BioSpeedia

Diagnostiquer vite pour agir

Spin-off from Institut Pasteur

BioSpeedia est une startup
de l'Institut Pasteur

SPE – Haiphong - 2017

At a glance

Our solution: We provide robust and easy to use diagnostic tools at Point of Care (POC) with **lateral flow Rapid Diagnostic Tests** (RDT - 15 min)

Emergency room | At the bed side | In the lab | In the dispensaries | In the field | With me

Value to impact Physicians:

Pertinent therapeutic decision – No delay to treat

Economic value:

Low cost analysis - Rapid epidemic control

Value for the Patient :

Fast healing

Portfolio

- 26 hybridoma (15 pathogens & virulence factors)

Licence

- Right of first refusal to exploit RDT from Inst. Pasteiur's R&D
- Exclusivity under conditions

Infectious Diseases
Problem – Medical Needs - Opportunity

Simple Symptoms
(fever, headache, vomiting…) (diarrhea, vomiting, fever, …)

Many potential pathogens

2 major questions asked

Type of infection?
Type of treatment?

- Should it be treated?
- Virus or bacteria or parasite?
- Antibiotic (which one: C3G, Cm,..) or not ?

Today answered through

Classical biological diagnostic: slow, complex with different steps

- BioSpeedia at the key stages of its product development and sales -

From its resources

Reagent Sourcing
- Academic R&D
- Industrial Partnership
- On the shelf

R&D
- Academic Partnerships
- Industrial Partnerships
- In House

Sample Sourcing
- Academic R&D

BioSpeedia
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To test conception & development (R&D one stop shoping)

Prototyping
- Conception
- Evaluation

Validation
- POCs
- Field
- Laboratory

Regulatory
- Quality
- CE mark
- FDA Registration

Production
- In house
- With industrial partners

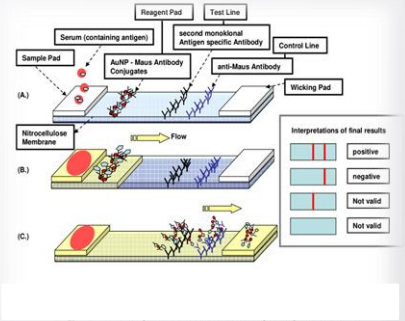
To Product sales and Services

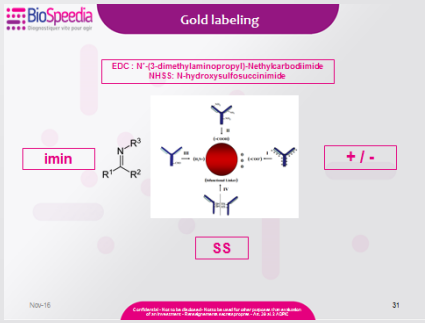
Sales
- Distributor / B2B
- Direct / B2B & B2C

Services
- Customized Gold labeling
- Customized RDT development

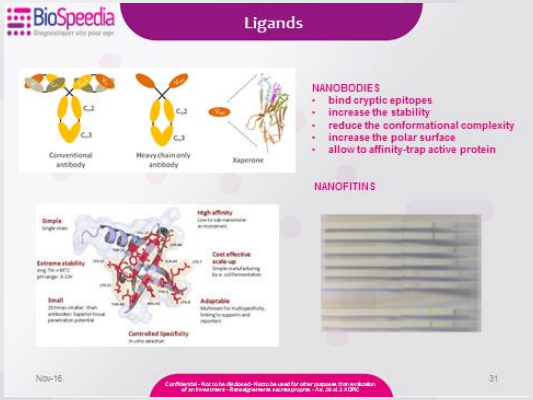
BioSpeedia's assets
- top notch technological customized services -

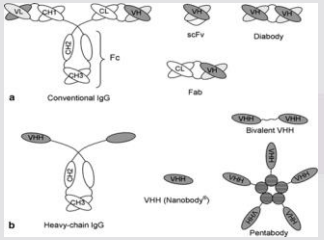
Micro-optimization
&
Conjugation service





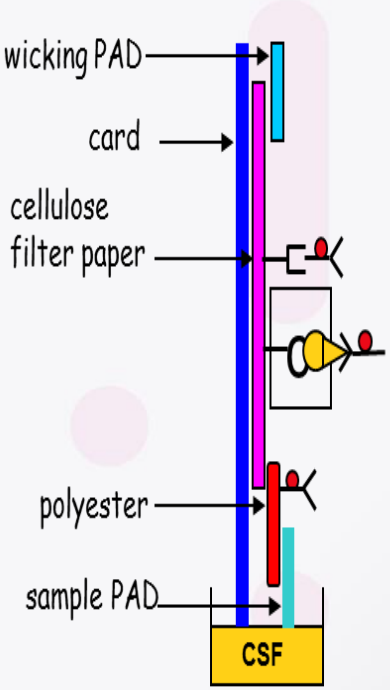
New ligands

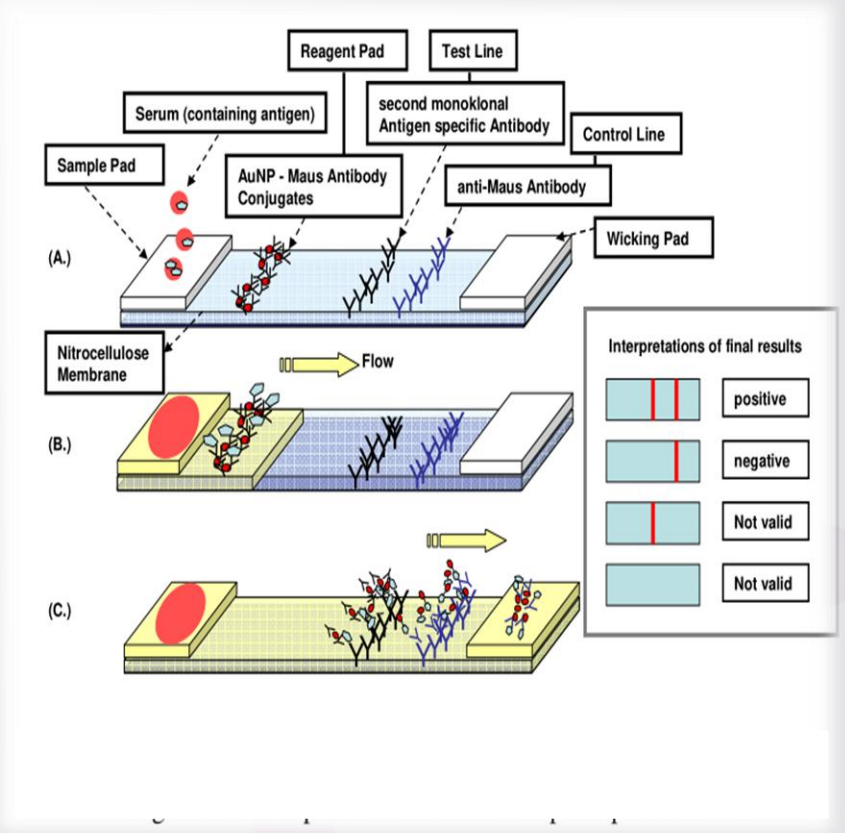




Clinical validations
(*Institut Pasteur International Network****)***

Illustration of BioSpeedia PoC solution





- https://www.youtube.com/watch?v=qIJd-lT1Eog
- https://www.youtube.com/watch?v=aHi4fyUgG5A
- https://www.youtube.com/watch?v=CMKsvyygcqU

New rapid diagnostic tests for Neisseria meningitidis serogroups A, W135, C, and Y. Chanteau S, et al. PLoS Med. 2006 Sep;3(9):e337.

