

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

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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)

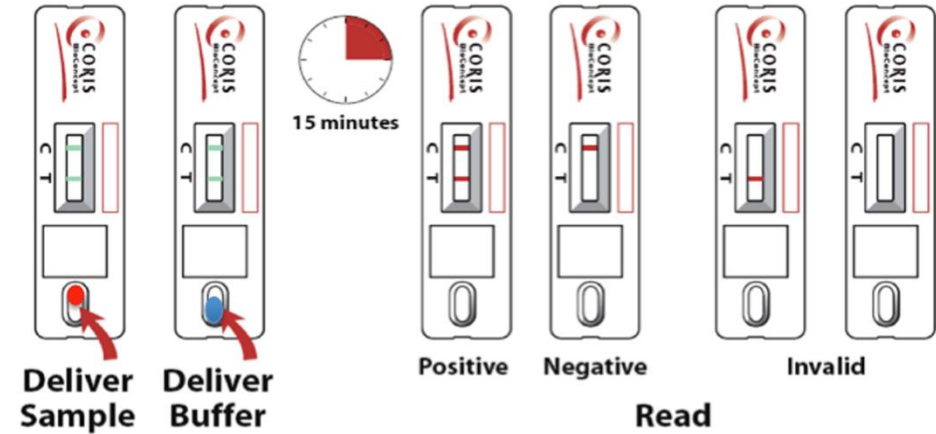
- By INMI “L. Spallanzani” (Italy) in collaboration with the Italian NGO ‘EMERGENCY’ in Sierra Leone, using residual samples collected during the 2013-2016 Ebola outbreak in West Africa



Performance of the *EBOLA Ag K-SeT* rapid test

- 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

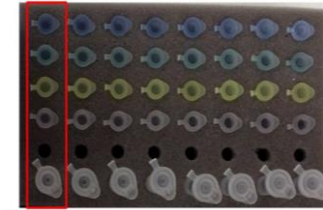


	Percentage (95% CI)
Sensitivity	88.6% (82.5 - 94.7)
Specificity	98.1% (95.5 - 100.7)
PPV	97.9% (95.0 - 100.8)
NPV	89.6% (84.0 - 95.2)

	Percentage (95% CI)	
	EBOV RNA >6.2 cp/ml	EBOV RNA <6.2 cp/ml
Sensitivity	98.7% (96.1 - 101.2)	62.1% (44.4 - 79.7)
PPV	97.4% (93.8 - 101.0)	90.0% (76.9 - 103.1)
NPV	99.4% (97.2 - 100.9)	90.3% (84.9 - 95.8)

Performance of the *Quanty ZEBOV FAST* kit & the *Q3-Plus PCR* system

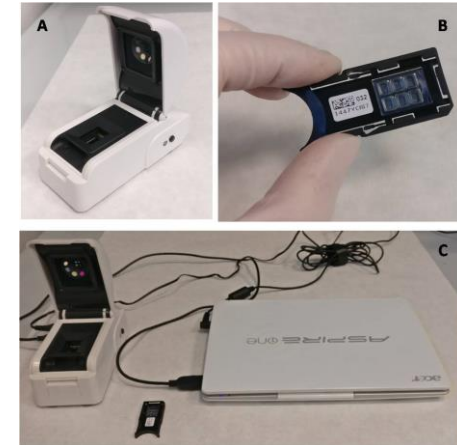
- RT-qPCR ready-to-use with Ebola RNA quantification
- Miniaturized RealTime thermal cycler based on fluorescence detection and disposable lab-on-chip cartridge



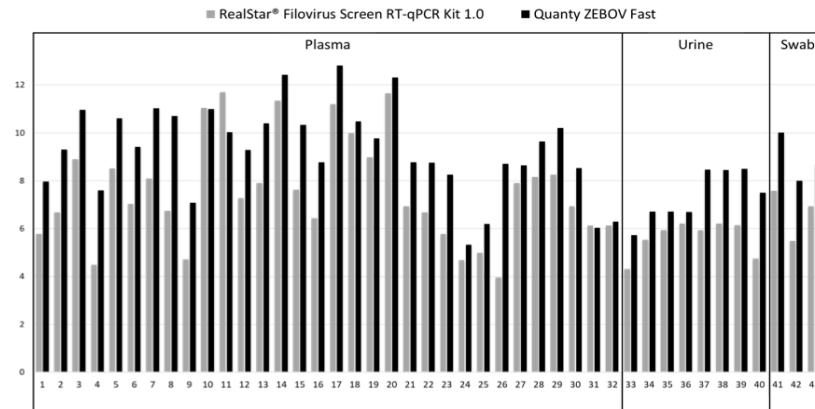
- 116 **RNA extracted** samples:

