Online consultation on eligibility criteria for WHO Prequalification of in vitro diagnostics
Contents

1. Background & Aim
2. Methods
3. Results
   I. Survey
   II. Burden of disease
   III. IVD diagnostic performance
   IV. Patient management & treatment
   V. Final ranking
4. Remarks for your consideration
Background

- Essential diagnostics list (EDL) first published in May 2018
- Goal: to provide countries with a list of safe and effective (in vitro) diagnostic tests
- New update in 2019 through the Strategic Advisory Group of Experts (SAGE) on IVDs
Background

- Current EDL (nov 2018)
  - General & disease-specific IVDs
  - Primary care & health care facilities with clinical laboratories
  - 5 general fields
  - 7 diseases
  - 81 diagnostic tests
  - >30 assay formats
Aim consultation

To develop a proposal for future eligibility for prequalification of in vitro diagnostics based on ranking for priority setting
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2. Methods

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Methods

General survey information

- Sent to various organizations in worldwide public health (51 contacts in 26 organizations)
- Data collection Dec 2018 to March 1st 2019
Methods

General survey information

- Collect additional data (KJ) where information was lacking
  - Burden of disease
  - IVD diagnostic performance
  - Patient management & treatment
Methods

Burden of disease

- Global burden of disease publications

Outcomes

- Disability-adjusted life years (DALYs)
- Prevalence
- Incidence
- Basic reproductive number (R0)
- Case fatality rate (CFR)
Methods

Burden of disease

- DALYs per person = YLD (QoL) + YLL (mortality)
- DALYs on a population level = (YLD + YLL) * prevalence / incidence
- Prevalence and incidence are influenced by R0 and CFR
- Example
  - Athlete's foot = low YLD + no YLL + High incidence
  - Ebola = High YLD + High YLL + Very low incidence
  - Pneumonia = High YLD + High YLL + High incidence
Methods

IVD diagnostic performance

- Search for systematic reviews
  - (Cochrane) review or meta-analysis
  - Disease of interest
  - IVD assay format

- Quality appraisal: modified AMSTAR

- Data extraction: sensitivity & specificity

- Additional: disease subclassification, IVD subclassification, context of use
Methods

Patient management & treatment

- Disease specific information on availability of
  - Curative treatment
  - Relief treatment
  - Other interventions (e.g. quarantine)
- Worldwide availability checked using the EML
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Due to early viremia during infection, direct detection of viral RNA is preferred for diagnosing ebolavirus. However, despite their availability, the current molecular diagnostics are complex and may only feasible for use within a laboratory facility. The 2013–2016 West Africa Ebola outbreak did result in the rapid development of new commercially benective and point of care molecular diagnostics to allow for rapid detection in lower resource laboratories; however, there is better safety concern remains.

Likewise, only a few NIAIDs are able to test for multiple ebolavirus subtypes, which can potentially result in false negatives during outbreak responses or surveillance activities. Further development is needed for easily deployable molecular diagnostics that can distinguish multiple viral subtypes for future outbreaks and improved surveillance.

Early trage and treatment of Ebola patients results in higher likelihood of survival; however, because of the non-specific symptoms at early onset of disease, the need to rule out other etiologic agents for fever early during infection is important. Similarly, in regions where viral hemorrhagic fever viruses may be endemic and maintained through natural reservoirs, a panel for distinguishing the viral family causing infection and, potentially, co-infection, will be useful for surveillance as well as appropriate isolation and infection prevention and control measures. In terms of filoviruses, while the majority of Ebola outbreaks are caused by EBOV and Sudan, current tests do not have full rule out that strain. A multiplex, syndromic approach is useful and efficient strategy for surveillance, differential diagnosis and definition of endemic populations.
Survey

In vitro diagnostic test

- Immunochromatographic: 35%
- NAT: 15%
- ELISA: 10%
- Unknown: 5%
- Immunofluorescence: 20%
- Lateral flow rapid: 25%
- CBNAT: 20%
- Immunochromogenic: 5%
- Lateral flow: 5%
- Serology: 0%
Survey

Target disease

% of responders

- Zika virus
- Dengue virus
- Ebola virus
- Measles
- Yellow Fever
- Rubella
- Tuberculosis
- Hepatitis C
- HIV
- Chlamydia
- Marburg virus
- Syphilis
- Cryptococcal meningitis
- Hepatitis B
- Malaria
- Pneumonia
- Sickle Cell disease
- Trypanosomiasis
Survey: ranking

