-Rad

Syphilis Total Ab EIA II
# 72518 – 1 plate
# 72518SP – 1 plate
# 72519 – 5 plates
# 72519SP – 5 plates

Manufactured by Bio-Rad

Syphilis Total Ab
# 72530 – 1 plate
# 72531 – 5 plates
Syphilis Total Ab

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Product Description

<table>
<thead>
<tr>
<th><strong>Commercial Name</strong></th>
<th>Syphilis Total Ab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Part Number</strong></td>
<td>72530 / 72531</td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td>96 Tests / 480 Tests</td>
</tr>
</tbody>
</table>

**Intended Use**

These kits are intended to be used for the **qualitative detection** of antibodies to *Treponema pallidum* in **human serum** and **plasma**.

The product may be used for the screening of **blood donors**, and to **assist** in the **diagnosis** of patients where syphilis infection is suspected.
Kit Picture
Common features with Bio-Rad assays

- Colored and barcoded reagents
- Same generic reagents (*Wash, TMB and Stop*)
- Microplate and Strip identification
  - Syphilis Total Ab : Specific ID Number = 97
- Sample and reagent monitoring

-effects Enhanced security features
Protocol: Syphilis Total Ab 72530-72531

- Plate coated with *T. pallidum* recombinant Antigens (rAg)
- Dispense **50 µl** of ready-to-use controls (Negative and Positive controls), undiluted sample into the appropriate well
- Dispense **50 µl** of Conjugate in each well
- Incubate for 30 to 35 minutes at 37°C

**WASH**

- Dispense **50 µl** of Development Solution (R8+R9) into each well
- Incubate for **25 to 35 minutes at room temperature in the dark**
- Dispense **50 µl** of stopping solution

Read at dual wavelength 405/620-690 nm

* For positive control and positive samples
Interpretation of the results

Cut-off = Mean Negative Control (R3) + 0,100

<table>
<thead>
<tr>
<th>Sample Ratio</th>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD sample &lt; Cut-off</td>
<td>Negative</td>
<td>Samples considered negative by Syphilis Total Ab</td>
</tr>
<tr>
<td>OD sample ≥ Cut-off</td>
<td>Positive</td>
<td>Samples considered positive by Syphilis Total Ab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive samples should be re-tested in duplicate before final interpretation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Re-tested samples that are above the COV in at least one duplicate are considered positive and should be investigated further.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is recommended to confirm positive samples following the current national recommendations and algorithms</td>
</tr>
</tbody>
</table>
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## Performance

### Specificity

<table>
<thead>
<tr>
<th>Population</th>
<th>Sample Type</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Donors from 2 French blood banks</td>
<td>Serum SST</td>
<td>3125 / 3125 (100%)</td>
</tr>
<tr>
<td></td>
<td>Plasma EDTA K2</td>
<td>2066 / 2066 (100%)</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>5191 / 5191 (100%)</strong></td>
</tr>
<tr>
<td></td>
<td>[95 % CI : 99.93% - 100.00%]</td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td>Serum</td>
<td><strong>350 / 351 (99.72%)</strong></td>
</tr>
<tr>
<td></td>
<td>[95 % CI : 98.42% - 100.00%]</td>
<td></td>
</tr>
</tbody>
</table>

 Excellent specificity: High rate of release for donations and derived blood components → **Reduce the cost associated to a False Positive result**
### Performance: Analytical Specificity

<table>
<thead>
<tr>
<th>Samples</th>
<th>Analytical Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>124 from potentially interfering samples, patients at risk group or</td>
<td>No cross reaction - 100%</td>
</tr>
<tr>
<td>patients with immune system disorders</td>
<td></td>
</tr>
</tbody>
</table>

**Excellent Analytical Specificity:** No cross reaction with other infectious pathogen and other immune system disorders

→ **Reduce unnecessary treatment**
### Performance: Sensitivity

<table>
<thead>
<tr>
<th>Study</th>
<th>Sensitivity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retrospective Study including patients from early stage of the infection</strong></td>
<td>348/348 (100%) [95 % CI : 98.95% - 100.0%]</td>
</tr>
<tr>
<td><strong>Prospective Study including patients and samples from anonymous center</strong></td>
<td>109* /111 (98.20%) [95 % CI :93.64% - 99.78%]</td>
</tr>
<tr>
<td><strong>Both Studies</strong></td>
<td>457/459 (99.56%) [95 % CI : 98.44% - 99.95%]</td>
</tr>
</tbody>
</table>

* Discrepant results with the reference assays during the prospective study:
  1 sample positive with the reference test, negative with Bio-Rad assay. The patient was asymptomatic.
  1 sample positive with the reference test, Initial negative with Bio-Rad and positive in retest with Bio-Rad assay.

—from *Excellent sensitivity: Reliable information about potential risk of infection or history of disease—*
The analytical sensitivity has been evaluated on 2 NIBSC Standards, and calculated at the cut-off value using a regression.

