

MEETING THE NEW FORENSIC ISO STANDARD: ISO 18385:2016

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Greatly improved sensitivity of DNA testing methods has increased the potential for inadvertent contamination by manufacturers to interfere with forensic analysis. To mitigate against these inadvertent contamination events, ISO 18385:2016, *Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes – Requirements*, was developed as a global standard for manufacturers of forensic products used in human DNA analysis. The process of developing a new ISO standard which has significant implications for both forensic laboratories and manufacturers was a daunting endeavor. ISO 18385:2016 stands as a testament to the dedication of the world-wide ISO committee members, both forensic leaders and manufacturers, who had the shared goal of providing the assurance that products with the “ISO 18385 Forensic DNA Grade” label were manufactured using control measures specifically designed to minimize the risk of human DNA contamination.

Here we discuss the overall goals of the ISO Standard, the steps manufacturers can take to meet the ISO Standard requirements and how forensic labs will know which products have been manufactured in accordance with ISO 18385:2016. Specifically for Promega Corporation, we discuss the control measures already in place which meet the Standard requirements as well as new control measures. When establishing any new manufacturing process or control measure, it is critical to demonstrate that it is both effective and safe. We will discuss the testing performed at Promega Corporation to ensure that our products comply with ISO 18385:2016 while maintaining their high quality and performance.