VIDEO

BioSpeedia
Diagnostiquer vite pour agir

Rapid Diagnostic Tests
Point of Care (PoC)

RDT / available

RDT / Clinical validation in progress
(Looking for new sites)

RDT / in development
(Collaborations – PhD)

Independant clinical validations (IC 95 % - p < 0,05) :

PATH

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ

NATIONAL INSTITUTES OF HEALTH

Service de santé des armées

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse

DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC

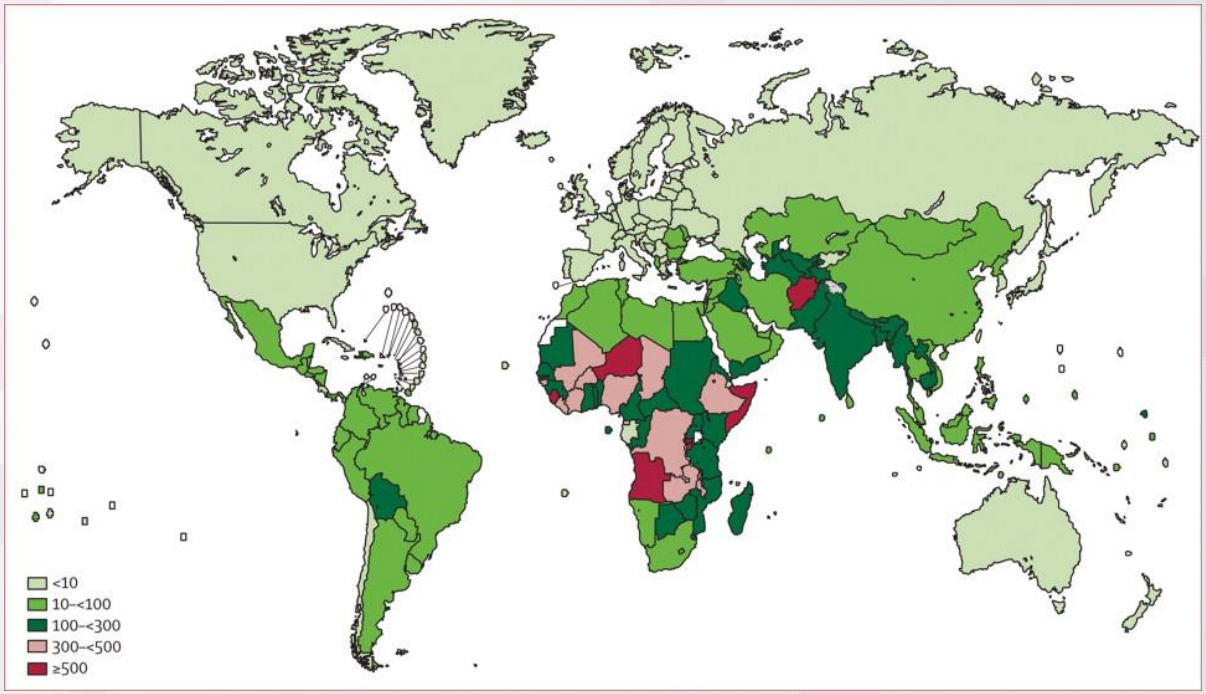
UdeSantiago

Réseau International des Instituts Pasteur

Post Graduate Institute of Medical Education and Research

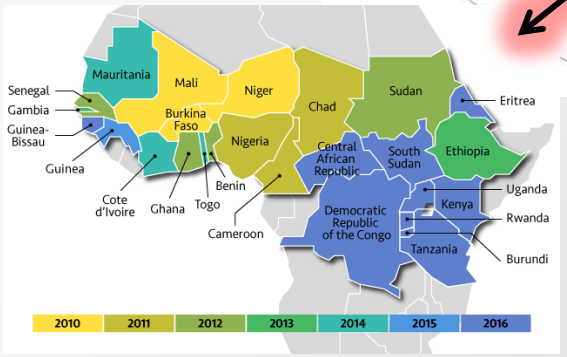
Meningitis
Streptococcus pneumoniae

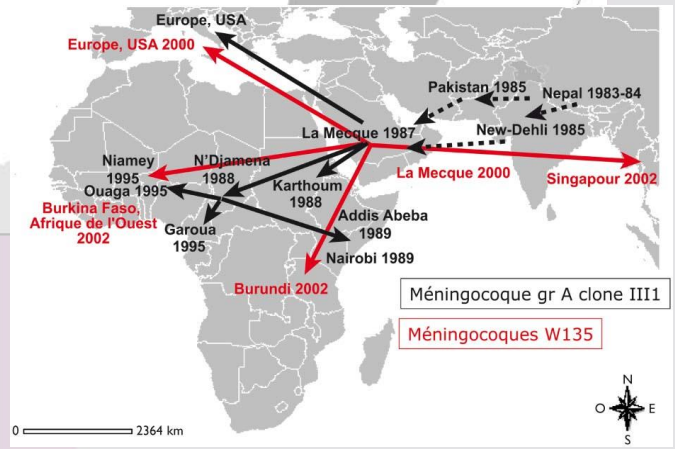
Burden of disease caused by *Streptococcus pneumoniae* … : global estimates DOI: http://dx.doi.org/10.1016/S0140-6736(09)61204-6



http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61204-6/fulltext?elsca1=&elsca2=email&elsca3=segment

Meningitis
Neisseria meningitidis





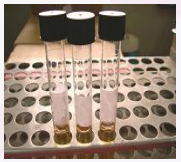
- R&D focus (why bacterial meningitis?) – umo – Meningo – HiB / THE SOLUTION

- Time consuming
- Equipment and laboratory
- Cold chain
- Trained staff

ps and **48/72 hours** delay required

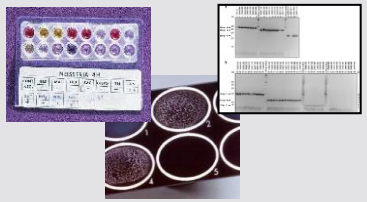
Cerebro spinal puncture

Biology Stocking



12 to 24 hours

Identification & typing



- Faster
- Stable 2 years at 30° C
- No special equipment
- Bed side / on the field
- All staff

