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BD launches high-throughput molecular diagnostic platform for US labs

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The BD COR System integrates and automates the complete molecular laboratory workflow from sampleprocessing to diagnostic test results

BD (Becton, Dickinson and Company) has launched a new, fully automated high-throughput diagnostic system using robotics and sample management software algorithms to set a new standard in automation for infectious disease molecular testing in core laboratories and other centralised laboratories in the US.

The launch will make the BD Onclarity HPV Assay with extended genotyping for the BD COR System available to the high-throughput labs that process the majority of cervical cancer screening specimens in the US Persistent infection with human papillomavirus (HPV) is one of the primary causes of cervical cancer.

The BD COR System integrates and automates the complete molecular laboratory workflow from sample processing to diagnostic test results. The system is modular and scalable and designed to address multiple needs within laboratories for expanding molecular testing and increasing test volumes. It has onboard capacity for reagents and samples that provide six to eight hours of unimpeded system processing, eliminating multiple technologist interactions currently required per shift.

The BD COR System will be initially available with the BD Onclarity HPV Assay with extended genotyping, a qualitative*in vitro* test for the detection of HPV in cervical specimens collected by a clinician and placed in a BD SurePath vial. The BD Onclarity HPV Assay offers extended genotyping capabilities by detecting 14 high-risk (HR) HPV types in a single analysis. The BD Onclarity HPV Assay is the only FDA-approved HPV test that can identify and report genotypes beyond 16, 18 and 45, to include individual results for 31, 51, 52 and group results for 33/58, 35/39/68, and 56/59/66. The BD Onclarity™ HPV Assay can be used as a component of routine cervical cancer screening programs, with indications for HPV primary screening, triage for ASC-US cytology and co-testing with cytology.

The system enables the processing of samples directly from liquid-based cytology vials, the creation of molecular aliquot tubes and assay testing — automating labour-intensive and error-prone manual processes.

With this approval, the BD COR™ System offers two instruments. The BD COR PX instrument integrates and automates the sample workflow for diagnostic specimens and assays and the BD COR GX instrument automates the BD Onclarity HPV Assay with extended genotyping, specifically. The PX instrument will prepare the samples by performing the appropriate pre-analytical processing steps and automatically deliver the samples to the GX instrument for analysis. The GX instrument will perform the analytical steps of the BD Onclarity HPV Assay, including extraction, amplification and detection.