<table>
<thead>
<tr>
<th>NIBSC Standards</th>
<th>Analytical Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Standard IgM/ IgG</td>
<td>Limit of detection for IgG / IgM : 0.53 mIU/ml with CI 95%</td>
</tr>
<tr>
<td>(NIBSC code: 05/132)</td>
<td>[0.10 mIU/ml – 1.30 mIU/ml] on 3 lots</td>
</tr>
<tr>
<td>WHO Standard IgG</td>
<td>Limit of detection for IgG : 0.11 mIU/ml with CI 95%</td>
</tr>
<tr>
<td>(NIBSC code: 05/122)</td>
<td>[0.02 mIU/ml – 0.27 mIU/ml] on one lot</td>
</tr>
</tbody>
</table>

- Excellent analytical sensitivity:
  - Earlier patient treatment
  - Earlier identification of seroconversion and reliable donation screening
### Internal study: Comparison with Lab21

<table>
<thead>
<tr>
<th>Study</th>
<th>Samples</th>
<th>Lab21</th>
<th>Bio-Rad</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td>34 positive diluted samples</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>50 negative hospitalised patients</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Commercial panels</strong></td>
<td>3 panels (22 samples)</td>
<td>100% of correlation</td>
<td>100% of correlation</td>
</tr>
<tr>
<td><strong>Analytical sensitivity</strong></td>
<td>NIBSC panels</td>
<td>1.6 mIU/ml</td>
<td>0.53 mIU/ml</td>
</tr>
</tbody>
</table>

- Equivalent results for specificity and sensitivity
- Bio-Rad shows better analytical sensitivity results
Syphilis Total Ab

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### System integration

<table>
<thead>
<tr>
<th>Instrument</th>
<th>CD or USB key to order</th>
<th>REF / LOT</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVOLIS</td>
<td>CD EVOLIS Software Version 2.0 APF Version 19</td>
<td>93489 / V2.0-19-1-L2</td>
<td>Week 47 (1)</td>
</tr>
<tr>
<td>PW 40-41 Microplate Washer</td>
<td>CD PW 40-41 APF Manuals V8</td>
<td>88329 / V8-1411-1-L11</td>
<td>Week 47</td>
</tr>
<tr>
<td>PR 4100 Microplate Reader</td>
<td>USB key PR 4100 Software Version 7.0 APF Version 10</td>
<td>94195 / V7.10-14-11-1-L6</td>
<td>Week 47</td>
</tr>
<tr>
<td>PR 3100 TSC Microplate Reader</td>
<td>USB key PR 3100 TSC Software Version 5.2 APF Version 10</td>
<td>93169 / V10-1411-1-L12</td>
<td>Week 48</td>
</tr>
</tbody>
</table>

(1): English and French versions only. Other language versions will be available in the following weeks. In case of upcoming orders, please contact **Michel Gunzburger**

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**EVOLIS™ Premium**

**EVOLIS™ Twin Plus**

**Washer, Reader, Incubator**
APFs Statement

The goal of the CE-IVD validation process is to guarantee our customers that a Bio-Rad assay exhibits the same level of performances on EVOLIS than the performances claimed in the corresponding assay package insert.

Bio-Rad guarantees the CE-IVD validation for:

- **Reagent**
- **Instrument**
- **Reagent used on Instrument** *(Assay Protocol Files or APFs)*

⇒ highest level of Guarantee for Result Safety, in the same way as a Closed System

EN ISO 9001:2000
EN ISO 13485

CE IVD
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<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
<th>Proofs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent specificity</td>
<td>High rate of release for donations and derived blood components → <strong>Reduce the cost associated to a False Positive result</strong></td>
<td>100% for Blood donors 99.72% for patients *</td>
</tr>
<tr>
<td>High analytical specificity</td>
<td>No cross - reactivity with other infectious pathogens and other immune disease disorders → <strong>Reduce unnecessary treatment</strong></td>
<td>100% on 124 interfering samples*</td>
</tr>
<tr>
<td>High analytical sensitivity</td>
<td>Improved diagnosis in the early stages of syphilis → <strong>Earlier patient treatment</strong> → <strong>Earlier identification of seroconversion and reliable donation screening</strong></td>
<td>0.53mIU/ml on WHO Standard IgM/IgG*</td>
</tr>
<tr>
<td>Detection of all stages of the infection</td>
<td>Detection of early and late syphilis → <strong>Information about potential risk of infection or a history of disease</strong></td>
<td>100% on 348 samples including 7 early stage samples *</td>
</tr>
<tr>
<td>Automated process</td>
<td>Better productivity, reliable results, reduction of costs, easier to use</td>
<td>CE marked APF</td>
</tr>
<tr>
<td>Complete Syphilis menu and EIA menu</td>
<td>Biologist has in hand all tools to select the right syphilis test (screening / confirmatory) as well as a complete EIA menu to give the correct status of the patient or the donor</td>
<td>Bio-Rad Catalog</td>
</tr>
</tbody>
</table>