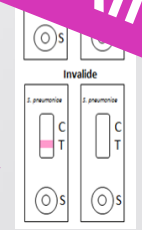
BioSpeedia solu nd **10 mi utes** required

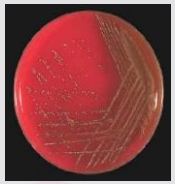
Direct diagnosis from Cereb Urine or Bacterial colonies

Cerebro spinal puncture

Biology Chemistry Stocking

TAT= 10 mn



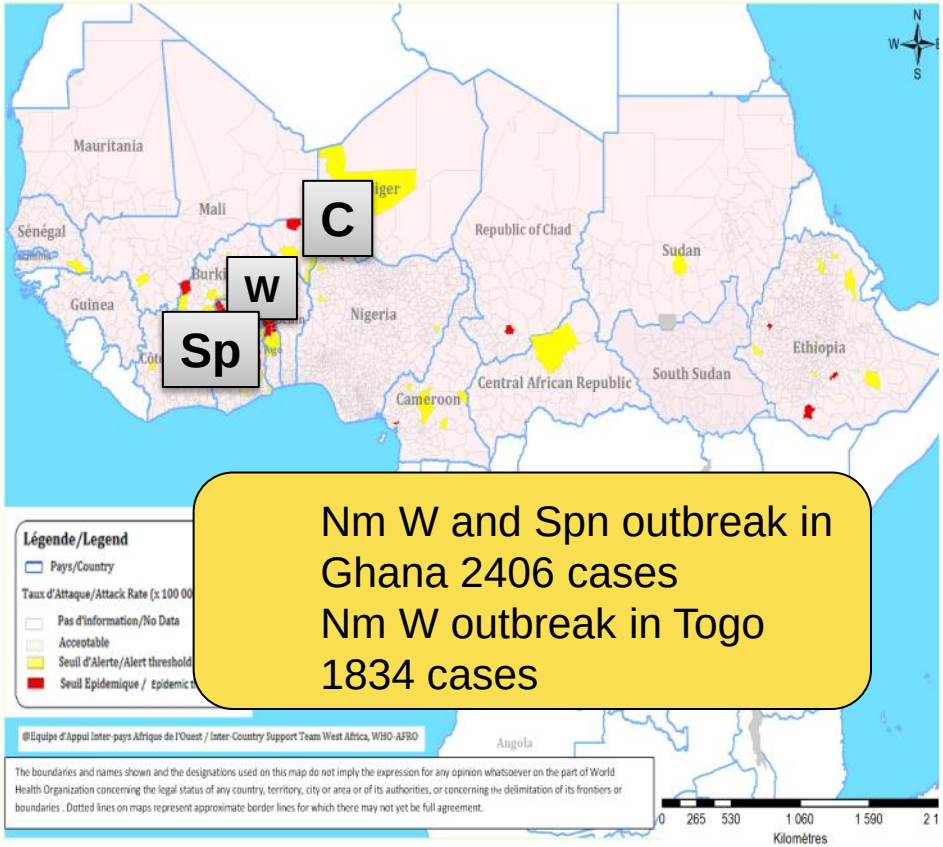


Identification & typing

PNEUMO

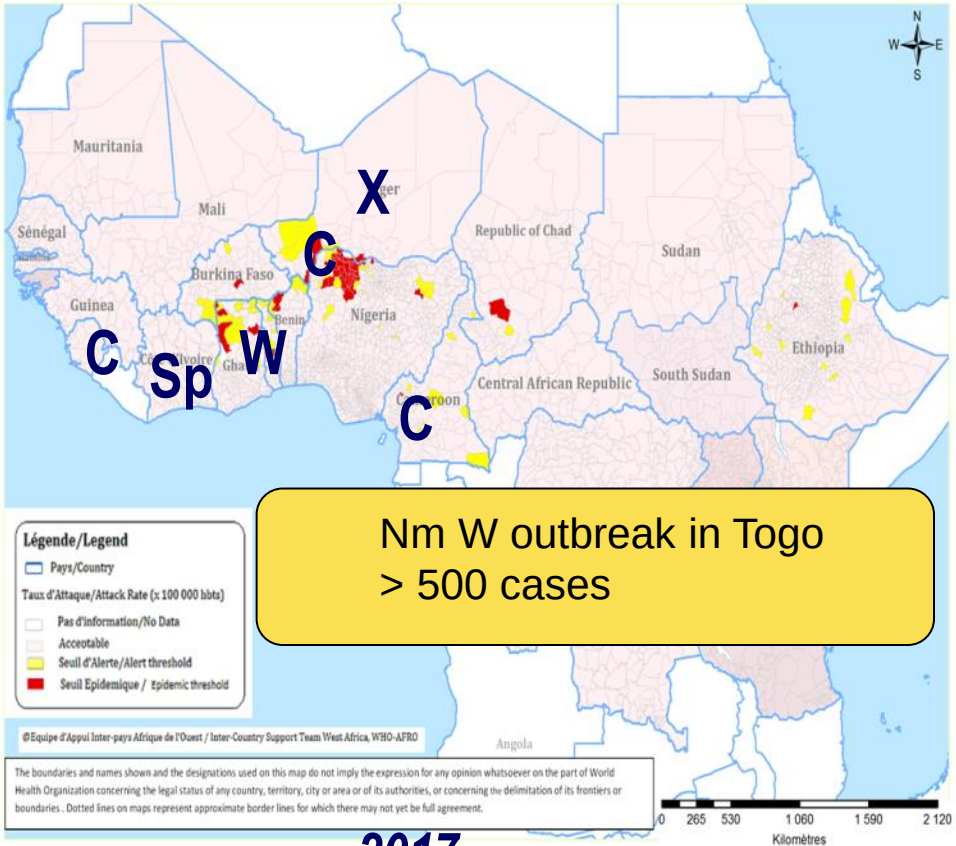
MENINGO (validated on infected mice)

Main pathogens detected, 2016 and 2017



Nm W and Spn outbreak in Ghana 2406 cases
Nm W outbreak in Togo 1834 cases

2016



Nm W outbreak in Togo
> 500 cases

2017

World Health Organization

Clinical validation

MENINGOSPEED

vs PCR	PCR +	PCR -
RDT+	244	14
RDT-	14	101
SE	0.95	
SP	0.89	
PPV	0.95	
NPV	0.89	

vs culture & PCR	culture +	culture -
RDT +	58	3**
RDT -	0	46
SE	1	
SP	1	
PPV	1	
NPV	1	

*3 samples are Culture NEG but PCR POS

From Basic Science to Biomarkers and Tools in Global Health
Institut Pasteur International Network Symposium (Paris, Nov 29th – Dec 2nd 2016)
POSTER & ORAL presentation