Top-10 Survey (frequency)

1. Zika (n=14)
2. Dengue (n=11)
3. Ebola (n=6)
4. Measles (n=6)
5. Yellow Fever (n=6)
6. Rubella (n=3)
7. Tuberculosis (n=3)
8. Hepatitis C (n=2)
9. HIV (n=2)
10. Chlamydia (n=2)

Green: Not on the EDL 2018
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Burden of disease (absolute numbers)

DALYs worldwide
Burden of disease (log scale)

DALYs worldwide

000's DALYs

Pneumonia
HIV
Malaria
Tuberculosis
Syphilis
Measles
Hepatitis B
Sickle Cell disease
Dengue fever
Meningococcal
Schistosomiasis
Onchocerciasis
Cryptococcal meningitis
Leishmaniasis
Rubella
Chlamydia
Yellow Fever
Hepatitis C
Trypanosomiasis
Zika virus disease
Ebola virus disease
Marburg virus disease
Burden of disease

DALYs worldwide

000’s DALYs

Pneumonia, HIV, Malaria, Tuberculosis, Syphilis, Measles, Hepatitis B, Sickle Cell disease, Dengue fever, Meningococcal, Schistosomiasis, Onchocerciasis, Cryptococcal meningitis, Leishmaniasis, Rubella, Chlamydia, Yellow Fever, Hepatitis C, Trypanosomiasis, Zika virus disease, Ebola virus disease, Marburg virus disease
Burden of disease

DALYs by target disease within continent

- Pneumonia
- HIV
- Malaria
- Tuberculosis
- Syphilis
- Hepatitis B
- Measles
- Sickle Cell disease
- Dengue fever
- Meningococcal meningitis
- Schistosomiasis
- Onchocerciasis
- Cryptococcal meningitis
- Leishmaniasis
- Chlamydia
- Yellow Fever
- Hepatitis C
- Trypanosomiasis

000’s DALYs
Burden of disease

Socio-demographic index (SDI) based

- Pneumonia
- HIV
- Malaria
- Tuberculosis
- Syphilis
- Measles
- Hepatitis B
- Sickle Cell disease
- Dengue fever
- Meningococcal meningitis
- Schistosomiasis
- Onchocerciasis
- Cryptococcal meningitis
- Leishmaniasis
- Chlamydia
- Yellow Fever
- Hepatitis C
- Trypanosomiasis
## Burden of disease: ranking

### Top-10 Survey (frequency)

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<th>Rank</th>
<th>Disease</th>
<th>Frequency (n)</th>
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### Top-10 DALYs

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<td>10.</td>
<td>Meningocccal meningitis</td>
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</tbody>
</table>

**Green:** Not on the EDL 2018
Burden of disease

Prevalence

000's prevalence

Tuberculosis, Hepatitis B, Schistosomiasis, Malaria, Hepatitis C, Chlamydia, HIV, Syphilis, Onchocerciasis, Pneumonia, Dengue fever, Leishmaniasis, Sickle Cell disease, Meningococcal...

Measles, Cryptococcal...

Zika virus disease, Trypanosomiasis, Yellow Fever, Ebola virus disease, Rubella, Marburg virus...
Burden of disease

Incidence

- Pneumonia
- Chlamydia
- Malaria
- Hepatitis B
- Dengue fever
- Schistosomiasis
- Measles
- Syphilis
- Tuberculosis
- Hepatitis C
- Onchocerciasis
- Zika virus disease
- HIV
- Leishmaniasis
- Sickle Cell disease
- Meningococcal
- Cryptococcal
- Yellow Fever
- Rubella
- Trypanosomiasis
- Ebola virus disease
- Marburg virus disease

000's incidence
Burden of disease: ranking

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<th>Top-10 DALYs</th>
<th>Top-10 Prevalence / incidence</th>
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<td>1. Zika (n=14)</td>
<td>1. Pneumonia</td>
<td>1. Tuberculosis / Pneumonia</td>
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<td>2. HIV</td>
<td>2. Hepatitis B / Chlamydia</td>
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<td>4. Measles (n=6)</td>
<td>4. Tuberculosis</td>
<td>4. Malaria / Hepatitis B</td>
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<td>5. Yellow Fever (n=6)</td>
<td>5. Syphilis</td>
<td>5. Hepatitis C / Dengue</td>
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<td>7. Tuberculosis (n=3)</td>
<td>7. Hepatitis B</td>
<td>7. HIV / Measles</td>
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<td>8. Hepatitis C (n=2)</td>
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<td>10. Chlamydia (n=2)</td>
<td>10. Meningococcal meningitis</td>
<td>10. Pneumonia / Hepatitis C</td>
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Green: Not on the EDL 2018
Already on prequalification list?

