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Emergency Use & Vaccine Approval

FDA Grants Emergency Use for 2 Rapid H1N1 Tests

The FDA has granted Emergency Use Authorization (EUA) for two rapid tests for detecting novel H1N1:

ELITech's Molecular Diagnostics 2009-H1N1 Influenza A Virus Real-Time RT-PCR

- Letter of Authorization
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190811.htm>
- Fact Sheet for Healthcare Providers
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190812.htm>
- Fact Sheet for Patients
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190813.htm>
- Labeling (PDF)
<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM190810.pdf>

Roche's RealTime Ready Influenza A/H1N1 Detection Set

- Letter of Authorization
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190740.htm>
- Fact Sheet for Healthcare Providers
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190741.htm>
- Fact Sheet for Patients
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm190742.htm>
- Labeling (PDF)
<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM190739.pdf>

The FDA previously approved six other pandemic flu tests for emergency use. See <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>

FDA Approves Additional Vaccine for H1N1

The FDA has approved a fifth vaccine for protection against the H1N1. The vaccine is manufactured by ID Biomedical Corp., owned by GlaxoSmithKline. Labeling/Package Insert:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf>