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Letter to the Editor

Manufacturer contamination of disposable plastic-ware and other reagents—An agreed position statement by ENFSI, SWGDAM and BSAG

Recently, a number of laboratories in Europe, the United States and New Zealand have obtained results with STR analysis that indicated apparent links from unconnected cases that had been processed in geographically different areas in different laboratories. Further investigation suggested that the DNA had been introduced during the process of manufacturing consumables and products used in the DNA analysis process. This was confirmed after comparing DNA profiles obtained from staff working in the plastic-ware factory and DNA profiles derived during the course of casework in the United Kingdom [1]. Contamination of disposable plastic-ware at a manufacturing source was originally suggested [2] in relation to the analysis of mitochondrial DNA. SWGDAM recommends that this position statement be limited to nuclear DNA.

Although existing manufacturing processes are undoubtedly well designed, there is still a residual risk of contamination of 'sterile' materials. This risk is manufacturer dependent and laboratory specific (since laboratories use different manufacturers or suppliers). It is difficult to generalise but an estimate provided by the Forensic Science Service from the internal use and batch testing of large numbers of consumable items indicates that approximately 1 in 25,000 affected items may provide a full DNA profile, although the frequency of partial profiles of 1 or more alleles may be much higher [3]. Therefore, it is possible that no matter how well designed the process is, there is always some residual risk of a manufactured induced contaminant. The problem is that no QC testing can hope to detect contamination levels this low, unless >25,000 items are tested. Clearly this is not a realistic proposition. In laboratories that use hundreds of thousands of consumables in their processes per year, this is an issue to consider as just one contamination event can have serious consequences. This issue is also relevant to materials used to collect evidence at the crime scene. Often materials, such as swabs, are procured as being 'sterile' but this label does not necessarily mean that they are 'DNA free'.

The purpose of this statement is to raise awareness and to encourage interaction between manufacturers and the forensic community in order to devise methods and protocols that address this issue. We propose that a new product grade be introduced for forensic applications that should include:

(a) Automation of manufacturing lines.
(b) Minimising interaction of staff with manufacturing lines.
(c) Ensuring that products that come into contact with staff are adequately protected (i.e., staff gowned and masked, with feet and hair covered).
(d) Use of positive pressure airflow through HEPA filters, i.e., Class 10,000 clean room standard or equivalent.
(e) Continual QC checks, using PCR analysis, of a number of consumable items—preferably sensitive enough to detect a single cell with all profiles observed being recorded for future comparison.
(f) Once the consumables have been manufactured, an additional stage may be used to physically destroy any DNA contaminant that may have been inadvertently introduced. For example, effective removal of DNA has been demonstrated with Ethylene Oxide gas treatment [4] or UV cross-linking under modified conditions [5], although specifications would need to be defined. The former would be suited to large-scale decontamination, ideally by the manufacturers of consumables, while the latter would be suited to small-scale, end user decontamination.
(g) QC checks and the use of process controls to ensure the post-production treatment have been effective.

While stages (a)–(d) will minimise contamination, sporadic events may still occur, either pre- or post-manufacturing. Many manufacturers of molecular biology products already use clean room conditions but their QC checks do not involve PCR analysis as an addition to their quality system.

Stages (f)–(g) are more likely to eliminate *any* DNA contamination introduced during the manufacturing process. It will be important to devise QC checks to ensure that contaminating DNA is successfully removed. For example, consumables could be deliberately 'contaminated' with control DNA and success of the process demonstrated by subsequent removal of the contaminant sample.

To the extent permitted, forensic laboratories should maintain an Elimination Database(s) against which DNA results may be screened, as appropriate. It is recommended, for example, that such database(s) contain or grant access to profiles from:

- Forensic Laboratory Staff.
  - DNA laboratory staff.
  - Evidence recovery staff.
  - Other support staff.
  - [Retain profiles from former staff.]
- Regular visitors to laboratory areas.
- Contractors, e.g. service engineers and cleaning staff (where possible).
- Manufacturing staff of suppliers of forensic kits and consumables (where possible).
- Unexplained profiles observed in negative controls.
- Police personnel, forensic medical examiners, mortuary staff and pathologists should also be available for screening.

It is important that forensic laboratories develop quality control methods for detecting contamination in DNA results. This may include automated screening against elimination databases and checking the potential for contamination.

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The ENFSI group has been comparing 'unexplained' profiles from negative controls with each other and identified several common contaminant profiles as a result. Going forward, we propose a central database containing these unexplained profiles from negative controls. It is proposed that all forensic laboratories would then be able to add contaminant profiles and to carry out searches. It is also proposed that manufacturing staff profiles are either held anonymously on a central database or held by individual suppliers with access available to their customers.

Sharing of information and developing improved methods for the reduction and detection of contamination should be implemented to improve the results of international comparisons e.g. under the Prüm Treaty.

ENFSI meeting Lisbon 24th April 2009, endorsed with revisions by SWGDAM on July 16th 2009, endorsed by BSAG July 27th 2009.

Conflict of interest

The authors state that they have no interests which might be perceived as posing a conflict or bias.

References

[1] T. Howitt, Ensuring the integrity of results: a continuing challenge in forensic DNA analysis, 2003 http://www.promega.com/geneticidproc/ussymp14proc/oralpresentations/Howitt.pdf.
[2] T. Schmidt, S. Hummel, B. Herrmann, Evidence of contamination in PCR laboratory disposables, Naturwissenschaften 82 (1995) 423–431.
[3] P. Gill, A. Kirkham, Development of a simulation model to assess the impact of contamination in casework using STRs, J. Forensic Sci. 49 (2004) 485–491.
[4] K. Shaw, I. Sesardic, N. Bristol, C. Ames, K. Dagnall, C. Ellis, F. Whittaker, B. Daniel, Comparison of the effects of sterilisation techniques on subsequent DNA profiling, Int. J. Legal Med. 122 (2008) 29–33.
[5] J. Tamariz, K. Voynarovska, M. Prinz, T. Caragine, The application of ultraviolet irradiation to exogenous sources of DNA in plasticware and water for the amplification of low copy number DNA, J. Forensic Sci. 51 (2006) 790–794.

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