Added in 2018 (first in 2010)

**Malaria:** First Response® Malaria Antigen P. falciparum (HRP2) Card Test; First Response® Malaria Ag. pLDH/HRP2 Combo Card Test; First Response®Malaria Ag. P.f / P.v. Card Test; SD BIOLINE Malaria Ag P.f/P.f/P.v; One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag

**HIV:** INSTI® HIV Self Test; One Step HIV1/2 Whole Blood/Serum/Plasma Test;

**CD4 Technologies:** CyFlow® Counter System with CD4 easy count kit and CD4% easy count kit; Muse Auto CD4/CD4% kit

**HBsAg RDT:** Vikia HBsAg

**HPV Virological Technologies:** care HPV Test

**HCV EIA:** INNOTEST HCV Ab IV
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# IVD diagnostic performance

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<tr>
<th>Disease focus</th>
<th>Assay</th>
<th>Extra info disease</th>
<th>Extra info test</th>
<th>Single test or comparator?</th>
<th>Year</th>
<th>Analyte</th>
<th>Context of usage</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Remarks</th>
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<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>Immun</td>
<td>Leishmaniasis pELISA</td>
<td>Leishmaniasis</td>
<td>Single test</td>
<td>2018</td>
<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>Immun</td>
<td>Leishmaniasis ELISA</td>
<td>Leishmaniasis</td>
<td>Single test</td>
<td>2018</td>
<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>Immun</td>
<td>Leishmaniasis IHC</td>
<td>Leishmaniasis</td>
<td>Single test</td>
<td>2018</td>
<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>Immun</td>
<td>Leishmaniasis IFA</td>
<td>Leishmaniasis</td>
<td>Single test</td>
<td>2018</td>
<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
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<tr>
<td>Leishmaniasis</td>
<td>Immun</td>
<td>Leishmaniasis pELISA</td>
<td>Leishmaniasis</td>
<td>Single test</td>
<td>2018</td>
<td>Antibody</td>
<td>None gran</td>
<td>0.52 (0.30 - 0.77)</td>
<td>0.97 (0.85 - 1.00)</td>
<td></td>
</tr>
</tbody>
</table>
# IVD diagnostic performance

<table>
<thead>
<tr>
<th>Disease</th>
<th># of SR</th>
<th># of specific tests</th>
<th>Proportion high quality SR based on modified AMSTAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dengue fever</td>
<td>7</td>
<td>7</td>
<td>4/7</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>1</td>
<td>1</td>
<td>0/1</td>
</tr>
<tr>
<td>HIV</td>
<td>1</td>
<td>1</td>
<td>0/1</td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>2</td>
<td>5</td>
<td>1/2</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1</td>
<td>1</td>
<td>0/1</td>
</tr>
<tr>
<td>Syphilis</td>
<td>3</td>
<td>5</td>
<td>2/3</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>25</td>
<td>10+</td>
<td>14/25</td>
</tr>
</tbody>
</table>

No SRs on: Malaria, measles, sickle cell disease, meningococcal meningitis, cryptococcal meningitis, schistosomiasis, onchocerciasis, chlamydia, yellow fever, hepatitis C, trypanosomiasis, rubella, zika virus disease, ebola virus disease, marburg virus disease
# Burden of Disease: Ranking

## Top-10 Survey (frequency)
1. Zika (n=14)  
2. Dengue\(^D\) (n=11)  
3. Ebola (n=6)  
4. Measles (n=6)  
5. Yellow Fever (n=6)  
6. Rubella (n=3)  
7. Tuberculosis\(^D\) (n=3)  
8. Hepatitis C (n=2)  
9. HIV (n=2)  
10. Chlamydia (n=2)

