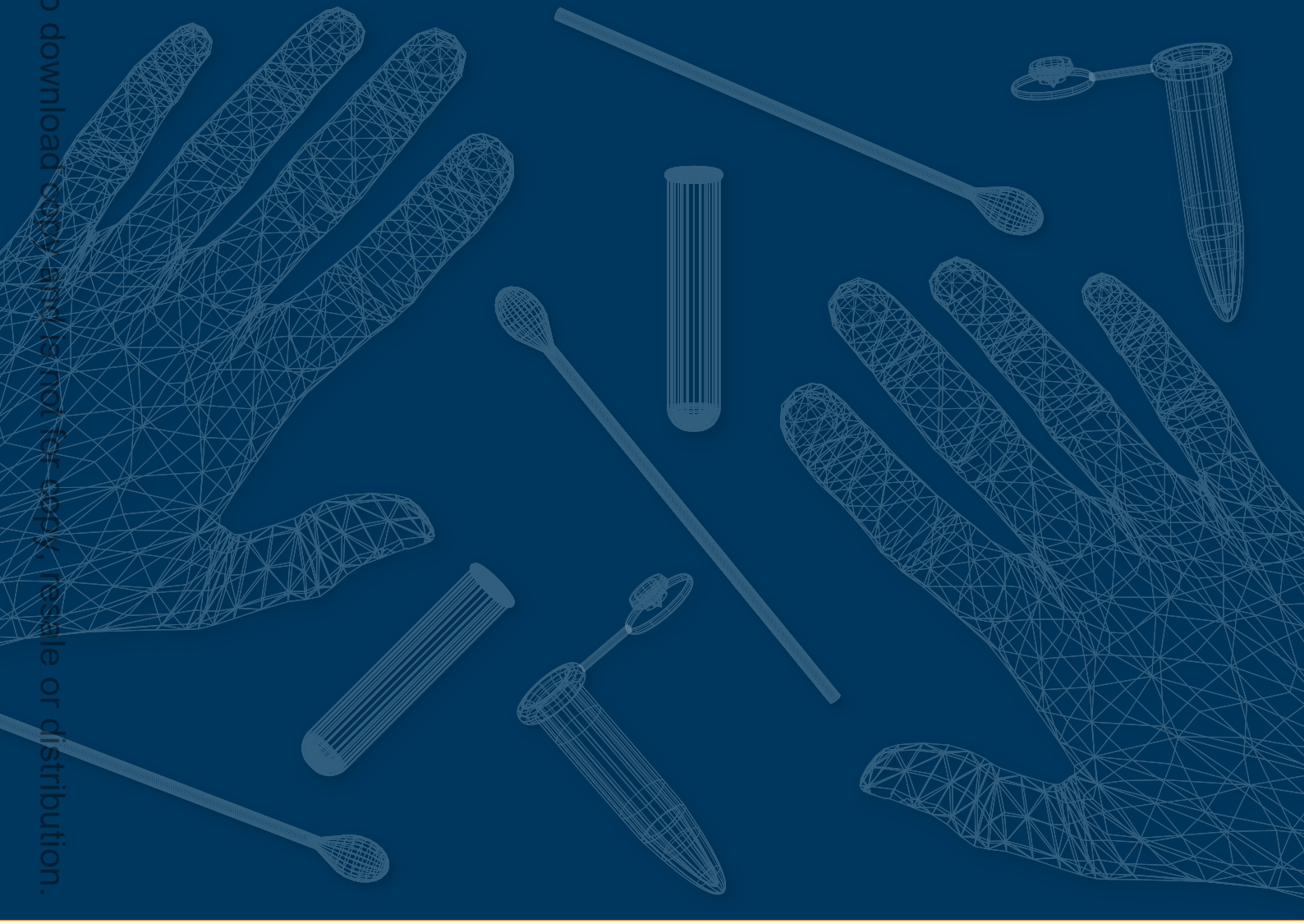
PAS 377:2023

Consumables used in the collection, preservation and processing of material for forensic analysis – Product, manufacturing and forensic kit assembly – Specification



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Foreword

This PAS was commissioned by the Forensic Science Regulator and sponsored by the Home Office. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 January 2023.

Acknowledgement is given to June Guiness OBE BSc (Hons) DMS as the technical author, and the following organizations that were involved in the development of this PAS as members of the steering group:

- Association of Forensic Science Providers
- Bedfordshire, Cambridgeshire and Hertfordshire Police Scientific Services Unit
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Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

The PAS process enables a specification to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Supersession

This PAS supersedes PAS 377:2012, which is withdrawn.