* Data extracted from IFU
Syphilis Total Ab

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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial Name</strong></td>
<td>Bio-Rad Syphilis Total Ab</td>
<td>Lab21 Syphilis Total Ab</td>
<td>BioElisa Syphilis 3.0</td>
<td>Murex ICE Syphilis</td>
<td>Treponema pallidum Screen ELISA</td>
<td>EIA Treponema pallidum Total</td>
<td>Trep-Sure EIA</td>
<td>SD Syphilis ELISA 3.0</td>
<td>PATHOZYME Syphilis</td>
</tr>
<tr>
<td><strong>Format</strong></td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
<td>ELISA Qualitative Test Total Ab</td>
</tr>
<tr>
<td><strong>Sample volume</strong></td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
<td>100 µl</td>
<td>50 µl</td>
<td>100 µl</td>
<td>NAD</td>
<td>25 µl</td>
</tr>
<tr>
<td><strong>Specimen</strong></td>
<td>Serum Plasma (EDTA, sodium citrate, or heparin, ACD)</td>
<td>Serum Plasma</td>
<td>Serum Plasma</td>
<td>Serum Plasma</td>
<td>Serum Plasma</td>
<td>Serum Plasma</td>
<td>Serum Plasma (EDTA, sodium citrate)</td>
<td>Serum Plasma</td>
<td>Serum Plasma</td>
</tr>
<tr>
<td><strong>Sample dilution</strong></td>
<td>No</td>
<td>No</td>
<td>1:2</td>
<td>NAD</td>
<td>1:100</td>
<td>No</td>
<td>NAD</td>
<td>NAD</td>
<td>No</td>
</tr>
<tr>
<td><strong>Incubation Steps</strong></td>
<td>2 steps (60 min)</td>
<td>2 steps (60 min)</td>
<td>3 steps (120 min)</td>
<td>3 steps (120 min)</td>
<td>3 steps (90 min)</td>
<td>2 steps (60 min)</td>
<td>3 steps (90 min)</td>
<td>NAD</td>
<td>2 steps (105 min)</td>
</tr>
<tr>
<td><strong>% Sensitivity</strong></td>
<td>Retrospective study: 100%</td>
<td>Prospective study: 98.2%</td>
<td>99.4</td>
<td>100</td>
<td>&gt; 99.9</td>
<td>99.9</td>
<td>100</td>
<td>99.3</td>
<td>100</td>
</tr>
<tr>
<td><strong>% Specificity</strong></td>
<td>99.98</td>
<td>99.95</td>
<td>95.9</td>
<td>97.8</td>
<td>99.8</td>
<td>99.8</td>
<td>99.5</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

NAD: Not Available Data
## ELISA Competition analysis - Protocol

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis Total Ab</td>
<td>Syphilis Total Ab EIA</td>
<td>BioElisa Syphilis 3.0</td>
<td>Murex ICE Syphilis</td>
<td>Treponema pallidum Screen ELISA</td>
<td>EIA Treponema pallidum Total</td>
<td>Trep-Sure EIA</td>
<td>SD Syphilis ELISA 3.0</td>
<td>PATHOZYME Syphilis</td>
</tr>
</tbody>
</table>

### Main Advantage

<table>
<thead>
<tr>
<th>Analytical sensitivity</th>
<th>Sensitivity</th>
<th>Praticability</th>
<th>Sample volume and Praticability</th>
<th>Specificity</th>
<th>Sample volume and Praticability</th>
<th>Sensitivity</th>
<th>Sample Type and Incubation time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(Bio-Rad, 2 step assay - 60 min vs Biokit 3 steps assay -120 min)</td>
<td>(50 µl Bio-Rad vs 100 µl+ dilution 1:1000 ) (Bio-Rad, 2 step assay+ 60 min vs Sekisui 3 steps assay + 90 min)</td>
<td>(Bio-Rad 100% vs Test Line 97,8%)</td>
<td>(50 µl Bio-Rad vs 100 µl) (Bio-Rad, 2 step assay - 60 min vs Trinity 3 steps assay-105 min)</td>
<td>Bio-Rad 100 % vs SD 99,3%</td>
<td>(Bio-Rad 60 min vs 105mn)</td>
</tr>
</tbody>
</table>

NAD: Not Available Data
## Selling points *versus* competition: Focus on Lab21 and Biokit

