Field validation of novel diagnostic tools for Ebola virus detection in Sierra Leone
EbolaMoDRAD project in Sierra Leone

- Field evaluation of promising tools for the diagnosis of Ebola virus developed in the framework of the EbolaMoDRAD consortium:
  - Fast RT-qPCR for Ebola RNA detection
    *(by CLONIT S.r.l. and STMicroelectronics S.r.l., Italy)*
  - Rapid test for Ebola Antigen detection
    *(by Coris BioConcept, Belgium)*

- By INMI “L. Spallanzani” (Italy) in collaboration with the Italian NGO ‘EMERGENCY’ in Sierra Leone, using residual samples collected during the 2013-2016 Ebola outbreak in West Africa
Lateral flow immunoassay → Ebola Zaire virus VP40 viral matrix protein

Amount of sample: 30 mL of plasma or serum, or 50 mL of whole blood

210 plasma samples tested:
- 105 Ebola-positive
- 105 Ebola-negative

<table>
<thead>
<tr>
<th>Percentage (95% CI)</th>
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<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
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<tr>
<td><strong>Specificity</strong></td>
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<tr>
<td><strong>PPV</strong></td>
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<td><strong>NPV</strong></td>
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<tr>
<th>EBOV RNA &gt;6.2 cp/ml</th>
<th>EBOV RNA &lt;6.2 cp/ml</th>
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<tr>
<td><strong>Sensitivity</strong></td>
<td>98.7% (96.1 - 101.2)</td>
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<tr>
<td><strong>PPV</strong></td>
<td>97.4% (93.8 - 101.0)</td>
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<tr>
<td><strong>NPV</strong></td>
<td>99.4% (97.2 - 100.9)</td>
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Performance of the *Quanyt ZEBOV FAST* kit & the *Q3-Plus PCR* system

- RT-qPCR ready-to-use with Ebola RNA quantification
- Miniaturized RealTime thermal cycler based on fluorescence detection and disposable lab-on-chip cartridge
  - 116 RNA extracted samples:
    - 43 Ebola positive
      (32 from plasma, 8 from urine, 3 from oral swabs)
    - 76 Ebola negative

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<tr>
<td>Sensitivity</td>
<td>100%</td>
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<tr>
<td>Specificity</td>
<td>98.63% (96.34 – 100.92)</td>
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<tr>
<td>PPV</td>
<td>97.73% (94.77 – 100.68)</td>
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<tr>
<td>NPV</td>
<td>100%</td>
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Possible algorithm for Ebola virus Disease (EVD) diagnosis

Screening of EVD Suspect case during the triage

EBOLA Ag K-SeT

NEGATIVE result*

POSITIVE result

Confirmationary Quanty ZEBOV Fast PCR test *

Patient affected by EVD

Blood samples withdrawn after the first 48 hrs of symptom onset?

NO

YES

Request a second sample withdrawn at least 48 hrs after symptom onset*

Patient not affected by EVD

POSITIVE result

NEGATIVE result

Patient affected by EVD

Blood samples withdrawn after the first 48 hrs of symptom onset?

NO

YES

Request a second sample withdrawn at least 48 hrs after symptom onset*

The results are not sufficient. Request a second sample for the final result *

Isolation and treatment (if available) of the patient

* If the PCR is not available, send the sample to the reference laboratory for PCR test confirmation

# Isolation measures must be adopted until two negative RT-PCR test results, at least 48 hours apart, are obtained.