Relationship with other publications

Forensic kits and consumables that conform to this PAS are intended for use by end users in conjunction with the Forensic Science Regulator Code of Practice [1].

Information about this document

This is a full revision of the PAS, and introduces the following principal changes:

a) new dedicated sections for risk assessment and kit assembly have been added;

b) product release replaces and expands the previous clause titled ‘provision of information to the end user’;

c) The quality management section is in the new informative Annex A; and

d) Annex B has been replaced with requirement to comply with BS ISO 18385 and the drug/metabolite concentration table listed has been updated to produce an informative annex.

Assessed capability. Users of this PAS are advised to consider the desirability of quality system assessment and registration against the appropriate standard in the BS EN ISO 9000 series by an accredited third-party certification body.

Test laboratory accreditation. Users of this PAS are advised to consider the desirability of selecting test laboratories that are accredited to BS EN ISO/IEC 17025 by a national or international accreditation body.

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Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

Presentational conventions

The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the *Shorter Oxford English Dictionary* is used (e.g. "organization" rather than "organisation").

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Compliance with a PAS cannot confer immunity from legal obligations.

Introduction

Forensic science is the application of science pertaining to the law. This includes the investigation and prosecution of crime by the police and other agencies, and assisting the courts in determining guilt or innocence of those accused of having committed a crime.

In general terms, the forensic science process includes the following steps:

a) location and recovery of material of potential forensic interest;
b) preservation and transportation of material of potential forensic interest; and
c) analysis of material and interpretation of the results.

Depending on the forensic science process being undertaken, the analysis and interpretation includes comparison against controls or reference samples.

These steps typically utilize forensic kits and other consumables, depending on the type of evidence being recovered and analyzed. This includes:

1) swabs, gauze, forceps, combs, paper sheets, blades, gels and tapes used for recovery;
2) vessels to physically contain material during transport; and
3) glass vials, plastic tubes and analytical reagents used in laboratory analytical processes.

It is crucial that consumables and forensic kits do not compromise the integrity of the samples collected or adversely affect the analytical process in any way. To do so could potentially diminish the value and reliability of the forensic evidence. This, in turn, would increase the risk of an investigation being misled, poor judicial outcomes being made in the courts or could even result in a miscarriage of justice.

Examples of compromised consumables that have occurred within the UK include:

i) hair on disposable scene suits;
ii) fibres in DNA swab tubes;
iii) propellant contamination of gunshot discharge residue kits from a nail/propellant gun used for building repairs at a kit assembler's facility;
iv) chemical constituents leaching out of the rubber septum used on vials to analyse for alcohol/drugs; and
v) leaching of constituents of nylon bags released when heated, interfering with ignitable liquid analysis.

The aim of this PAS is to provide a high-level specification that can be adopted by manufacturers of consumables and assemblers of forensic kits to minimize the risk of compromising the integrity of samples, such as through inadvertent contamination, or adversely affecting the analytical process by the nature of the consumables and reagents used.

Evidence of compliance with this PAS can assist end users of consumables and forensic kits with their procurement decisions, and provide assurance to other stakeholders in the criminal justice system by promoting confidence in the forensic science process.

***NOTE** This PAS is intended to assist assemblers in producing forensic kits that meet the requirements of the Faculty of Forensic and Legal Medicine's document," [2].*

This PAS is intended to provide an overarching framework for all consumables used for the collection, sampling, packaging, transport, storage and analytical testing of material recovered, so that consumables are suitable for intended use; this is a requirement set within the Forensic Science Regulators Code of Practice [1], therefore using consumables in compliance with this PAS should meet that requirement.

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1 Scope

This PAS specifies requirements for:

a) consumables used in the collection, preservation and processing of material for forensic analysis;
b) the manufacture and storage of these consumables; and
c) the assembly and packaging of forensic kits.

The PAS covers:

1) risk assessment;
2) product requirements;
3) traceability, continuity and integrity;
4) consumable manufacture and kit assembly;
5) personnel;
6) product release; and
7) quality management.

This PAS does not cover technical product specifications for consumables, although it could be used by manufacturers to assist in developing a technical product specification.

This PAS is intended for use by manufacturers and assemblers of consumables and kits, and is of interest to end-user organizations, such as police forces, forensic science laboratories, and sexual assault referral centres.

This PAS might also be of interest to anyone buying, selling, using or relying on the performance of consumables to conduct sampling, and to those who preserve, transport or analyse consumables within the forensic examination workflow.

This PAS is intended to apply to all consumables and forensic kits, regardless of where they are produced, and includes those that are assembled by end users themselves, such as police forces or forensic laboratories.

