Molecular standards, 7/15

July 2015—Microbiologics is expanding its line of Helix Elite Molecular Standards with two product formats: inactivated extraction controls and genomic DNA extracts. Used for validation, verification, proficiency testing, and quality control of molecular assays, Inactivated and Genomic Extract controls are available in multiple strains; the first genomic extracts are from low passage mycoplasma strains sourced from the National Collection of Type Cultures. The Helix Elite brand now encompasses three distinct formats supporting each phase of the molecular testing process—synthetic nucleic acids and



genomic extracts for amplification and detection and inactivated controls for extraction through detection.

Inactivated Helix Elite Molecular Standards are fully intact process controls that are FDA-listed and CE-marked as in vitro diagnostic medical devices for use in clinical laboratories. These nonviable viral and bacterial targets are produced in the form of lyophilized pellets, which are shipped and stored at room temperature. The quick-dissolving pellets may be reconstituted in relevant buffers or transport media and then processed using the same protocols as the patient sample. Respiratory and gastrointestinal targets are available and additional respiratory and sexually transmitted disease targets will be added throughout the year.

Genomic Extract Helix Elite Molecular Standards are dried, stabilized, and quantitated nucleic acid extracted from target pathogens. Used as a positive control for the amplification and detection steps in molecular assays, each preparation is assessed for purity and integrity, and a gene copy number is provided for quantitation.

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