Streamlined workflow for HPV test, 9/13

The FDA in June approved a workflow process for Roche Diagnostics' Cobas HPV test that allows sample processing from the primary sample collection vial after it has been used for cytology (Pap) testing. The approval allows labs to load the same vial used for a ThinPrep Pap test directly onto Roche's Cobas 4800 system for high-risk HPV and individual HPV 16 and 18 genotype testing.

The new workflow option uses a special primary vial rack for the fully automated Cobas 4800 system. The new process eliminates the need for lab technologists to pipette samples from the primary vials used for liquid-based cytology into a separate tube. They can instead load the same vial onto the Cobas 4800 directly after cytology processing. The new workflow can help labs reduce costs, improve turnaround time, and free staff to spend time on other critical tasks.

Clinically validated by the ATHENA trial, the Cobas HPV test provides specific genotyping information for HPV 16 and 18, the highest-risk types, while simultaneously reporting the 12 other high-risk HPV types as a pooled result, all in one run, from one patient sample. The test is approved to screen patients age 21 and older with abnormal Pap test results and to co-test with Pap in women ages 30 to 65 to assess the presence of high-risk HPV genotypes.

***Roche Diagnostics**, 317-521-3966*