<table>
<thead>
<tr>
<th>Differentiating Feature and Customer Benefit</th>
<th>Bio-Rad</th>
<th>Lab21/Trinity</th>
<th>Biokit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent specificity</td>
<td>100% for Blood donors 99.72% for patients *</td>
<td>99.9 % (2821/2824) (95%CI: 99.69-99.98)</td>
<td>99.8% for blood donors 100% for patients</td>
</tr>
<tr>
<td>→ Reduce the cost associated to a False Positive result</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High analytical sensitivity</td>
<td>0.53mIU/ml on WHO Standard IgM/IgG*</td>
<td>1.6mIU/ml on WHO Standard</td>
<td>30mIU/ml on WHO Standard</td>
</tr>
<tr>
<td>→ Earlier patient treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>→ Earlier identification of seroconversion and reliable donation screening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detection of all stages of the infection</td>
<td>100% on 348 samples including 7 early stage samples *</td>
<td>100% on 310 samples including 25 early stage samples</td>
<td>99.4% on 159 samples including samples of different stages of syphilis</td>
</tr>
<tr>
<td>→ Information about potential risk of infection or a history of disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Praticability</td>
<td>2 steps (60 min)</td>
<td>2 steps (60 min)</td>
<td>3 steps (120 min)</td>
</tr>
<tr>
<td>→ Better integration in laboratory routine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated process</td>
<td>With validated protocol</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>→ Confidence in results and in compliance with quality system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete Syphilis menu and Infectious Disease menu</td>
<td>Treponemal and non-Treponemal tests available + more than 60 EIA products</td>
<td>Complete Syphilis Menu only</td>
<td>Limited EIA menu</td>
</tr>
<tr>
<td>→ One qualified supplier for all infectious disease menu</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Agenda

- Objective of the release
- Product Description
- Performance
- System Integration
- Features and Benefit
- Competitors and Key selling Arguments

Selling Strategy
- Positioning
- Targeted customers
- Complete Syphilis Menu
- Selling Tools
Bio-Rad released a new home-made product:

**Syphilis Total Ab**

**The right test for the first line screening**

Syphilis Total Ab is part of a complete **Syphilis menu** that fits all lab activities and needs in perfect accordance with the national algorithms.

**Comprehensive offer to meet your Syphilis Testing Needs**
Agenda

- Objective of the release
- Product Description
- Performance
- System Integration
- Features and Benefit
- Competitors and Key selling Arguments
- Selling Strategy
  - Positioning
  - Targeted customers
  - Complete Syphilis Menu
  - Selling Tools
Priority 1: Our Lab21 customers

A switch is required by July 2015 the latest because Lab21 kits will not be anymore available at this date.

Features and Benefit:

- “Made by Bio-Rad” with the associated guarantee of quality and supply.
- Performance Improvement (analytical sensitivity) compared to Lab21 to ensure the accurate result.
- Standardized process as all our universal screening for Blood Banks (HIV, HBV and HCV): same generic reagents, microplate identification for a highest level of security and flexibility.
Our top 1 is to convert our current Lab21 customers.

Moreover, thanks to the high quality of the products, other customers will be interested.
Syphilis Total Ab: Targeted customers

Priority 2: Our Automated EIA customers
All Evolis/ Elite and ULTRA line customers that don’t use Syphilis Total Ab from Bio-Rad

Features and Benefit:

- Syphilis Total Ab is fully automated and validated on Evolis Family
- Better level of specificity without decreasing the sensitivity giving to the customer reliable result together with a high productivity.
- “Made by Bio-Rad” with the associated guarantee of quality and supply.
Syphilis Total Ab: Targeted customers

Priority 3: Large RPR customers

Features and Benefit:

- Offer the Syphilis Total Ab + Evolis Family as the most convenient offer to switch from traditional algorithm to the reverse algorithm
- High quality of performance that leading to a low rate of discordant results between the both algorithms
- Productivity improvement: traceability and high throughput.
Syphilis Total Ab : Targeted customers

Priority 4 : Manual TPHA customers + Algorithm with TT as first line screening

Features and Benefit :

- Offer the Syphilis Total Ab + Evolis Family as the most convenient offer as a first line screening
- High quality of performance
- Productivity improvement: Objective interpretation, traceability and high throughput.
Syphilis Total Ab

Agenda

• Objective of the release
• Product Description
• Performance
• System Integration
• Features and Benefit
• Competitors and Key selling Arguments
• Selling Strategy
  • Positioning
  • Targeted customers
  • Complete Syphilis Menu
  • Selling Tools
Complete Menu for all lab activities

Laboratory activity size

Automatisation level

- RPR
- TPHA
- Syphilis Total Ab / Evolis Family
- TPHA OC 2000
- PK7300
- Syphilis Total Ab / Elite
Agenda

• Objective of the release
• Product Description
• Performance
• System Integration
• Features and Benefit
• Competitors and Key selling Arguments
• Selling Strategy
  • Positioning
  • Targeted customers
  • Complete Syphilis Menu
  • Selling Tools
Selling tools

- Technical worksheets for Syphilis Total Ab
- Product flyer: Complete Syphilis Offer (ongoing)
- Product presentation

Technical worksheet
Syphilis Total Ab shows:

- **Highest security features** thanks to Bio-Rad manufacturing tool: Microplate frame and strip identification which is mandatory for blood bank.

