

Quality controls, critical raw materials, 10/16

At the AACC show 2016

October 2016—Bio-Rad Laboratories launched Amplichek II quality control, which was issued a de novo clearance from the FDA. Amplichek II is the first in a series of infectious disease controls that the company is introducing to the molecular diagnostic testing market. It is an independent, multianalyte quality control that monitors the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of health care-associated infections.

Amplichek I quality control, the second in the series, was also launched. The FDA 510(k)-cleared Amplichek I is an independent, multianalyte quality control for the assessment of HIV-1, hepatitis B (HBV), and hepatitis C (HCV) nucleic acid tests that can help mitigate the limitations of manufacturer controls. It can aid in reducing the risk associated with reporting inaccurate patient results by monitoring the performance of the complete analytical process and detecting lot-to-lot variation of assay reagents.

“We are pleased to expand our offering of controls for the molecular diagnostics testing market,” John Hertia, Bio-Rad president, Clinical Diagnostics Group, said in a statement. “The introduction of Amplichek I represents Bio-Rad’s continued commitment to improve laboratory analytical performance and ultimately the quality of patient care.”

Expanding the company’s portfolio of critical raw materials for the in vitro diagnostics market, Bio-Rad launched two human recombinant antigens. These cell culture and recombinant antigens provide customers with reliable critical assay components for use in lung and ovarian cancer diagnostics. The new antigens include the HE4 Antigen, used as an aid in monitoring recurrence or progressive disease in patients with epithelial and endometrial ovarian cancer, and the Squamous Cell Carcinoma Antigen 1 (SCCA-1), used for detecting, staging, and monitoring response to therapy in patients with squamous cell carcinoma of the lung.

Bio-Rad’s line of critical raw materials are intermediate and semi-finished goods that are used for re-manufacture into standards, controls, and calibrators as well as for research into future assay development.

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