Clinical validation

PNEUMOSPEED

Side-by-side study:
- 178 urines
- 32 CSF
- Study on additional CSF is in progress

Gold standard methods:
- Gram / MGG
- Bacterial culture
- PCR
- Agglutination (Pastorex)
- Other commercial PoC lateral flow test

	SE	SP	PPV	NPV
Urine (*vs* PCR and other PoC test)**	0,93	0,96	0,92	0,97
CSF (*vs* isolation - Pastorex)	1	0,89*/1	0,87/1	1
CSF (*vs* PCR)	0,94	1	1	0,94
CSF (*vs* Gram & MGG)	1	1	1	1

** Culture NEG – PCR POS – SP = 1*
*** POS if at least one Gold Standard test is POS*

From Basic Science to Biomarkers and Tools in Global Health
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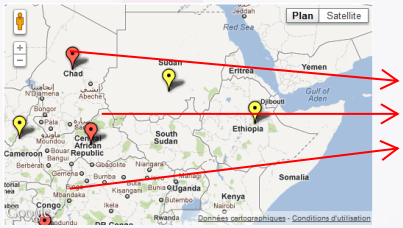
BioSpeedia
Diagnostiquer vite pour agir

Needs & Solution

مـــركز القيادة و الـتحـــكم
Command & Control Center

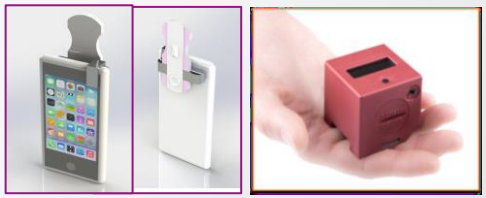
WEAK /STRONG SIGNALS FROM THE FIELD



وزارة الصحة
Ministry of Health

World Health Organization

ALERT



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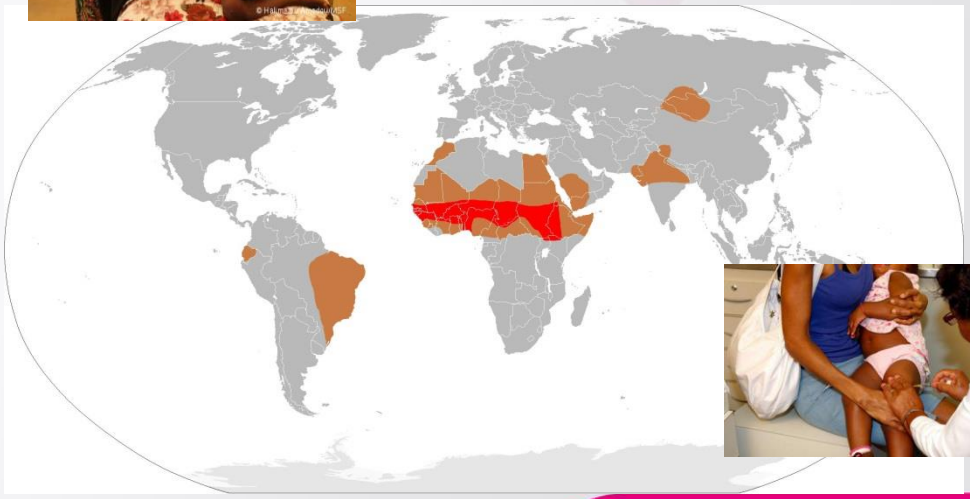
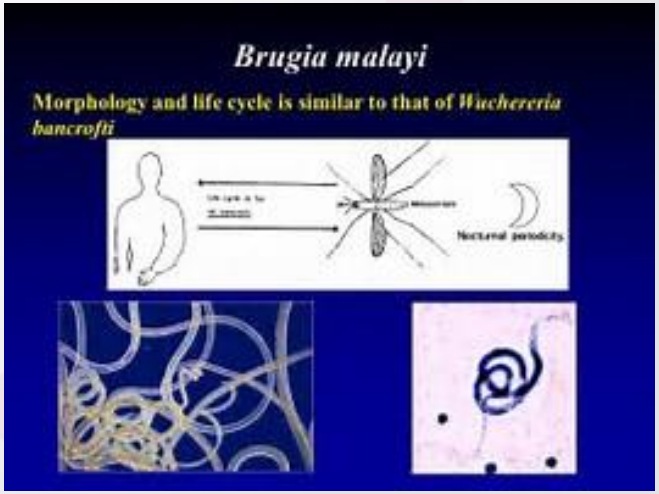
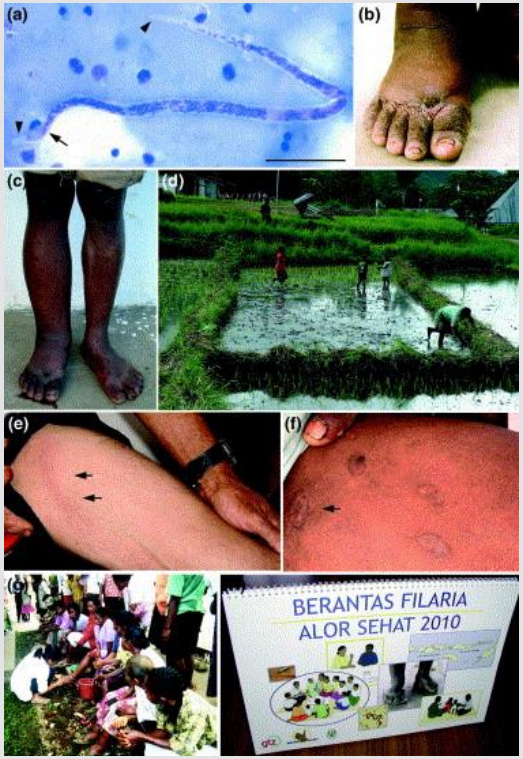
TREATMENT

RESPONSE



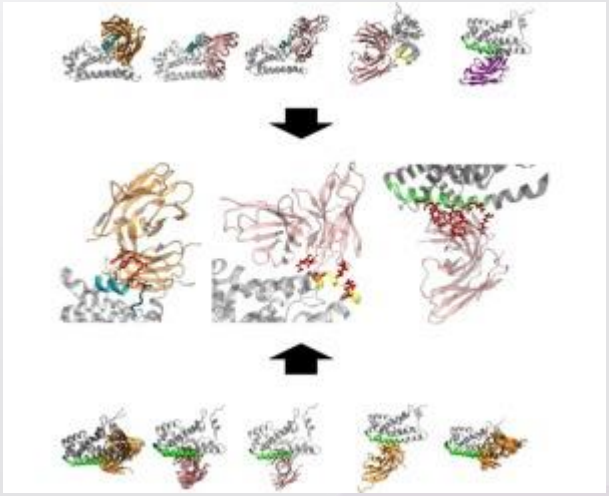
Filariosis *Brugia malayi* and *Brugia timori*

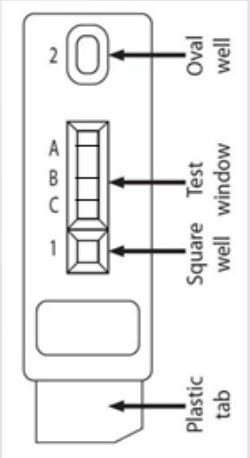




research papers

Structure of the virulence-associated protein VapD from the intracellular pathogen Rhodococcus equi





BrugiaSpeed is an indirect solid-phase immunochromatographic assay for IgG4 to Brugia antigen.

