



Overlooking the Importance of Immunoassays - Authors' Reply

Authors	Cnops, L; van Griensven, J; Honko, AN; Bausch, DG; Sprecher, A; Hill, CE; Colebunders, R; Johnson, JC; Griffiths, A; Palacios, GF; Kraft, CS; Kobinger, G; Hewlett, A; Norwood, DA; Sabeti, P; Jahrling, PB; Formenty, P; Kuhn, JH; Ariën, KK
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Authors' reply

We appreciate and agree with the statement by Ranu Dhillon and colleagues that immunoassays have been and still are a critical tool for the diagnosis of many viral diseases. The focus of our Personal View¹ was on the quantification of the viral load of filoviruses, for which molecular tests are the most suitable. We do not question or undervalue the usefulness of immunoassays in filovirus disease diagnosis or other viral diseases. Such assays, however, are not quantitative and therefore do not pose a solution for the lack of comparison between quantitative assays, facilities using such assays, and clinical studies dependent on such assays.¹

Immunoassays as tools for the diagnosis of filovirus disease also face challenges. First, nucleic acid tests (NATs) such as RT-PCR can be developed and adapted more rapidly in response to newly identified filoviral variants than can immunoassays—ie, they can be easier and quicker to implement. Second, we agree with Piriou and colleagues² that immunoassays for Ebola virus disease diagnosis have imperfect sensitivity and specificity, and that a confirmatory NAT will still need to

be obtained to exclude false-negative immunoassay results.³ Third, there are biosafety concerns associated with the use of immunoassays for filovirus detection, especially in a resource-limited context.^{2,4} Piriou and colleagues² note that immunoassays “can be safely used only in a setting with strict biosafety measures” and suggest that many such settings will already have PCR available. Consequently, NATs have been a standard in filovirology for many years and serve as a powerful tool for clinical care and molecular-epidemiological investigations.^{4,5}

Dhillon and colleagues raise important points in regards to the lack of infrastructure in African countries for any kind of diagnostic operation, and the need for tools for triage. In the case of filovirus disease diagnosis, specialised infrastructure was becoming increasingly available in several African countries in terms of (mobile) reference laboratories, maximum-containment facilities in Gabon and South Africa, WHO viral haemorrhagic fever reference laboratories in numerous countries, and ongoing training programmes for local personnel on diagnostic testing for Ebola virus disease. There are still many ongoing challenges, such as the lack of refrigeration and electricity, that must be overcome to enable the most widespread deployment of all forms of diagnostic capacity.⁴

Lastly, we would like to emphasise that our Personal View¹ is a call to develop standardised reagents and filovirus assays to increase comparability between varied assays and testing facilities.

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*Lieselotte Cnops, Johan van Griensven, Anna N Honko, Daniel G Bausch, Armand Sprecher, Charles E Hill, Robert Colebunders, Joshua C Johnson, Anthony Griffiths, Gustavo F Palacios, Colleen S Kraft, Gary Kobinger, Angela Hewlett, David A Norwood, Pardis Sabeti, Peter B Jahrling, Pierre Formenty, Jens H Kuhn, *Kevin K Ariën*
karien@itg.be

Department of Clinical Sciences, Institute of Tropical Medicine, Antwerp, Belgium (LC, JvG); Integrated Research Facility at Fort Detrick, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Frederick, MD, USA (ANH, JHK, JCJ, PBJ); WHO, Geneva, Switzerland (DGB, PF); Médecins Sans Frontières—Operational Center of Brussels, Brussels, Belgium (AS); Molecular Diagnostics Laboratory, Emory University Hospital, Atlanta, GA, USA (CEH); International Health Unit, Global Health Institute, Faculty of Medicine and Health Sciences, Antwerp University, Antwerp, Belgium (RC); Department of Virology and Immunology, Texas Biomedical Research Institute, San Antonio, TX, USA (AG); United States Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD, USA (GFP, DAN); Pathology and Laboratory Medicine, Emory University Medical School, Atlanta, GA, USA (CSK); National Microbiology Laboratory, Public Health Agency of Canada, University of Manitoba, Winnipeg, MB, Canada (GK); University of Nebraska Medical Center, Omaha, NE, USA (AH); FAS Center for Systems Biology, Department of Organismic and Evolutionary Biology, Harvard University, Cambridge, MA, USA (PS); and Department of Biomedical Sciences, Institute of Tropical Medicine, Antwerp, Belgium (KKA)

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