RSV test provides rapid results
The FDA has approved using nasopharyngeal swab specimens on the BD Veritor System (BD Diagnostics, Franklin Lakes, NJ) to provide rapid detection of respiratory syncytial virus (RSV). It is the first commercially available rapid Clinical Laboratory Improvement Amendments-waived RSV test system that incorporates a digital result. It is approved for use in clinicians’ offices, hospitals, and other patient-care settings.
When used in conjunction with the BD Veritor System Reader, the RSV test utilizes advanced nanoparticle and adaptive read technologies to obtain accurate results while providing objective results on a hand-held reader with an easy-to-read digital display.

FDA clears test to aid diagnosis of encephalitis
The FDA approved Quest Diagnostics’ (Madison, NJ and Cypress, CA) new Simplexa HSV 1 & 2 direct molecular test on the 3M Integrated Cycler. It is the first molecular test to be cleared by the FDA for the qualitative detection and differentiation of herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) in cerebrospinal fluid from patients suspected of HSV CNS infection, including encephalitis.

The test uses a proprietary process that eliminates nucleic acid extraction so that clinicians can expect results within approximately 1 hour after providing a specimen for testing.

New cochlear implant approved by FDA
The FDA has approved Cochlear Ltd’s (New South Wales, Australia) Nucleus Hybrid L24 Cochlear Implant System, a new type of cochlear implant for adults with severe bilateral sensorineural hearing loss at middle and high frequencies but who can hear low-frequency sounds unaided. It is the first implantable device for this indication and is designed for use on one ear only.

The device combines the functions of a cochlear implant and a hearing aid and consists of an external microphone and speech processor that picks up sounds from the environment and converts them into electrical impulses. The impulses are transmitted to the cochlea through a small bundle of implanted electrodes, creating a sense of sound that the user learns to associate with the mid- and high-frequency sounds they remember. The hearing aid part is inserted into the outer ear canal like a conventional hearing aid and can amplify sounds in the low-frequency range.

In a clinical study of 50 people tested before and after being implanted with the device, a majority of patients reported statistically significant improvements in word and sentence recognition at 6 months after the device’s activation compared with their baseline, preimplant performance using a conventional hearing aid.

Sixty-eight percent of the study subjects experienced one or more anticipated adverse events, such as low-frequency hearing loss and tinnitus. The FDA notes that while the risk of low-frequency hearing loss is of concern, the FDA determined that the overall benefits of the device outweigh this risk for those who do not benefit from traditional hearing aids.

Smaller, thinner ICDs and defibrillators available
Boston Scientific (Natick, MA) has received FDA approval for its latest generation of defibrillators and heart failure devices designed to advance patient care. The newly approved devices include the DYNAGEN MINI and INOGEN MINI ICDs, as well as the DYNAGEN X4 and INOGEN X4 CRT-Ds.

The X4 line of quadripolar CRT-Ds offers 70% more pacing options to address high capture thresholds and phrenic nerve stimulation effectively, along with the largest battery capacity in the industry.

The ICDs in the MINI family are the smallest and thinnest devices currently available and are designed for patient comfort, particularly smaller-framed patients.