# TOTELS

### [Approved Drugs]

- The Food and Drug
  Administration (FDA) approved
  asparaginase Erwinia<sup>TM</sup>
  chrysanthemi (Erwinase,
  injection) (EUSA Pharma (USA),
  Inc., www.eusapharma.com) as
  a component of a multi-agent
  chemotherapeutic regimen for the
  treatment of patients with acute
  lymphoblastic leukemia (ALL) who
  have developed hypersensitivity to
  E. coli-derived asparaginase.
- The FDA has approved cetuximab (Erbitux®)
  (Bristol-Myers Squibb, www. bms.com) in combination with platinum-based chemotherapy with 5-fluorouracil (CT) for the first-line treatment of patients with recurrent locoregional disease and/or metastatic squamous cell carcinoma of the head and neck.

## [GENETIC TESTS AND ASSAYS IN THE NEWS]

■ The FDA has approved the **APTIMA HPV assay** (Gen-Probe Incorporated, *www. gen-probe.com*). The APTIMA HPV assay is an amplified nucleic acid test that detects high-risk strains of human papillomavirus (HPV) that

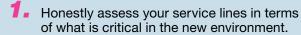
human papillomavirus (HPV) that are associated with cervical cancer and precancerous lesions. The test has been approved to run on Gen-Probe's fully automated, high-throughput TIGRIS instrument system.

■ Abbott (www.abbott.com) announced FDA 510(k) clearance for **Vysis EGR1 FISH Probe Kit**, a new *in vitro* diagnostic test to aid in determining the prognosis of patients with acute myeloid leukemia (AML).

■ Ventana Medical Systems, Inc., (www.ventana.com), a member of the Roche Group, received FDA 510(k) clearance for the Ventana Companion Algorithm HER2

### Fast Facts

#### Top 10 Ways to Reposition Service Lines for an Accountable Care World



- 2 Prioritize your organization's focus.
- Identify and develop physician leadership.
- Implement structures that give responsibility and incentives to physicians for the management of patient care and overall performance of the service line.
- Negotiate with payers for compensation structures that align financial incentives, such as bundled payments, gain sharing, and shared savings.
- Standardize your care process and protocols.
- Eliminate your silos and focus on the continuum of care.
- Redefine the role of your service line leader.
- Leverage information technology.
- 10. Create a culture of continuous improvement.

Source: Riegel BZ. Top 10 Ways to Reposition Service Lines for an Accountable Care World. The Camden Group. Available online at: <a href="https://www.thecamdengroup.com/pdfs/10Aug\_Riegel\_formatted.pdf">www.thecamdengroup.com/pdfs/10Aug\_Riegel\_formatted.pdf</a>.

(4B5) for image analysis applications with associated Virtuoso software and iScan Coreo Au scanner. Ventana is now the only company with a complete workflow solution for determining HER2 (4B5) expression in breast cancer.

Ventana also received FDA clearance for the digital read application that allows the pathologist to view HER2 (4B5) stained slides as images on a computer monitor with Virtuoso software and iScan Coreo Au scanner.

[Devices in the News]

■ The FDA granted Accuray
Incorporated (www.accuray.com)
510(k) clearance to market the
Dose Control System, a new feature of Accuray's TomoTherapy®
System that improves
system performance.

■ Hologic, Inc., (www.hologic. com) received

FDA clearance for the company's **Trident specimen radiography system**. Trident is a mobile system designed to reduce procedure steps, streamline workflow, and give physicians increased confidence in the accuracy of their procedures.

The Trident specimen radiography system is designed for use in the operating room where breast tissue is surgically excised, and in biopsy suites where minimally-invasive, stereotactic or ultrasound biopsies are performed. The new system is self-contained and eliminates the need for samples to be taken to the radiology department for X-ray imaging.

