

ISO18385: IMPLEMENTATION OF A NEW FORENSIC MANUFACTURING STANDARD

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Forensic DNA laboratories rely on reagent and plastics manufacturers to supply high-quality products with minimal interference from contaminating DNA. With the increasing sensitivity of short tandem repeat (STR) amplification systems, levels of DNA that were previously undetected may now generate partial profiles. To address the concern of laboratories worldwide regarding the potential of low-level DNA contamination in consumables, ISO18385 has been developed to provide guidelines for minimizing the risk of human DNA contamination events during the manufacturing process.

ISO18385 was approved for publication by the ISO committee in April, 2015. This standard is intended for manufacturers of forensic products used to collect, store, and analyze biological material for forensic purposes. The standard does not include new requirements for individual forensic DNA laboratories. As a manufacturer of forensic consumables, Promega has been involved in the drafting of ISO18385 as a member of the United States Technical Advisory Group (TAG), created by ANSI and administered by ASCLD. This has allowed Promega to provide direct feedback to the IOS committee to ensure the requirements of the standard are stringent enough to minimize human DNA contamination throughout the manufacturing process, while allowing manufacturers to continue to produce a high quality and cost-effective product.

Promega's current manufacturing capabilities already include numerous process controls to ensure our customers are receiving high quality material, free of human DNA contamination. However, in anticipation of the standards publication, Promega has taken several additional steps to ensure we are in alignment with the new guidelines. All primary containers will now be treated with Ethylene Oxide (EO) gas in order to render any potentially contaminating DNA unamplifiable. We have performed numerous studies to establish an EO treatment process that exceeds the DNA knockdown requirement of the standard. We have also performed an extensive review of our entire manufacturing process and are updating our risk assessments as necessary. In addition, we are revising our quality control testing procedures and certificates of analysis to ensure alignment with the standard. All product manufactured under ISO18385 guidelines will be clearly labeled.

With the development and implementation of ISO18385, consumers of forensic products can be assured that all manufacturers are held to the same universal guidelines when producing forensic reagents and plastics. Promega's investment in the development and implementation of ISO18385 highlights our continued commitment to delivering high quality, safe, and effective product to our customers worldwide.