Put It on the Board

Cobas HPV test approved for first-line screening using SurePath preservative fluid

August 2018—Roche received FDA approval for the Cobas HPV test to be used as the first-line screening test for cervical cancer in women 25 and older using specimens collected in SurePath preservative fluid.

The Roche test is now the only HPV test approved for use as a primary screening test with both SurePath and ThinPrep PreservCyt Solution. It is approved for all of the screening indications supported by guidelines—primary screening in women 25 and older, reflex testing of unclear Pap test results in women 21 and older, and cotesting with a Pap test in women 30 and older—with both of the primary collection media types.

“With this additional approval for the Cobas HPV Test, laboratories and clinicians now have an approved option that can be used for all of their HPV screening indications and sample types,” Ann Costello, head of Roche tissue diagnostics, said in a statement.

Beckman, Arkray announce iQ Workcell launch

Beckman Coulter and U.S. Arkray announced a new partnership and the launch of the iQ Urinalysis Workcell.

The iQ Workcell pairs the Beckman Coulter Iris iQ200 Digital Flow Morphology system and the Arkray Aution Max AX-4030 fully automated urine analyzer. This total urinalysis offering is available in the U.S. exclusively through Beckman Coulter, which also offers the Arkray Aution Max AX-4030 and the Arkray Aution Eleven AE-4022 analyzers as standalone solutions.

“Through this partnership with Beckman Coulter, Arkray can respond to the market demand to pair Aution chemistry with sediment solutions. This combination of a fully automated urinalysis solution combined with a back-up solution and standardized test strips deliver continuity within laboratory networks,” Shane Hawes, Arkray general manager, said in a statement.

The new iQ Workcell will be offered in three configurations: iQ 3000, 2000, and 1500 Workcells.

FDA grants breakthrough device designation for Elecsys CSF assays

The FDA has granted breakthrough device designation to Roche’s Elecsys β-Amyloid (1–42) CSF and Elecsys Phospho-Tau (181P) CSF. These immunoassays are for the measurement of the β-amyloid (1–42) and phospho-tau concentrations in cerebrospinal fluid in patients with cognitive impairment who are being evaluated for Alzheimer’s disease or other causes of dementia.

“We are excited about FDA’s recognition of the potential clinical benefit the Elecsys CSF assays can bring to clinicians, laboratories, and their patients in diagnosing AD at an early stage,” Roland Diggelmann, CEO of Roche Diagnostics, said in a statement.

Ipilimumab approved for MSI-H or dMMR metastatic colorectal cancer

The FDA on July 10 granted accelerated approval to ipilimumab (Yervoy, Bristol-Myers Squibb) for use in combination with nivolumab for the treatment of patients age 12 and older who have microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.

This new use has also been added to the Opdivo (nivolumab) labeling. Nivolumab received accelerated approval for this indication as a single agent on July 31, 2017.

The approvals were based on data from study CA209142 (CHECKMATE 142; NCT02060188), a multicenter, non-randomized, multiple parallel-cohort, open-label study that enrolled 82 patients with dMMR or MSI-H metastatic CRC with disease progression during or following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Local laboratories determined the assessment of dMMR or MSI-H tumor status.

Final positive LCD issued for use of ConfirmMDx for Prostate Cancer

Palmetto GBA, a Medicare administrative contractor that assesses molecular diagnostic technologies, has issued a positive final local coverage determination to expand Medicare coverage of the ConfirmMDx for Prostate Cancer test.

The final LCD, which expands Medicare coverage to all providers, becomes effective on Sept. 3.

The prior LCD, established in 2014, limited coverage to only those providers enrolled in a certification and training registry program. The new LCD removes other conditions to continuing Medicare coverage by deleting references to the Pascual clinical study, removing patient number limitations, and eliminating certain other conditions associated with the former MolDX coverage with data development program.

Sysmex partners with Advanced Instruments

Sysmex America and Advanced Instruments announced a partnership that will broaden the Sysmex portfolio with Advanced Instruments' automated GloCyte cell counter system.

Andy Hay, chief operating officer of Sysmex America, said in a statement: "While diagnostic technology like our XN-3100 and XN-9100 provide highly accurate and reliable results for an array of health conditions, for laboratories testing CSF, adding GloCyte is a solution that provides accurate cell counts at clinically relevant low levels while offering maximum efficiency and minimum workflow disruption." Under the agreement, Sysmex will be the exclusive distributor of GloCyte in the U.S., Canada, and Latin America.

FDA clears Simplexa HSV 1 & 2 Direct for extended swab sample claims

DiaSorin Molecular LLC received FDA clearance extending the sample type claims of its Simplexa HSV 1 & 2 Direct assay.
The clearance expands the type of samples that can be tested, from genital swabs to all cutaneous and mucocutaneous swab samples. FDA clearance of the assay for testing cerebrospinal fluid samples was received in 2014.

Qiagen's CareHPV wins WHO prequalification

Qiagen's CareHPV test for HPV screening in low-resource settings has been added to the World Health Organization list of prequalified in vitro diagnostics. The test was launched worldwide in 2010. The WHO's evidence-based listing is expected to expand the availability of the test in countries that rely on the global organization's list to make purchasing decisions.