- **Better performance level** thanks to the raw material developed in house.

- **Easy integration in lab’s routine** (Same protocol as Lab21 product, same sample volume, same turn around time) → **No need of specific training**

- **Full control on all manufacturing process**

Syphilis Total Ab is the only test to **show statistically significant improvement in analytical sensitivity compared to the other products.** This allow an earlier patient treatment and an earlier identification of seroconversion for a reliable donation screening.
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500)

RPR (100 – 500)

TPHA OC 2000 for PK7200-PK7300 systems

Syphilis IgM EIA

Conclusion
TPHA 200 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure
• Selling Strategy
  • Positioning
  • Targeted customers
Following the acquisition of our syphilis supplier Lab21 by Trinity and the upcoming new registration process (new brand name and new manufacturing sites), Bio-Rad decided to release new syphilis products besides continuing with Trinity on products with low revenue and lower number of customers.

- **TPHA OC 2000 Syphilis IgM + Malaria EIA Ab CMV Total Ab**
  - Manufactured by Trinity and distributed by Bio-Rad

- **Syphilis Total Ab TPHA 200-500 RPR 100-200**
  - Manufactured by Bio-Rad

**Registration:**
- Trinity documents are now available
- Documents are available for all new Bio-Rad Syphilis Products
The switch of our Lab 21–Trinity customers is required by end of October 2015 the latest.

We will not receive new lots from Trinity –lab 21 and already have constituted a safety stock to allow the registration of the Bio-Rad kits outside Europe.
TPHA 200 - 500 tests

Agenda

- Objective of the release and Switch Timing
- Product Description
- Performance
- Using Procedure
- Selling Strategy
  - Positioning
  - Targeted customers
Two new products with 2 pack size designed to replace the Trinity /Lab21 kits

Manufactured by Lab21/ Trinity and distributed by Bio-Rad
- TPHA 200 (72501)
- TPHA 500 (72502)

Manufactured by Bio-Rad
- TPHA
  - # 72503 – 200 tests
  - # 72504 – 500 tests
TPHA 200 and TPHA 500

Comparison with Trinity Kits

• Same intended use, with a specific claim for the use for screening of blood donors and to aid in the diagnosis of patients where syphilis infection is suspected

• Same content

• Same using procedure

• Same positioning

To Facilitate The Switch
Kit Content

Same content as Trinity/Lab21

(components, volume, number of vials with exception of controls

with increased volume 1 ml instead of 0.5 ml)
## TPHA 200, TPHA 500
### Kit Content

<table>
<thead>
<tr>
<th>Identification on label</th>
<th>Description</th>
<th>Presentation 72503 200 tests</th>
<th>Presentation 72504 500 tests</th>
</tr>
</thead>
</table>
| R1 Test Cells           | Test Cells  
Suspension of Avian erythrocytes coated with antigens of *T. pallidum*, containing Bovine Serum Albumin (BSA) | 2 vials 7.8 ml                | 2 vials 20 ml                |
| R2 Control Cells        | Control Cells  
Suspension of Avian erythrocytes, containing BSA                          | 2 vials 7.8 ml                | 1 vial 20 ml                 |
| R3 Diluent              | Diluent  
Saline solution containing Rabbit serum                                    | 2 vials 20 ml                 | 1 vial 125 ml                |
| R4 Positive Control     | Positive Control  
Human serum containing antibodies to *T. pallidum*, negative for HBs Antigen, anti-HIV1/2, and anti-HCV antibodies diluted in phosphate buffer | 1 vial 1 ml                   | 1 vial 1 ml                  |
| R5 Negative Control     | Negative Control  
Rabbit serum in phosphate buffer                                               | 1 vial 1 ml                   | 1 vial 1 ml                  |

*Similar to Trinity / Lab 21 kits (ref 72501, 72502)  
With slight differences (refer to PI)*
TPHA 200 - 500 tests

Agenda

- Objective of the release and Switch Timing
- Product Description
- Performance
- Using Procedure
- Selling Strategy
  - Positioning
  - Targeted customers
TPHA 200 and TPHA 500: Performance

Specificity

- Blood donors: 99.72% (99.53% - 99.85%) CI 95%
- Frozen samples from patients: 99.5% (97.3% - 100%) CI 95%

Sensitivity

- Analytical sensitivity limit at 0.05 IU/ml
- Clinical sensitivity: 100% (99.2% - 100%) CI 95%
TPHA 200 - 500 tests

Agenda

- Objective of the release and Switch Timing
- Product Description
- Performance
- Using Procedure
- Selling Strategy
  - Positioning
  - Targeted customers
TPHA 200, 500
Same Using Procedures