Filariosis / clinical validation

Sensitivity

a) Assessed by 207 serum samples from 6 institutions from 3 countries (Malaysia, Indonesia & India) Se (200/207 = **96.6%**)

b) Assessed by 270 serum samples from multicenter laboratories (LUMC, TDMC, NIH & STI) Se (251/270 = **92.96%**)

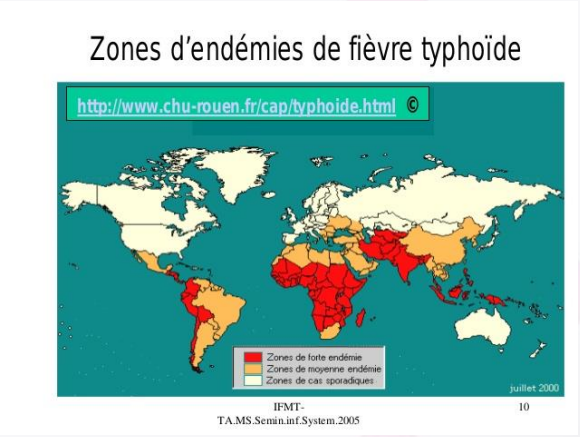
Specificity

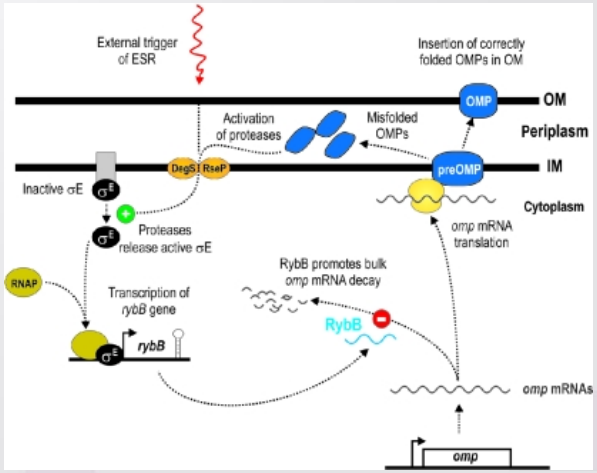
a) Assessed by 546 serum samples from 6 institutions from 3 countries (Malaysia, Indonesia & India) Sp (540/546 = **98.7%**)

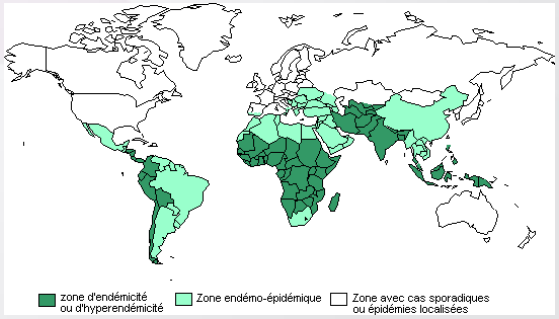
b) Assessed by 266 serum samples from multicenter laboratories (LUMC, TDMC, NIH & STI) Sp (266/266 = **100%**)

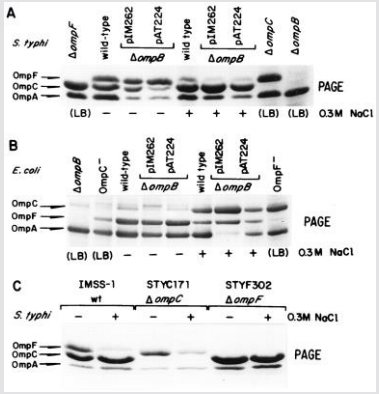
Typhoid

outer membrane protein (*OMP*) / porines = en se polymérisant forment des canaux assurant le passage des molécules hydrophiles à travers cette membrane externe par ailleurs très hydrophobe

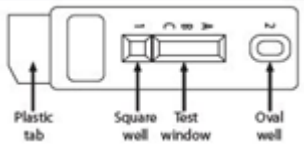


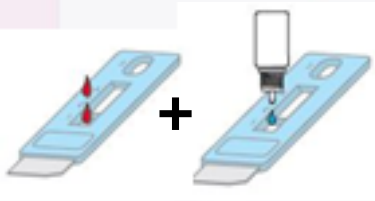


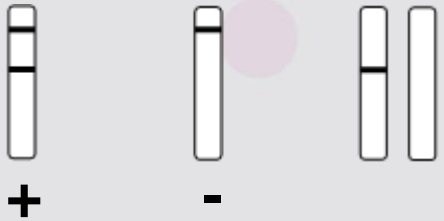




IFU ThiphoidSpeed







Typhoid / validation in progress

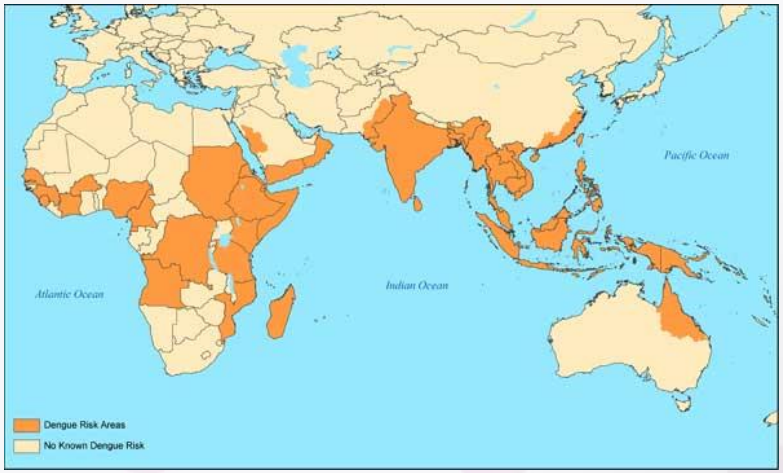
A total of 149 sera samples (57 culture-positive Typhoid sera, 57 non-Typhoid fevers sera and 35 sera from normal healthy volunteers) from various sources were used. Below is the summary of the results:

- Sensitivity: 49/57 = 85.9%
- Specificity: 89/92 = 96.7%
- Positive Predictive Value: 49/52 = 94.2%
- Negative Predictive Value: 89/97 = 91.7%

