

VHFMoDRAD 4th newsletter

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VHFMoDRAD: what has been done?

Development of innovative and novel diagnostic tools for hemorrhagic fever virus diseases in endemic and non-endemic areas

The development of several essential tools for rapid molecular multiplex and serological antigen/antibody detection methods for use as Point-of-Care (POC) and surveillance at the level of clinical diagnostic laboratories and at healthcare centers has been developed further.

Transfer of reference TaqMan assay to open cartridges developed by CEPHEID (Flex04) operated on GeneXpert platforms:

Target viruses are YFV, RVFV, MARV, LASV, CCHFV and SFTSV

The prerequisite tasks for the transfer of reference Polymerase Chain Reaction (PCR) assays into the Cepheid Flex-C platform have been moved forward. The protocol and conditions have been setup and all the materials required for the transfer and testing validation are available at the Partners laboratories. The transfer has been initiated for Yellow fever virus, Rift valley fever virus, Marburg virus, Lassa virus and Crimean Congo hemorrhagic fever virus.

Development of a novel low-cost high-performance molecular POC In Vitro Diagnostic (IVD) test using Recombinase Polymerase Amplification (RPA):

Due to interrupted access to key reagents for isothermal RPA amplification (i.e. SARMS primers and RPA reagents), isothermal LAMP method was selected as an alternative isothermal molecular method. The feasibility of the detection of LAMP products in a closed carry-over contamination-proof cassette was demonstrated.

The RPA has been resumed thanks to the MHB-hired post-doctoral fellow. prototype for the detection of Zika virus was successfully tested by a team at the IPGMER- Institute of Post-Graduate Medical Education and Research in Kolkata, India.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement N° 823666. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and CEPHEID Europe SAS.





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Team member of the IPGMER handling the RPA lateral flow prototype.

Serological antigen/antibody detection methods for point-of-care and routine laboratories at very early diagnosis stage.

Sensitive lateral flow POC tests for detection of antigens and antibodies against hemorrhagic fever virus for POC diagnostic: requires no/little equipment, delivers data less than 30 minutes, and is user-friendly to general health care workers, technicians and nurses.

New reagents (antigens and antibodies) have been developed for the serological diagnostic test of CCHF and Lassa viruses. An ELISA assay for CCHF virus detection has been developed. Six LFA (lateral flow assays) prototypes were developed: a CCHF Ag K-SeT and a Lassa Ag K-SeT (for antigen detection), a CCHF IgM Ab K-SeT and a Lassa IgM Ab K-SeT (for IgM detection) and a CCHF IgG Ab K-SeT and a Lassa IgG Ab K-SeT (for IgG detection). All 6 LFAs are serological assays to be used with whole finger-pricked or veinous blood, serum or plasma.

In order to develop the Ag K-SeT assays , new monoclonal antibodies were developed, selected and optimized in a sandwich test.

For the Ab K-SeT assays, a sandwich assay using an anti-IgG or an anti-IgM and a virus protein was developed.

efpia

Cepheid.



Validation of newly developed diagnosis tools

Progresses have been made for Cepheid (molecular) and Coris (serological) diagnosis tools regarding preclinical and clinical validation: first results were collected and few experiments are still ongoing.

All the trainings by Cepheid on the equipment has been organized at the partners' laboratories. The shipment of the GeneXpert Flex-04 cartridges and reagents was organised to complete and replace the expired reagents within the WP4 facilities. The GeneXpert machine was sent to Sivas Cumhuriyet Universitesi (SCU) who joined the project in September 2020.

In addition to the inventory of the archived samples, partner SCU continued to collect acute and convalescent stage CCHF clinical samples for validation studies.

Implementation of a capacity-building programme in West Africa

The market analysis has been conducted and finalized. According to the market analysis, GASTROVIR test (Rotavirus/Adenovirus duo test) from Coris has been transferred to Dakar (IPD) for a first production. These activities have been facilitated thanks to the DiaTropix platform built in IPD campus, independently of the VHFMoDRAD project, aimed to implement the capacity to manufacture LFA (lateral flow assays) in Dakar.

Ethical clearance for project activities in the field has been obtained in Turkey (SCU) in April 2021 and study protocol has been submitted by IPD in Senegal in November 2021.

Communication and dissemination of the results

First VHFMoDRAD newsletter has been published and is accessible on the <u>VHFMoDRAD website</u>. A plan to engage with related initiatives was prepared and is starting to be implemented.

Activities within the WP6 have been affected by COVID-19 situation (travel restrictions, cancellation of events, partners involved in the crisis). The website has been updated and a new version of the exploitation plan is available.













News from VHFMoDRAD

Relevant publications, abstracts, conferences

"Lyophilized Matrix Containing Ready-to-Use Primers and Probe Solution for Standardization of Real-Time PCR and RT-qPCR Diagnostics in Virology" (*Charrel et Al., Viruses. 2020 Jan 30;12(2). pii: E159. doi: 10.3390/v12020159*) <u>https://www.mdpi.com/1999-4915/12/2/159</u>

November 21st, 2019: MEDICA (Dusseldorf, Germany) Participation of partner CORIS, VHFMoDRAD project leaflet presented.

June 14-16th, 2019: 7th European seminar in Virology (Padova, Italy) Presentation by partner UCPH (O. Blixt) – "Efficient identification of immunodominant (glycol) peptides for type-specific serology and monoclonal antibody developments" <u>EuSeV 2019</u>

April 15-16th, 2019: European Congress of Clinical Microbiology and Infectious Diseases (Amsterdam, The Netherland)

Poster presentation by CORIS: "Evaluation of new rapid diagnostic tests for Ebola virus disease" <u>ESCMID eLibrary</u>

October, 2020: International Conference on (re-)Emerging Infectious Diseases (Addis Abbaba, Ethiopia) ICREID Program

Poster to be presented by Partner INMI: "Full-Length Genome Sequence of a Dengue serotype 1 virus isolate from a traveler returning from Democratic Republic of Congo to Italy", July 2019, Francesco Vairo

Useful Links

VHFMoDRAD <u>https://vhfmodrad.eu/</u> <u>https://www.imi.europa.eu/projects-results/project-factsheets/vhfmodrad</u>

IMI Ebola+ programme

https://www.imi.europa.eu/projects-results/project-factsheets/ebola

EbolaMoDRAD

http://www.ebolamodrad.eu/ https://www.imi.europa.eu/projects-results/project-factsheets/ebolamodrad

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VHFMoDRAD Partners

- Folkhälsomyndigheten (FoHM), Sweden
- Inserm Transfert (IT), France
- University of Stirling (UoS), United Kingdom
- Department of Health, Public Health England (DH-PHE), United Kingdom
- Coris BioConcept SRL (CORIS), Belgium
- Institut national de la Santé et de la recherche médicale (INSERM), France
- University of Copenhagen (UCPH), Denmark
- Istituto Nazionale per le Malattie Infettive "L. Spallanzani" I.R.C.C.S (INMI), Italy
- Institut Pasteur de Dakar (IPD), Senegal
- RD-Biotech (RD-B), France
- CEPHEID, France
- Aix-Marseille University (AMU), France
- Emergency (EMR), Italy
- Sivas Cumhuriyet Üniversitesi (SCU), Turkey
- Medizinische Hochschule Brandenburg (MHB), Germany

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