## Top-10 DALYs
1. Pneumonia  
2. HIV  
3. Malaria  
4. Tuberculosis\(^D\)  
5. Syphilis\(^D\)  
6. Measles  
7. Hepatitis B  
8. Sickle cell disease  
9. Dengue\(^D\)  
10. Meningococcal meningitis

## Top-10 Prevalence / Incidence
1. Tuberculosis\(^D\) / Pneumonia  
2. Hepatitis B / Chlamydia  
3. Schistosomiasis / Malaria  
4. Malaria / Hepatitis B  
5. Hepatitis C / Dengue\(^D\)  
6. Chlamydia / Schistosomiasis  
7. HIV / Measles  
8. Syphilis\(^D\) / Syphilis\(^D\)  
9. Onchocerciasis / Tuberculosis\(^D\)  
10. Pneumonia / Hepatitis C

*Notes:  
Green: Not on the EDL 2018; \(^D\): High quality SR evidence on diagnostic test performance*
1. Background
2. Methods
3. Results
   I. Survey
   II. Burden of disease
   III. IVD diagnostic performance
   IV. Patient management & treatment
   V. Final ranking
4. Remarks for your consideration
## Patient management & treatment

<table>
<thead>
<tr>
<th>Disease</th>
<th>Curative treatment</th>
<th>Other patient management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia</td>
<td>X</td>
<td>Vaccination</td>
</tr>
<tr>
<td>HIV</td>
<td>X*</td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>X</td>
<td>Vaccination, quarantine</td>
</tr>
<tr>
<td>Syphilis</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Measles</td>
<td>X**</td>
<td>Vaccination</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>X</td>
<td>Vaccination</td>
</tr>
<tr>
<td>Sickle Cell disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dengue virus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal meningitis</td>
<td>X</td>
<td>Vaccination</td>
</tr>
<tr>
<td>Cryptococcal meningitis</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

* Not completely curative, but significant suppression of symptomatic disease
** Only vaccination 72 after exposure
## Patient management & treatment

<table>
<thead>
<tr>
<th>Disease</th>
<th>Curative treatment</th>
<th>Other patient management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schistosomiasis</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Onchocerciasis</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Leishmaniasis</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Chlamydia</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Yellow Fever</td>
<td></td>
<td>Vaccination</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Trypanosomiasis</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Rubella</td>
<td></td>
<td>Vaccination</td>
</tr>
<tr>
<td>Zika virus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ebola virus</td>
<td>X*</td>
<td>Quarantine</td>
</tr>
<tr>
<td>Marburg virus</td>
<td></td>
<td>Quarantine</td>
</tr>
</tbody>
</table>

* Experimental treatment being evaluated
Contents

1. Background
2. Methods
3. Results
   I. Survey
   II. Burden of disease
   III. IVD diagnostic performance
   IV. Patient management & treatment
   V. Final ranking
4. Remarks for your consideration
## Final Ranking (DALYs)

<table>
<thead>
<tr>
<th>Top-10 Target diseases</th>
<th>Assay formats</th>
<th>HQ DTA evidence</th>
<th>Curative treatment</th>
<th>Other patient management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pneumonia</td>
<td>Immunochromatographic</td>
<td>-</td>
<td>X</td>
<td>Vaccination</td>
</tr>
<tr>
<td>2. HIV</td>
<td>Immunochromatographic, immunofluorescence</td>
<td>-</td>
<td>X*</td>
<td>-</td>
</tr>
<tr>
<td>3. Malaria</td>
<td>Immunochromatographic</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>4. Tuberculosis</td>
<td>Immunofluorescence, immunochromogenic, NAT</td>
<td>X</td>
<td>X</td>
<td>Vaccination, quarantine</td>
</tr>
<tr>
<td>5. Syphilis</td>
<td>Immunochromatographic, lateral flow</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>6. Measles</td>
<td>Immunochromatographic, lateral flow, ELISA, RDT</td>
<td>-</td>
<td>X**</td>
<td>Vaccination</td>
</tr>
<tr>
<td>7. Hepatitis B</td>
<td>Immunochromatographic</td>
<td>-</td>
<td>X</td>
<td>Vaccination</td>
</tr>
<tr>
<td>8. Sickle cell disease</td>
<td>Immunochromatographic</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>9. Dengue</td>
<td>Immunochromatographic, lateral flow, NAT, serology, ELISA, immunofluorescence</td>
<td>X</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10. Meningococcal meningitis</td>
<td>Immunochromatographic</td>
<td>-</td>
<td>X</td>
<td>Vaccination</td>
</tr>
</tbody>
</table>