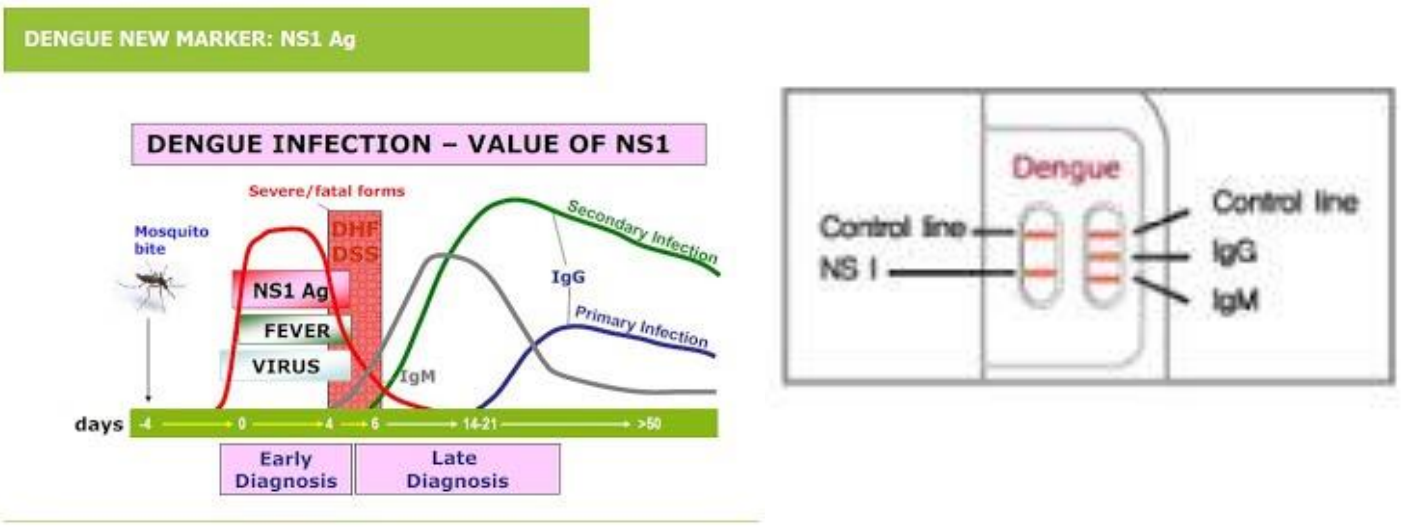
	Culture-positive	Normal healthy sera	Non-Typhoid fevers	Total
TyphiSpeed IgM +	49	2	1	52
TyphiSpeed IgM -	8	33	56	97
Total	57	35	57	149

Looking for more data

Dengue



- There are approximately 50 to 100 million cases of dengue infection annually. http://dx.doi.org/10.1016/j.vhri.2013.10.002



Overall Sensitivity and Specificity

The evaluation study was carried using a total of 145 well characterized clinical samples, consisting of:
a) 45 dengue antigen positive sera samples
b) 50 dengue antibody positive sera samples (specimens positive for both IgG/IgM)
c) 50 dengue negative samples

	Sensitivity	Specificity
NS1	80 %	96 %
IgG & IgM	90 %	64 %

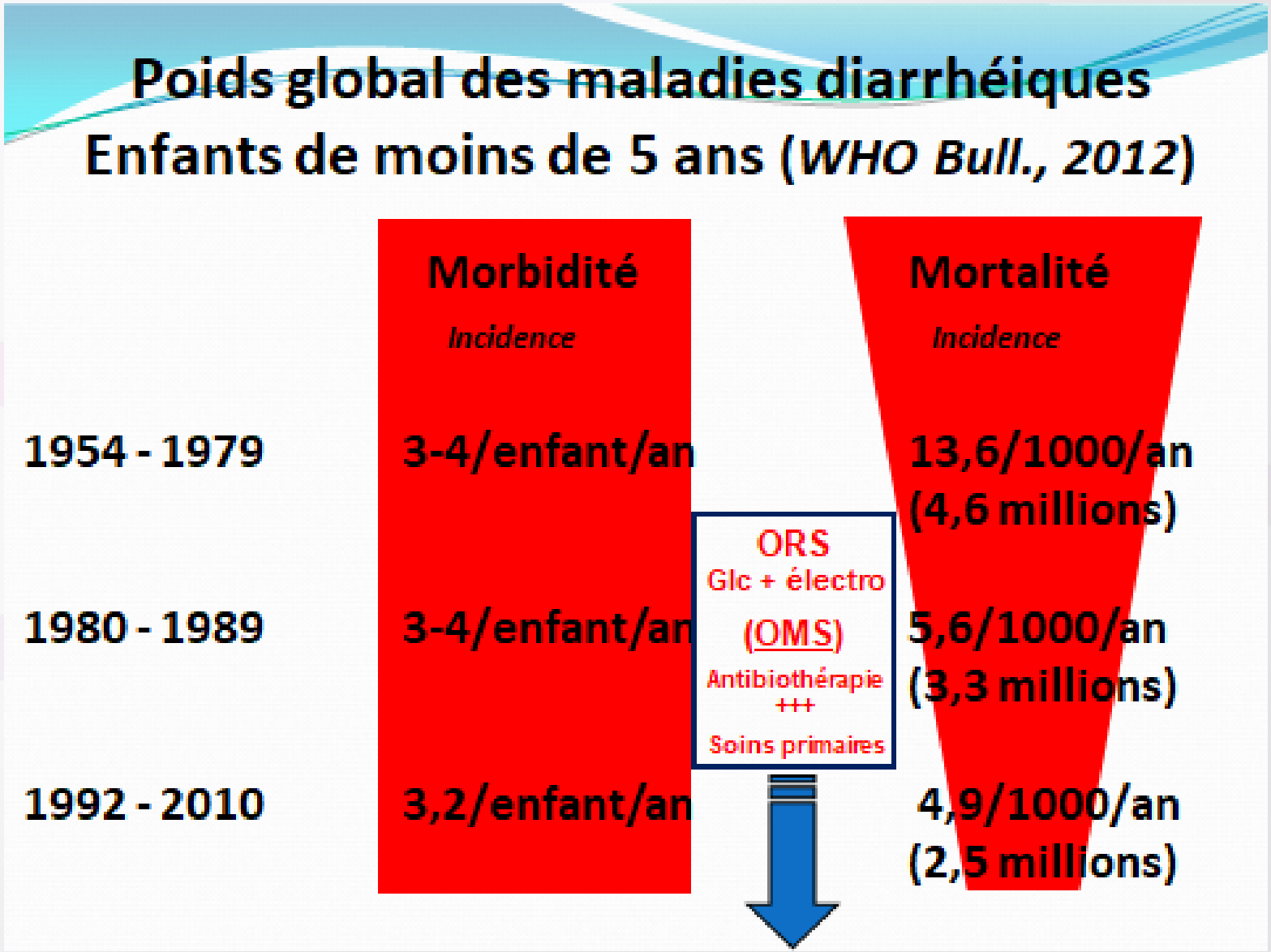
Dengue NS1 Rapid Test (vs commercial tests)