- 43 Ebola positive
(32 from plasma, 8 from urine, 3 from oral swabs)

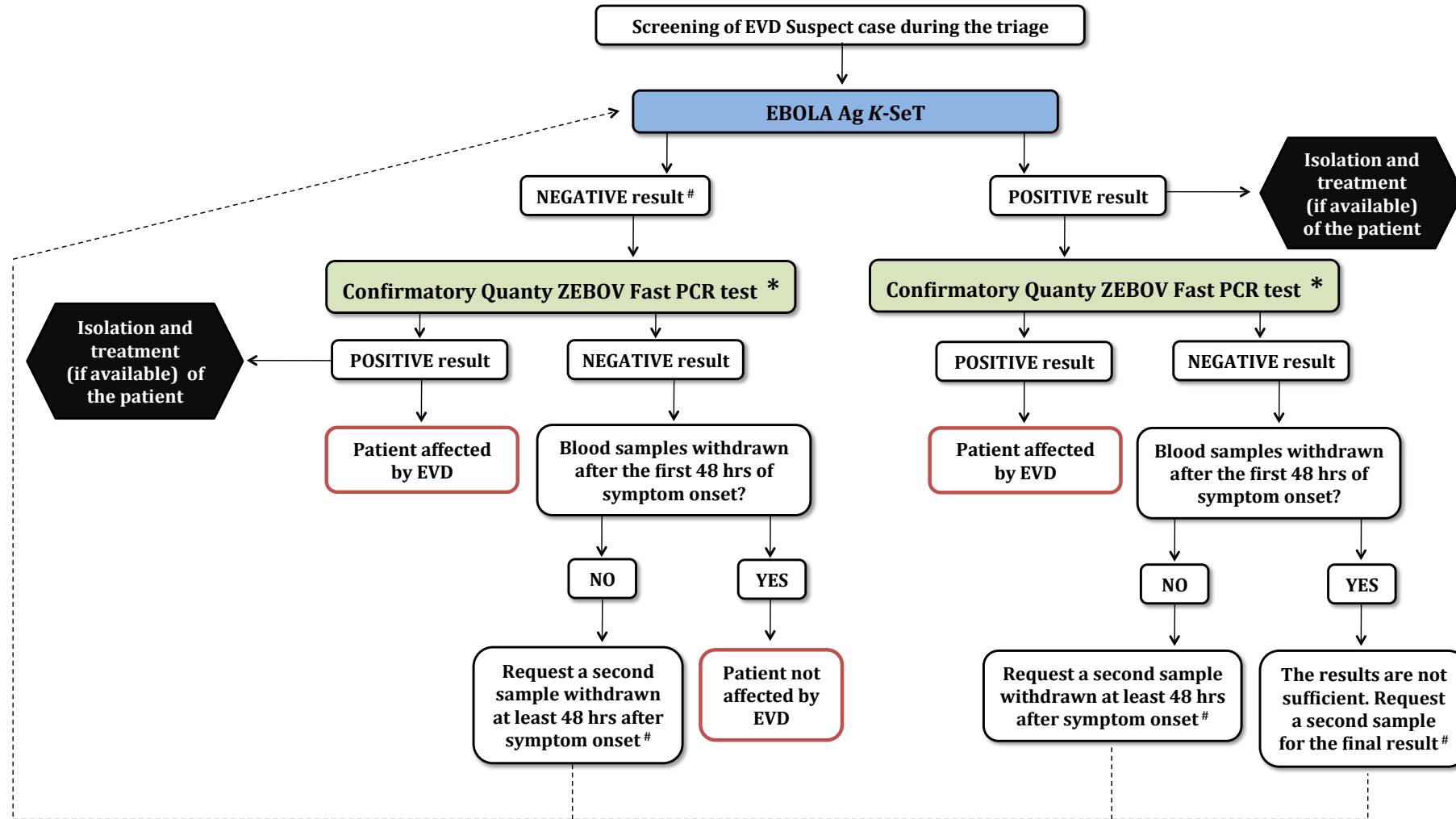
- 76 Ebola negative



	Percentage (95% CI)
Sensitivity	100%
Specificity	98,63% (96,34 – 100,92)
PPV	97,73% (94,77 – 100,68)
NPV	100%



Possible algorithm for Ebola virus Disease (EVD) diagnosis



* 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