Bio-Rad TPHA (qualitative)

Three wells from the U microplate are needed for each specimen.
The TPHA 500 Kit (Product No. 72504) is intended for screening large numbers of specimens and contains only a small volume of Control Cells. It is intended that specimens are screened using only Test Cells in the first instance, and the Control Cells should be used when repeating tests on specimens giving a positive result when first tested.

a. Specimen and Controls Dilution (to 1 in 20)
Add 190 µl of the diluent (R3) to one well.
Add 10 µl of specimen or Positive Control (R4) or Negative Control (R5) to the same well.
Mix thoroughly.

b. Test
Transfer 25 µl of diluted control or diluted specimen from dilution step to test well.
Transfer 25 µl of diluted control or diluted specimen dilution step to control well.
Re-suspend the Test Cells (R1) and the Control Cells (R2) by shaking the vial. Examine for complete suspension.
Add 75 µl of Test Cells (R1) to test well and 75 µl of Control Cells (R2) to the control well.
Final specimen dilution is 1:80.
Mix wells thoroughly.
Incubate at room temperature (15-30 °C) on a vibration-free surface for a minimum of 45 minutes.
Read the settling patterns. Agglutination patterns are stable for at least three hours if undisturbed.

Trinity / Lab 21 TPHA (Qualitative)

Three wells are needed for each specimen.

NB: The TPHA 500 Kit (Product No. 72502) is intended for screening large numbers of specimens and contains only a small volume of Control Cells. It is intended that specimens are screened using only Test Cells in the first instance, and the Control Cells be used when repeating tests on specimens giving a positive result when first tested.

1. Specimen Dilution (to 1 in 20)
Add 190 µl of the diluent to one well.
Add 10 µl of specimen to the same well.
Mix thoroughly.
Note: Positive and negative controls provided must be treated as specimens; (i.e. diluted 1 in 20).

2. Test
Add 25 µl of diluted specimen from step 1 to test well.
Add 25 µl of diluted specimen from step 1 to control well.
Resuspend the Test and Control Cell suspensions by shaking the vial. Examine for complete resuspension.
Add 75 µl of Test Cells to test well, and 75 µl of Control Cells to the control well (Final specimen dilution after addition of cells is 1 in 80).
Mix thoroughly.
Incubate at room temperature (15-30 °C) on a vibration-free surface for a minimum of 45 minutes.
Read the settling patterns. Agglutination patterns are stable for at least three hours if undisturbed.
TPHA 200, 500
Same Using Procedures

Bio-Rad TPHA (quantitative)

9 wells of the U microplate are needed for each specimen:
One well for the specimen or control dilution and 8 wells for
the titration.
Note: The Positive and Negative Controls (R4 and R5) must
be run with each lot of tests, using the procedure given
below.

a. Specimen and Controls Dilution (to 1 in 20)
Add 190 µl of the diluent (R3) to one well.
Add 10 µl of specimen or Negative Control (R5) or Positive
Control (R4) to the same well. Mix thoroughly.
See dilution table in Pack Insert

b. Titration
Leaving the first well empty, add 25 µl of diluent (R3) to each
of the remaining 7 wells.
Transfer 25 µl of diluted control or specimen to the 1st well
and to the 2nd well, then mix.
Then serially dilute along the well sequence, discarding the
excess 25 µl from the final well.
See serial dilution table in Pack Insert

c. Test
Gently mix the Test Cells (R1) to ensure thorough
resuspension.
Add 75 µl of Test Cells (R1) to each well. Final specimen
dilution range after addition of cells is 1: 80 – 1 :10240.
Mix thoroughly
See table in Pack-Insert
Incubate at room temperature (15-30 ° C) on a vibration-free
surface for a minimum of 45 minutes.
Read the settling patterns. Agglutination patterns are stable
for at least three hours if undisturbed.
The titre of the specimen is the reciprocal of the highest
dilution giving agglutination.

Trinity / Lab 21TPHA(Qualitative)

9 wells are needed for each specimen.

Note: The kit positive and negative controls must be run with
each lot of tests, using the quantitative procedure given below.

1. Specimen Dilution (to 1 in 20)
Add 190 µl of the diluent to a well.
Add 10 µl of specimen to the same well.
Ensure thorough mixing.
Note: Positive and negative controls provided must be treated as
specimens (i.e. diluted 1 in 20).

2. Titration
Leaving the 1st well empty, add 25 µl of diluent to each of the
remaining 7 wells in a row of 8 wells.
Add 25 µl from step 1 to the 1st well.
Add 25 µl from step 1 to the 2nd well and mix, then serially dilute
along the well sequence, discarding the excess 25 µl from the
final well.