	Pos	Neg
Pos	27	0
Neg	2	12

Relative sensitivity: 27/29 = 93.1%
Relative Specificity: 12/12 = 100%
Overall % agreement: 39/41 = 95%

Validations on field / in hospitals (IC 95%: IgG/IgM NS1

Severe Diarrhea
Burden of the disease



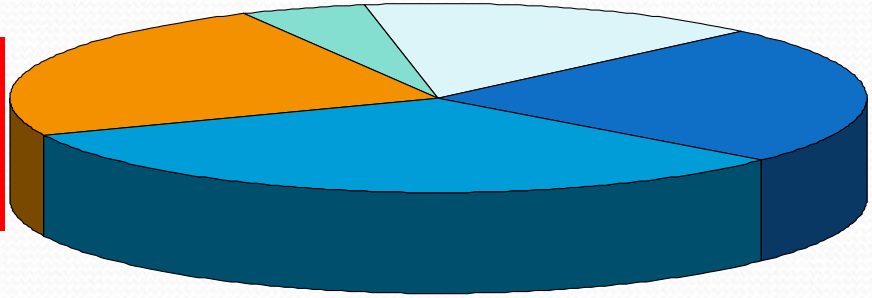
SIX MAIN PATHOGENS

sont responsables de l'essentiel de la mortalité :

Cholera
Cases/year: 5,000,000
Deaths/year: 120,000

Diarrheogenic *E. coli (ETEC, EHEC, EAEC, …)*
Cases/year: > 650,000,000
Deaths/year: 380,000

Typhoid
Cases/year: 17,000,000
Deaths/year: 600,000



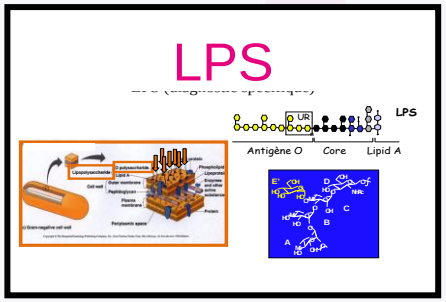
Rotavirus
Cases/year: 130,000,000
Deaths/year: 650,000

Shigella
Cases/year: 163,000,000
Deaths/year: 500,000

E. histolytica
Cases/year: 50,000,000
Deaths/year:100,000

AUTRES PATHOGENES
(*Campylobacter* spp, *Enterovirus* non Rota., …)
importance de *G. lamblia*, *Cryptosporidium* spp,

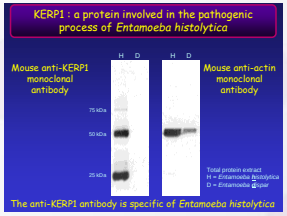
Targets / Pathogens / Portfolio (diarrhea)

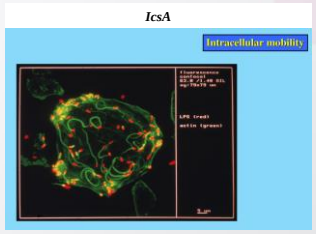


BioSpeedia's portfolio (diarrhea):
Institut Pasteur R&D areas:

Shiga tox, SLtx 1 & 2 (SUB)

Fraser, M. E. et al.
J. Biol. Chem.
2004;279:27511-27517





Bacteria:
Cholera O1, Cholera O139
Shigella spp, S. dysenteriae 1, S. sonnei, S. flexneri 2a
Stx1, Stx2, O157, Salmonella spp, S. typhi, S. paratyphi A / B
EAgEC, EPEC, Clostridium perfringens,
Campylobacter, ETEC (LT, ST)

Virus:
RotaV, AdenoV, NoroV

Parasites:
Entamoeba Histolytica
Cryprosporidium, Cyclospora,
Lamblia, Microsporidium

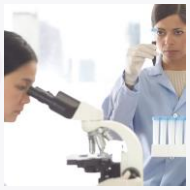
And more…

- Existing vs BioSpeedia solution - Diarrhea

Classical methods: 4 steps and **48/72 hours** required to identify a micro-organism from a biological sample

Stools sample, rectal swab…

Observation (agglutination)



12 to **24 hours**

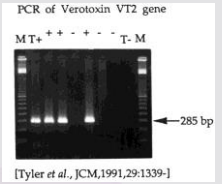
Isolation

12 to **24 hours**

Identification

12 to **24 hours**

typing



BioSpeedia Solution: 1 Step and **10 minutes** required to identify up to 23 micro-organisms from a biological sample

