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Preliminary evaluation of the EBOLA virus antigen detection K-SeT rapid test in Sierra Leone

Francesca Colavita[1], Mirella Biava*[1], Michela Delli Guanti[2], Antonio Petrocelli[2], Gianluca Cataldi[2], Céline Borlon[3], Pascal Mertens[3], Quentin Gilleman[3], Alhaji Thaimu Kamara[2], Santigie Abdul Kamara[2], Kelfala Konneh[2], Concetta Castilletti[1], Donatella Vincenti[4], Alì Mirazimi[5], Rossella Miccio[6], Antonino DI Caro[7]

[1]*National Institute for Infectious Diseases Irccs L.Spallanzani*

[2]*Emergency Ngo*

[3]*Coris Bioconcept*

[4]*National Institute for Infectious Diseases Inmi Irccs L. Spallanzani*

[5]*Swedish Institute for Infectious Disease Control*

[6]*Emergency Ong Onlus*

[7]*National Institute for Infectious Diseases L. Spallanzani - Irccs; Virology Laboratory*

Background: One of the main takeaways from the recent Ebola virus disease (EVD) epidemic in West Africa is that the efficient interruption of the EVD transmission chains critically depends on reliable and rapid diagnosis. EVD diagnosis is currently performed using reverse transcription-PCR (RT-PCR) method, which is highly sensitive and specific but requires skilled laboratory personnel and advanced equipment. New rapid and safe diagnostic tests, performed as point-of-care or in resources-poor settings are needed. Coris BioConcept (Gembloux, Belgium) developed within the EbolaMoDRAD project a rapid diagnostic test (RDT), EBOLA virus Antigen detection K-SeT. We evaluated its performance in the EVD laboratory established at the Princess Christian Maternity Hospital (PCMH) in Freetown (Sierra Leone) run by of Emergency NGO and the Italian National Institute for Infectious Diseases (INMI).

Material/methods: Residual aliquots of plasma samples (n=210, EVD prevalence 50%) collected from patients hospitalized at the Emergency NGO's Ebola Treatment Centre in Goderich (Sierra Leone) from 12 December 2014 to 21 June 2015 and stored at -20°C were anonymized and retrospectively used for the evaluation of the RDT. This is a lateral flow immunoassay which detects Ebola virus Zaire and Sudan strains Vp40 antigen and which is based on immunochromatography in a sandwich format.The diagnostic efficacy of the RDT was only evaluated for Ebola virus Zaire strain and comparing the clinical results obtained with the reference RT-PCR test (RealStar® Filovirus Screen RT-PCR Kit 1.0, Altona Diagnostics).

Results: Overall, the sensitivity of the RDT resulted 88.6% (95% Confidence Interval [CI]: 82.5%-94.7%) and the corresponding specificity was 98.1% (95% CI: 95.5%-100.7%), using Ebola virus RT-PCR as the reference method. The positive and negative predictive values for the samples prevalence were 97.9% (95% CI: 95.0–100.8%) and 89.6%% (95% CI: 84%–95.2%), respectively.

Conclusions: The recent EVD epidemic in West Africa emphasised the need for rapid, sensitive, reliable virus-specific diagnostic tests to control the spread of the EVD. Rapid and simple antigen detection tests are likely one of the options for early diagnosis for filovirus in the field, supporting their use as a rule-out screen tests. The results obtained in this preliminary field evaluation demonstrate that EBOLA virus Antigen detection K-SeT (Coris BioConcept) could represent a new promising effective and rapid diagnostic tool for EVD diagnosis, meeting the needs for minimal resources (in term of power supply as well as skilled laboratory personal), point-of-care and rapid diagnosis and triage individuals with EVD.