3. Test
Gently mix the Test Cells to ensure thorough resuspension.
Add 75 µl of Test Cells to each well. (Final specimen dilution
range after addition of cells is 1 in 80 – 1 in 10,240).
Mix thoroughly
Incubate at room temperature (15-30 ° C) on a vibration-free
surface for a minimum of 45 minutes.
Read the settling patterns. Agglutination patterns are stable for
at least three hours if undisturbed.
The titre of the specimen is the reciprocal of the highest dilution
giving agglutination.

+ dilution tables in the Bio-Rad TPHA PI
TPHA 200 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure
• Selling Strategy
  • Positioning
  • Targeted customers
TPHA kits
are easy to use products
designed for
any countries (developed or low incomes)
and any laboratories
to be used as a first line testing
as well as confirmatory tests

They are part of a complete Syphilis menu
that fits all lab activities and needs
in perfect accordance with the national algorithms

Comprehensive offer
to meet your Syphilis Testing Needs
Priority 1: Our Trinity-Lab21 customers

A switch is required by end of October 2015 the latest because Lab 21 kits are no more available (we currently have a safety stock to manage the switch in regards to registration timing.

Priority 2: Our Syphilis Total Ab customers

Complete the testing algorithm with RPR or TPHA.

Priority 3: All TPHA our RPR users

Features and Benefit:

- Products “Made by Bio-Rad” with the associated guarantee of quality and supply.
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500)

RPR (100 – 500)

TPHA OC 2000 for PK7200-PK7300 systems

Syphilis IgM EIA

Conclusion
RPR 100 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure
• Selling Strategy
  • Positioning
  • Targeted customers
Following the acquisition of our syphilis supplier Lab21 by Trinity and the upcoming **new registration process** (new brand name and new manufacturing sites), Bio-Rad decided to release new syphilis products besides continuing with Trinity on products with low revenue and lower number of customers.

**TPHA OC 2000 Syphilis IgM + Malaria EIA Ab CMV Total Ab**

Manufactured by Trinity and distributed by Bio-Rad

**Syphilis Total Ab TPHA 200- 500 RPR 100- 200**

Manufactured by Bio-Rad

**Registration**

Trinity documents are now available

**Registration**

Documents are available for all new Bio-Rad Syphilis Products
The **switch** of our Lab 21–Trinity customers is required by end of October 2015 the latest.

We will not receive new lots from Trinity –lab 21 and already have constituted a safety stock to allow the registration of the Bio-Rad kits outside Europe.
RPR 100 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure
• Selling Strategy
  • Positioning
  • Targeted customers
Two new products with 2 pack size designed to replace the Trinity /Lab21 kits

Manufactured by Lab21/ Trinity and distributed by Bio-Rad

RPR 100 (72501)
RPR 500 (72506)

Manufactured by Bio-Rad

RPR
# 72515 – 100 tests
# 72516 – 500 tests
Same intended use

Same content as the previous codes
(components, volume of reagents, number of vials)
to facilitate the switch

To Facilitate The Switch
RPR 100 - 500 tests

Agenda

- Objective of the release and Switch Timing
- Product Description
- Performance
- Using Procedure
- Selling Strategy
  - Positioning
  - Targeted customers
RPR 100 and RPR 500
Comparaison With Trinity Kits

- 100% Specificity (96.4% - 100%) CI 95%
- 100% Sensitivity (96.4% - 100%) CI 95%
- Same positioning with better quality

To Facilitate The Switch
RPR 100 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure
• Selling Strategy
  • Positioning
  • Targeted customers
Bio-Rad RPR (qualitative)

The kit positive (R2) and negative (R3) controls must be run with each run of tests.

1. Place 50 µL of specimen or control into a circle on the test card.
2. Spread the specimen and controls evenly over the test circle area.
3. Shake the vial of RPR antigen to ensure thorough mixing, just before use to avoid sedimentation.
4. Attach the dropping needle to the dropping bottle and take up the RPR antigen by suction.
5. Invert the dropper and gently squeeze to expel air from the needle.
6. Holding the dropping bottle vertically over the test specimen, dispense a single drop of RPR antigen.
7. Place test card on a card rotator and rotate at 100 rpm for 8 minutes.
8. Read immediately and interpret results visually in good light. (Refer to 7.4)

Note: If it is not possible to read immediately, card must be maintained on the card rotator up to 15 minutes.
9. Return unused antigen from dropper bottle to glass vial.
10. Clean out dropping bottle and needle with distilled water and allow drying before reusing.

Trinity / Lab 21 RPR (Qualitative)

The kit positive and negative controls must be run with each run of tests.

1. Place 50 µL of specimen or control into a circle on the test card.
2. Spread the specimen evenly over the test circle area.
3. Shake the vial of RPR antigen to ensure thorough mixing.
4. Attach the dropping needle to the plastic dropping bottle and take up the RPR antigen by suction.
5. Invert the dropping bottle and gently squeeze to expel air from the needle.
6. Holding the dropping bottle vertically over the test specimen, dispense a single drop of antigen.
7. Place test card on a card rotator and rotate at 100 rpm for 8 minutes.
8. Read and interpret results visually in good light. (See "Interpretation.")
9. Return unused antigen from dropper bottle to glass vial.
10. Clean out dropper bottle and needle with distilled water and allow to dry before reusing.