* Not completely curative, but significant suppression of symptomatic disease
** Only vaccination 72 after exposure
# Final Ranking (survey frequency)

<table>
<thead>
<tr>
<th>Top-10 Target diseases</th>
<th>Assay formats</th>
<th>HQ DTA evidence</th>
<th>Curative treatment</th>
<th>Other patient management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Zika</td>
<td>Immunochromatographic, lateral flow, NAT, serology, ELISA, immunofluorescence</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2. Dengue</td>
<td>Immunochromatographic, lateral flow, NAT, serology, ELISA, immunofluorescence</td>
<td>X</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3. Ebola</td>
<td>Immunochromatographic, lateral flow, NAT, CBNAT</td>
<td>-</td>
<td>-</td>
<td>Quarantine</td>
</tr>
<tr>
<td>4. Measles</td>
<td>Immunochromatographic, lateral flow, ELISA, RDT</td>
<td>-</td>
<td>X*</td>
<td>Vaccination</td>
</tr>
<tr>
<td>5. Yellow Fever</td>
<td>Immunochromatographic, lateral flow, ELISA, RDT, NAT</td>
<td>-</td>
<td>-</td>
<td>Vaccination</td>
</tr>
<tr>
<td>6. Rubella</td>
<td>Immunochromatographic, lateral flow, ELISA</td>
<td>-</td>
<td>-</td>
<td>Vaccination</td>
</tr>
<tr>
<td>7. Tuberculosis</td>
<td>Immunofluorescence, immunochromogenic, NAT</td>
<td>X</td>
<td>X</td>
<td>Vaccination, quarantine</td>
</tr>
<tr>
<td>8. Hepatitis C</td>
<td>Immunochromatographic, immunofluorescence</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>9. HIV</td>
<td>Immunochromatographic, immunofluorescence</td>
<td>-</td>
<td>X**</td>
<td>-</td>
</tr>
<tr>
<td>10. Chlamydia</td>
<td>Immunochromatographic, lateral flow</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
</tbody>
</table>

* Only vaccination 72 after exposure  
** Not completely curative, but significant suppression of symptomatic disease
WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 21 January 2019

<table>
<thead>
<tr>
<th>Year prequalified</th>
<th>Type of assay</th>
<th>Product name</th>
<th>Product code(s)</th>
<th>Regulatory version</th>
<th>Manufacturer</th>
<th>Manufacturing site(s)</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>SD BIOLINE Malaria Ag. P.f./P.v.</td>
<td>05FK120 and 05FK123</td>
<td>CE-mark</td>
<td>Standard Diagnostics, Inc.</td>
<td>65 Borahagol-ro, Gheungs-gu, Yongin-si, Gyeonggi-do, South Korea</td>
<td>25T/kit; 1T/kit</td>
</tr>
<tr>
<td>2018</td>
<td>HIV RDT for self-testing</td>
<td>INSTI® HIV Self Test</td>
<td>90-1071</td>
<td>rest-of-world</td>
<td>Biolytical Laboratories Inc.</td>
<td>Richmond, British Columbia, Canada</td>
<td>1T/kit</td>
</tr>
<tr>
<td>2018</td>
<td>HIV RDT</td>
<td>One Step HIV-1/2 Whole Blood/Serum/Plasma Test</td>
<td>W006-C4P2 and W006-C4P2-F</td>
<td>rest-of-world</td>
<td>Guangzhou Wondfo Biotech Co., Ltd.</td>
<td>8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China</td>
<td>25T/kit; 40T/kit</td>
</tr>
<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>One Step test for Malaria P/Pv Ag MERISCREEN Malaria P/Pv Ag</td>
<td>MFLRPD-02</td>
<td>rest-of-world</td>
<td>Meril Diagnostics Pvt. Ltd.</td>
<td>D1-03, Meril Park, Survey No. 135/2/B &amp; 174/2, Muktamand Marg, Chalia, Vapi 396191, Gujarat, India</td>
<td>30T/kit</td>
</tr>
</tbody>
</table>
Remarks for your consideration

