

EFFECTS OF ETHYLENE OXIDE TREATMENT ON PLASTIC LABWARE

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QIAGEN is a forerunner in quality initiatives for human identity and forensic testing. Our Investigator® branding and the new forensic grade labels represent the compliance of our kits to industry-leading quality control systems, exacting manufacturing standards, and rigorous validations. QIAGEN remains committed to meeting the highest possible standards and is already working with DIN and ISO towards future international standards. Regarding the Investigator products, we work towards compliance with ISO/DIS 18385 “Minimizing the risk of DNA contamination in products used to collect and analyze biological material for forensic purposes”.

QIAGEN's stringent and process oriented quality management system (QMS) is maintained according to regulatory requirements defined by leading QMS standards and covers all processes within the company. Our kits are manufactured in clean rooms that comply with ISO and GMP standards. Automated production systems are used, where feasible, for handling and primary packaging of chemicals and consumable devices. The applicability of ethylene oxide (EO) treatment is continuously monitored and its utilization is progressively expanded for Investigator products and relevant finished plastic accessories. In order to ensure product quality, the performance of EO treated materials is compared to non-treated materials and long term stability studies are conducted upfront of implementation into routine production. For two of tested plastic labwares we observed a negative impact of EO treatment on stability.

- 1) Treated QIAxSymphony extraction consumables led to reduced recovery of DNA after materials had been stored for more than 3 month.
- 2) STR assay control DNA showed decreasing concentration upon storage at 4°C in EO treated tubes.

Our findings indicate while EO treatment is a powerful tool to reduce potential exogenous human DNA from labware used in forensic applications, care must be taken to ensure performance and stability are fully maintained.

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