More precised informations
in the Bio-Rad RPR Pack-Insert
Bio-Rad RPR (quantitative)

1. Make doubling dilutions from undiluted to 1:16 in 0.9% saline solution.
2. Place 50 µL of each dilution and controls in to a separate circle on the test card.
3. Spread each dilution evenly over the test circle.
4. Continue as from Qualitative Test section 3.

The titre of the specimen is expressed as the reciprocal of the highest dilution showing agglutination of the carbon particles.
If the highest dilution tested (1:16) is reactive, proceed with a further dilution series by preparing doubling dilutions of the sample from 1:32 to 1:512 using 0.9% saline solution.
Mix well and continue as from step 2 in the semi-quantitative test.

Trinity / Lab 21 RPR (Qualitative)

1. Make doubling dilutions from undiluted to 1:16 in normal saline.
2. Place 50 µL of each dilution in to a separate circle on the test card.
3. Spread each dilution evenly over the test circle.
4. Continue as from Qualitative Test section 3.

The titre of the specimen is expressed as the reciprocal of the highest dilution showing aggregation of the carbon particles.
If the highest dilution tested (1:16) is reactive, proceed with a further dilution series by preparing doubling dilutions of the sample from 1:32 to 1:512 using physiological saline.
Mix well and continue as from step 2 in the semi-quantitative test.

More precised informations in the Bio-Rad RPR Pack-Insert
RPR 100 - 500 tests

Agenda

• Objective of the release and Switch Timing
• Product Description
• Performance
• Using Procedure

• Selling Strategy
  • Positioning
  • Targeted customers
RPR kits are easy to use products designed for any countries (developed or low incomes) and any laboratories to be used as a first line testing as well as confirmatory tests.

They are part of a complete Syphilis menu that fits all lab activities and needs in perfect accordance with the national algorithms.

Comprehensive offer to meet your Syphilis Testing Needs.
Priority 1: Our Trinity-Lab21 customers

A switch is required by end of October 2015 the latest because Lab 21 kits are no more available (we currently have a safety stock to manage the switch in regards to registration timing.

Priority 2: Our Syphilis Total Ab customers

Complete the testing algorithm with RPR or TPHA.

Priority 3: All TPHA our RPR users

Features and Benefit:

- Products “Made by Bio-Rad” with the associated guarantee of quality and supply.
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500)  New

RPR (100 – 500)  New

TPHA OC 2000 for PK7200-PK7300 systems

Syphilis IgM EIA

Conclusion
TPHA OC 2000 is intended to be used in Blood Banks on Olympus system PK7200 & PK7300

Manufactured by Trinity and distributed by Bio-Rad
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500)

RPR (100 – 500)

TPHA OC 2000 for PK7200-PK7300 systems

Syphilis IgM EIA

Conclusion
Manufactured by Lab 21- Trinity and distributed by Bio-Rad

CE marked product

Cat number : 72520 – 96 tests
Syphilis IgM EIA: Intended Use

Useful Indicator for Recent Infection

Helpful in the Diagnosis and Investigation of Syphilis Cases (Active Syphilis)

Efficient Tool in the Diagnosis of Congenital Syphilis

N.B:

Maternal syphilis can be transmitted to the unborn foetus, therefore detection of T.pallidum specific IgM Ab in neonatal blood samples can aid in the diagnosis of congenital syphilis.
Recombinant Antigens

→ High levels of sensitivity and specificity
→ Lower risk of missed positives and false positives

Well dilution of sample (10µl of serum or plasma)

→ Easy sample handling for both and manual use

Break well microplate

→ Use exact number of required wells
→ No waste
Agenda

Syphilis Background with Decision Algorithm

Syphilis Total Ab Assay

TPHA (200 – 500) **New**

RPR (100 – 500) **New**

TPHA OC 2000 for PK7200-PK7300 systems **New**

Syphilis IgM EIA

Conclusion
Following the acquisition of our syphilis supplier Lab21 by Trinity and the upcoming **new registration process** (new brand name and new manufacturing sites), Bio-Rad decided to release new syphilis products besides continuing with Trinity on products with low revenue and lower number of customers.

- **TPHA OC 2000**
  - Syphilis IgM + Malaria EIA Ab CMV Total Ab
  - Manufactured by Trinity and distributed by Bio-Rad

- **Syphilis Total Ab**
  - TPHA 200-500 RPR 100-200
  - Manufactured by Bio-Rad

**Registration:**
- Trinity documents are now available
- Documents are available for all new Bio-Rad Syphilis Products
Complete Menu for all lab activities

We always have a solution that fits to your need