

ANATOMY OF A FORENSIC DNA GRADE KIT – WHAT IS ISO18385 AND WHAT DOES IT MEAN TO ME?

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Inadvertent contamination of materials used in the forensic DNA testing workflow can have major impact on results generated; in particular materials used in pre-PCR steps. As Forensic labs are using increasingly more sensitive methods of analysis and identifying amounts of DNA that were previously undetectable, manufacturers of products used in pre-PCR workflows need to ensure that the materials they supply meet the evolving needs of their customers.

ISO18385 '*Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements*' was published in February 2016 and sets a global standard for the manufacture of pre-PCR products used in forensic DNA analysis. The publication of this standards aims to facilitate the reduction of situations where inadvertent human DNA contamination compromises a forensic investigation.

Thermo Fisher Scientific has a long history as a manufacturer of forensic DNA testing kits and many of the practices advocated in ISO18385 were based on Thermo Fisher Scientific manufacturing processes. When buying Applied Biosystems human identification products how many customers have thought about how the kits are made?

In this presentation we show the audience what it takes to make a forensic product like the GlobalFiler™ PCR amplification kit from raw materials through to final QC and shipping. With a specific focus on what it takes to make it 'ISO18385 Forensic DNA Grade'.