

# Quanta BioSciences Achieves Milestone with the FDA Clearance of the CDC Influenza IVD kit which utilizes the Quanta 1-Step RT-qPCR technology

GAITHERSBURG, Maryland, July 8, 2013

Quanta BioSciences today announced that the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Kit, which utilizes QUANTA Biosciences' qScript One-Step qRT-PCR Low ROX, has received FDA clearance. This announcement follows the emergency use authorization granted by the FDA on April 22, 2013 for use of the same kit for characterization and detection of H7N9 influenza.

For complete details please download the 510K document at:  
[http://www.accessdata.fda.gov/cdrh\\_docs/pdf13/K130551.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/K130551.pdf)

The U.S. FDA clearance of the CDC kit, which utilizes the Quanta BioSciences reagents, for influenza testing is a landmark event for Quanta BioSciences which is based in Gaithersburg, MD. The clearance is the result of substantial efforts by the teams in the CDC influenza branch and their colleagues in the public health laboratories who participated in the clinical trial.

Quanta BioSciences has created a strong track record in developing molecular biology reagents that offer superior performance in terms of sensitivity, reproducibility, and specificity. As a result, Quanta BioSciences' products have achieved broad adoption in Public Health laboratories around the world.

Quanta BioSciences' qScript One-Step qRT-PCR Low ROX kit is part of a complete portfolio of reagents developed by Quanta BioSciences designed to enable the sensitive and specific performance of RT-qPCR and qPCR in the presence of inhibitors common in public health samples. These "*Tough*" reagents are ideal for groups working with RNA or DNA isolated from stool, blood, saliva, mucus, plant, and soil samples.

Quanta BioSciences maintains a worldwide distribution network which offers the qScript One-Step qRT-PCR technology across the globe. For more information on this technology or to determine how to source these kits, please visit <http://www.quantabio.com/influenza>. For more information on the complete ToughMix portfolio, visit <http://www.quantabio.com>.

## **About Quanta Biosciences:**

Quanta BioSciences Inc., based in Gaithersburg, MD, USA, supplies superior quality reagents for demanding RT and PCR applications in life science, drug discovery and public health laboratories around the world. The Quanta BioSciences PCR and cDNA synthesis reagent portfolio defines the standard for reproducibility, specificity and sensitivity in the quantitative PCR market. The qScript technology named in CDC protocol LP-152 is part of a large family of polymerases designed and built for robust quantitative amplification and detection.

Contacts:

Media Contact:

Will Geist, Quanta BioSciences, +1 800-364-2149, ext. 702 or email [will.geist@quantabio.com](mailto:will.geist@quantabio.com)