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A simple and rapid assay for determination of susceptibility of influenza virus to neuraminidase inhibitors

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Zanamivir (Relenza®) and oseltamivir (Tamiflu®) are the current mainstays of antiviral therapy for influenza.As demonstrated in the 2008/2009 influenza season in US, when the vast majority of circulating A/H1N1 virus was resistant to Tamiflu, widespread drug resistance to an influenza antiviral can emerge rapidly. A simple and rapid influenza virus drug susceptibility assay could be useful in susceptibility surveillance and in clinical settings.Since zanamivir and oseltamivir (as well as a few in the pipeline) are inhibitors of influenza viral neuraminidase, we designed a luciferin derivatized substrate specific for this enzyme. The substrate was formulated in a master mix (Reagent I) for detection of influenza virus in a sample. Presence of influenza virus (hence viral neuraminidase) in the reaction mix leads to cleavage of the substrate, freeing the luciferin moiety which is immediately consumed by luciferase to generate detectable light signal. For detection of resistance to zanamivir or oseltamivir, we formulated a second master mix (Reagent II) which was identical to Reagent I mix except that it contained zanamivir or oseltamivir carboxylate. The signal of Reagent II in relation to that of Reagent I as determined by the signal ratio was used to measure the level of susceptibility of influenza virus tozanamivir or oseltamivir.The assay is rapid (17 min) and simple with essentially one manual step (i.e., sample addition). Use of a custom-designed analyzer which can simultaneously measure the signal of both Reagents I and II compute the signal ratio and interpret the test result further simplifies the assay.

Biography

X James Li completed his PhD at Washington State University and Postdoctoral studies from Harvard University (Cambridge, MA) and Stanford University(Carnegie Institution). He is the Founder and CEO of Cellex, a company focusing on development of diagnostic technologies and products. He is also the Founder and Chairman of the Board of Avioq, a company focusing on late stage diagnostic product development and GMP manufacturing; Avioq has a couple of FDA approved or licensed products.

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