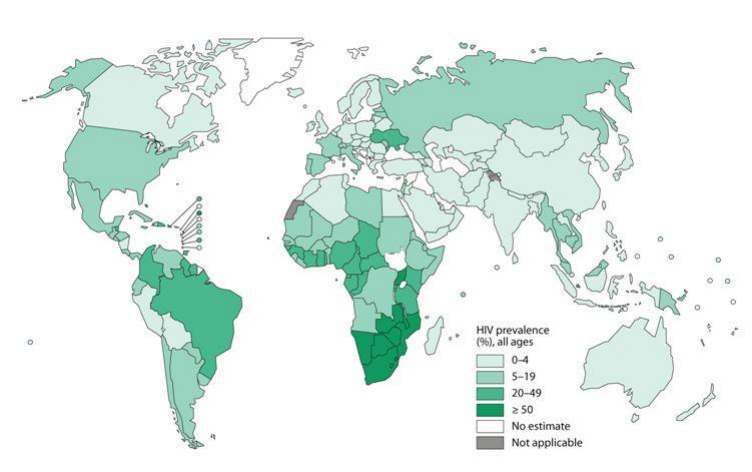
stools

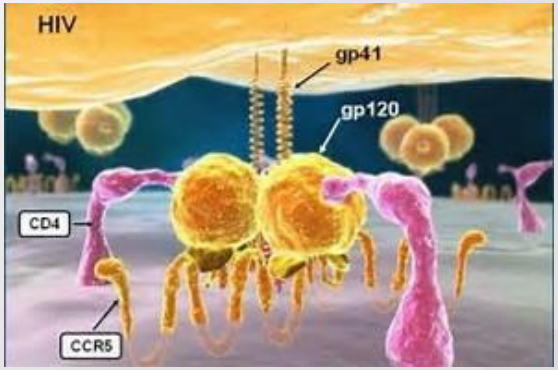
Reaction

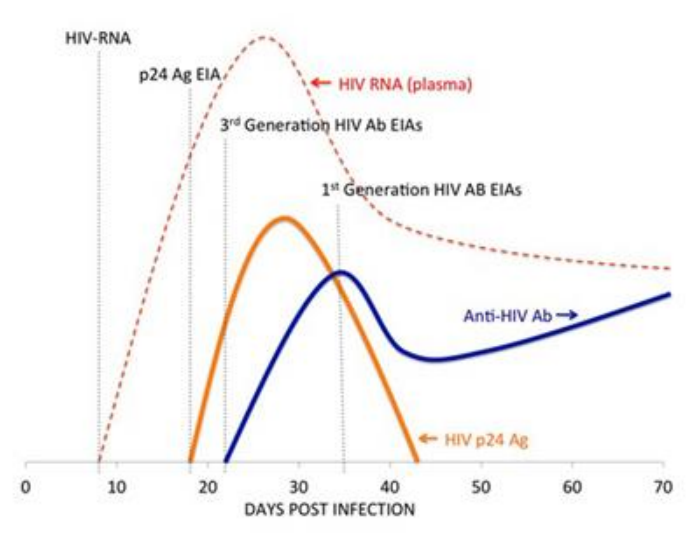
Reading

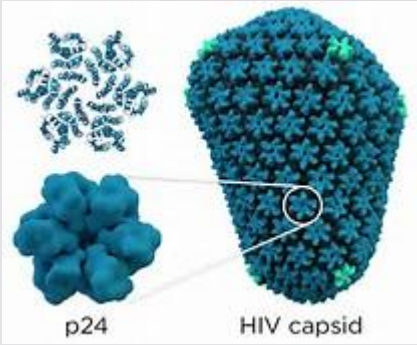
BioSpeedia
Lateral flow test solution

HIVSpeed in progress



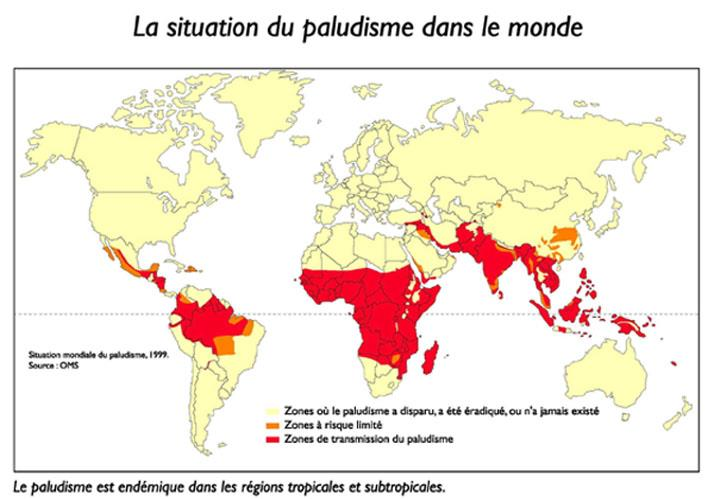




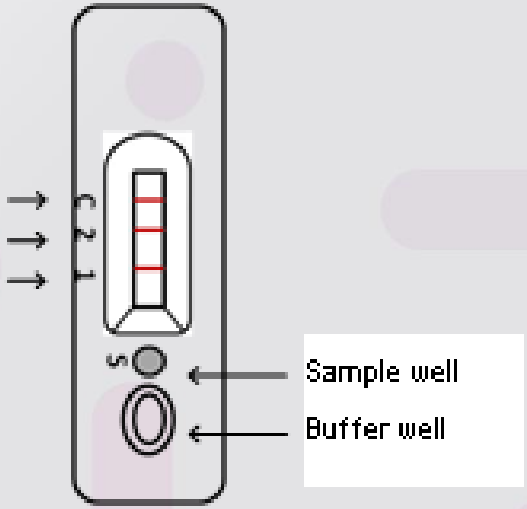


MalariaSpeed

Prev.: 210 10 ^{6}
Mortality: 630 000
36% worldwide / 90 countries.



MalariaSpeed uses antibodies that are specific for the histidine-rich protein 2 antigen (HRP-2) of malaria *P.f.* and Plasmodium lactate dehydrogenase (pLDH) for the detection of all malaria Plasmodium species. Se & Sp > 97%.

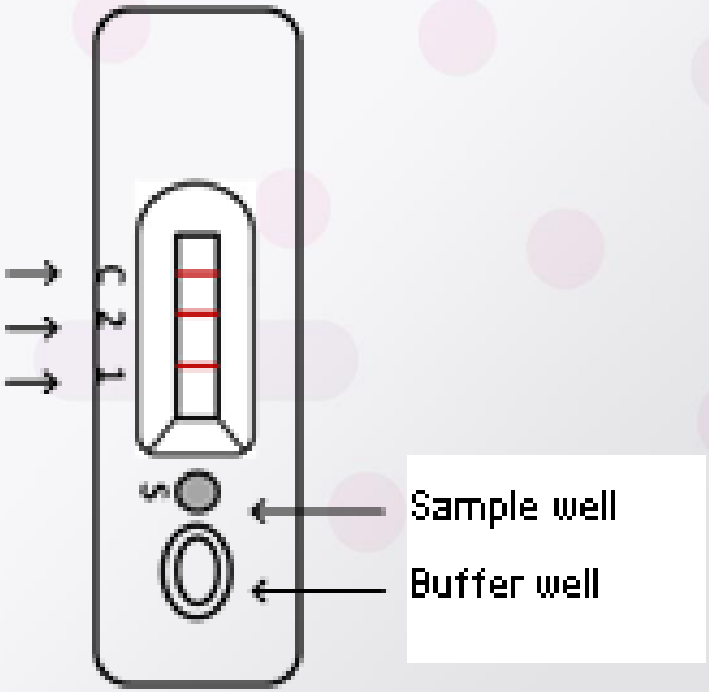


Plasmodium falciparum, *P. vivax,* *P. ovale,* *P. malariae*

***P. Knwolesi* (SE Asia) : R&D in progress**

R&D in progress

MalariaSpeed uses antibodies that are specific for the histidine-rich protein 2 antigen (HRP-2) of malaria *P.f.* and Plasmodium lactate dehydrogenase (pLDH) for the detection of all malaria Plasmodium species. Se & Sp > 97%.



- *Plasmodium falciparum*
- *P. vivax*
- *P. ovale*
- *P. malariae*

***P. Knwolesi* (SE Asia) : R&D in progress**

We are looking for partners

- To distribute our RDT
- To bump up, to boost the R&D (by welcoming PhDs) and to develop new tests (access to the license) in partnership with Institut Pasteur & other academic institutions

MERCI – THANK YOU

Yves Germani
Cofounder
CEO / CSO

PhD nat. sci. - PhD pharm. sci. - Institut Pasteur diploma - HDR – Qualified prof. Cell Biology
Business France Health International Network
Chief of Laboratory (Research Director / associate professor)
Institut Pasteur (Molecular Microbial Pathogenesis)
Institut Pasteur International Network
HEC – *Challenge Plus*

Evelyne Bégaud
Cofounder
CTO

PhD pharm. sci. – Institut Pasteur diploma
Biological Ressources Center
Institut Pasteur International Network
HEC - *Challenge Plus*

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