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## UMELISA EGF®: The companion kit for CIMAvax-EGF® vaccine

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**Background:** CIMAvax-EGF® is a Cuban therapeutic vaccine approved for treatment of advanced non-small cell lung cancer (NSCLC). By inducing antibodies vs. epidermal growth factor (EGF), it prevents binding of endogenous EGF to its receptor, thereby reducing tumor size and/or its progression. Phase II and III clinical trials carried out in Cuban patients revealed the pre-treatment predictive value of serum EGF concentrations ([sEGF]) for CIMAvax-EGF® efficacy. Therefore, it makes sense to identify the subset of patients which will be really benefitted with the use of the vaccine, through its stratification by [sEGF] (personalized medicine). The aim of this work was to develop and validate the UMELISA EGF® kit, the future companion diagnostic kit of CIMAvax-EGF® vaccine.

**Methods:** The ultra micro analytical system technology (Immunoassay Center, Cuba) was used. The system includes the plate washer and instrumentation for automatic reading, quantification, validation and interpretation of results.

**Results:** A simple sandwich-type ultramicroELISA assay UMELISA EGF®, based on the advantages of high affinity reaction between streptavidin and biotin, was developed for the measurement of [sEGF]. The best performance was achieved with: plates coated with mAb CBEGF-1 at 6 µg/mL, biotinylated mAb CBEGF-2 at 0.5 µg/mL, incubation time for sandwich formation of 18-20 hours at 37 °C and sample volumes of 30 µL.

**Conclusions:** The UMELISA EGF® kit exhibited similar characteristics to other commercially available assays, in terms of precision, accuracy and dynamic range. Regression analysis showed a good correlation with the commercially available Human EGF Immunoassay Quantikine® ELISA kit (n=130, Pearson r=0.92, p<0.01) (R&D Systems, USA).

### Biography

Idania González Pérez has completed her BSc in Physics from the Faculty of Physics, Moscow State University, Russia (1985-1990) and Master of Science in Physics and Mathematics from Faculty of Physics, Moscow State University, Russia. She is now involved in a PhD program at the University School of Medicine in Havana. She is a Senior Researcher at the Center for Molecular Immunology in Havana, Systems Biology Department, Biomarkers Group. She has published more than 15 papers in reputed journals and has been serving as a Reviewer in *Medical Science Monitor*, *Journal of Hospital and Clinical Pharmacy and International Blood Research & Reviews*.

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