- Priority setting for prequalification is dependent on the outcome of interest that is chosen.
- Evidence of diagnostic accuracy is abundant in some area’s, as opposed to completely lacking in others.
- Availability and effectiveness of patient management and treatment should be considered when setting priority.
Thank you for your attention
Questions?
Disclaimers:

- Pneumonia was classified as lower respiratory tract infections
- Trypanosomiasis was classified as African trypanosomiasis
- Cryptococcal meningitis incidence and prevalence from 2017 paper
- Cryptococcal meningitis DALYs calculated by taking proportion of incidence vs total meningitis incidence, and multiplying by DALYs from meningitis
- Rubella incidence was based on 2017 numbers (WHO report from 2018)
- Rubella DALYs were based on incidence and 32 average DALY loss per patient from CRS
- Hepatitis = acute + cirrhosis and other chronic liver diseases (excluding liver cancer)
- Ebola incidence and prevalence numbers from 2016 (from 2017 paper)
- Onchocerciasis incidence from 2016 (from 2017 paper)
- Schistosomiasis incidence from 2016 (from 2017 paper)
Methods

Additional survey information

- Availability of disease / IVD WHO documentation
- Availability of disease / IVD target product profile (TPP)
- Procurement
Methods: Survey (1)

**General**
- Name of Organization
  - e.g. WHO, Médecins sans Frontières
- Disease category/infection
  - e.g. syphilis, malaria
- Analyte
  - e.g. HBsAg, HRP2
- Assay format
  - e.g. Immunochromatographic, NAT-qualitative

**Reference documents**
- Reference to WHO documents
- WHO target product profile (TPP)
Methods: Survey (2)

**IVD and disease data**
- Burden of disease  
  e.g. DALY’s, incidence, prevalence
- Target use setting
- Target end user
- The context in which the IVD type is/will be used
- Product shortcomings
- Risks related to the product
Methods: Survey (3)

Procurement
- Which products are currently on the market / in the pipeline
- International procurement data
- Which procurers buy them (UN and non-UN) and in what quantities
- What drives the current demand
- Is demand focused on a few countries or regional/world-wide

Additional information
Burden of disease

DALYs by continent within target disease

000's DALYs

Pneumonia, HIV, Malaria, Tuberculosis, Syphilis, Measles, Hepatitis B, Sickle Cell disease, Dengue fever, Meningococcal, Schistosomiasis, Onchocerciasis, Cryptococcal meningitis, Leishmaniasis, Rubella, Chlamydia, Yellow Fever, Hepatitis C

Africa, America, Asia, Europe
Burden of disease

DALYs by social demographic index (SDI) within target disease

000's DALYs

- Pneumonia
- HIV
- Malaria
- Tuberculosis
- Syphilis
- Measles
- Hepatitis B
- Sickle Cell disease
- Dengue fever
- Meningococcal meningitis
- Schistosomiasis
- Onchocerciasis
- Cryptococcal meningitis
- Leishmaniasis
- Chlamydia
- Yellow Fever
- Hepatitis C
- Trypanosomiasis

Low SDI
Low-middle SDI
Middle SDI
Middle-high SDI
High SDI
Burden of disease

Basic reproductive number (R0) by disease

- Pneumonia
- HIV
- Malara
- Tuberculosis
- Syphilis
- Measles
- Hepatitis B
- Sickle Cell disease
- Dengue fever
- Meningococcal meningitis
- Schistosomiasis
- Onchocerciasis
- Cryptococcal meningitis
- Leishmaniasis
- Rubella
- Chlamydia
- Yellow Fever
- Hepatitis C
- Trypanosomiasis
- Zika virus disease
- Ebola virus disease
- Marburg virus disease
Burden of disease

Case-fatality rate (CFR) by disease

- Untreat. Case fatality rate
- Treat. Case fatality rate
<table>
<thead>
<tr>
<th>Category</th>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burden of disease</td>
<td>High prevalence</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>High incidence</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>High disability-adjusted life-years (DALYs)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Highly infectious</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IVD test performance</td>
<td>High sensitivity (low FN fraction)</td>
<td>0</td>
<td>0</td>
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<tr>
<td></td>
<td>High specificity (low FP fraction)</td>
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<tr>
<td>Patient management</td>
<td>Effective curative treatment available?</td>
<td>0</td>
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<tr>
<td></td>
<td>Effective containment strategy available?</td>
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</tr>
<tr>
<td></td>
<td>Effective preventative treatment available?</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>