This PAS is intended to be internationally applicable.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS ISO 3951-1, *Sampling procedures for inspection by variables – Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

BS ISO 18385:2016, *Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1 allele

one of a number of alternatives at a specific location on an individual's DNA

[SOURCE: BS ISO 18385:2016, **2.1**]

3.1.2 analytical threshold

relative fluorescence unit value at which a laboratory has determined to call a peak an allele (**3.1.1**)

[SOURCE BS ISO 18385:2016, **2.5**]

3.1.3 anti-contamination measure

action(s) taken to reduce contamination and/or its impact, including contamination avoidance, reduction and detection

3.1.4 assembler

organization that produces forensic kits

NOTE *The manufacturer (**3.1.14**) might also be the assembler of a forensic kit (**3.1.11**).*

3.1.5 batch release test

test performed by or on behalf of the assembler (**3.1.4**) or manufacturer (**3.1.14**) on a batch of components or products, which has to be satisfactorily completed before the batch can be released

[SOURCE: ISO/TS 21003-7:2019, **3.7** Modified – assembler included]

3.1.6 consumable

single-use commodity used in the collection, preservation and processing of material for analysis

NOTE 1 *Consumables used in forensic analysis include vessels, tamper-evident containers, swabs, implements and packaging that come into direct contact with the material for analysis, and can be made from various materials, such as plastic, glass or a metal. A consumable can be used for collecting the material (e.g. a disposable glove) or preserving the material (e.g. an airtight container for volatile liquid).*

NOTE 2 *A consumable is deemed as critical if it comes directly into contact with material that is to be analyzed, for example, swabs, tubes, containers, vials, pipette tips, scissors, blades and moistening agents such as water.*

3.1.7 container

item in which material is physically held during transportation or storage

3.1.8 contamination

undesirable introduction during the manufacturing or assembling processes of the analyte that is the subject of the specific forensic analysis

NOTE *For example, the introduction of propellant from nail/propellant guns used in the construction industry onto consumables for collecting gunshot discharge residues from hands; trace levels of cocaine in consumables used to detect illicit drugs; or ethanol into consumables used to collect blood for alcohol in blood measurement.*

3.1.9 DNA reduction factor

ratio of the DNA quantity of an untreated cell-spiked sample to the DNA quantity of an identical cell-spiked sample that has undergone appropriate post-production treatment

[SOURCE:BS ISO 18385:2016, **2.9**]

3.1.10 end user

organization or individual who procures a consumable (**3.1.6**) or forensic kit (**3.1.11**) for use

NOTE *An end user could be, for example, a police force, other agencies, or a forensic science laboratory.*

3.1.11 forensic kit (kit)

set of consumables and/or chemicals (or reagents), and instructions for use, packaged together and intended for use as specified by the manufacturer (**3.1.14**)

NOTE *Kits used to recover, preserve and transport material to a laboratory for analysis include, for example, gunshot discharge residue kits and forensic medical examination kits. Kits used to test recovered material include, for example, presumptive drug testing kits.*

3.1.12 forensic DNA grade

description given to products that have been produced in accordance with BS ISO 18385

3.1.13 interference

unintended impact on the detection of a material, analysis of a material or interpretation of the results following analysis of a material

3.1.14 manufacturer

organization that produces consumables and packages the product

NOTE *The manufacturer might also be the assembler of a kit.*

3.1.15 manufacturing environment

area, room or space identified for the production and/or packaging of products used to collect and analyze materials for forensic purposes

3.1.16 normal handling

routine use of the consumable or kit for the recovery, preservation, transportation and processing of material for forensic analysis based on the manufacturer's instructions

3.1.17 out-of-specification

test results that do not conform with the product specification

3.1.18 processing

performance of a series of mechanical or chemical operations on a sample of material in order to determine its characteristics

3.1.19 primary packaging

packaging designed to come into direct contact with the product

[SOURCE: BS ISO 21067-1:2016, **2.2.3**]

3.1.20 primary transport container

product designed to transport the sample

NOTE *Examples include envelopes, evidence bags, specimen jars, swab boxes, and collection devices with integrated transport mechanisms.*

3.1.21 product

consumables and reagents which do not require cleaning for continued use and are used to collect, store and analyse biological material for forensic purposes, but not used in post-amplification analysis

3.1.22 production

process or method for the manufacture of products

3.1.23 risk

effect of uncertainty on objectives

NOTE 1 *An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats.*

NOTE 2 *Objectives can have different aspects and categories and can be applied at different levels.*

[SOURCE: BS ISO 31000:2018, **3.1**]

3.1.24 tamper-evident container

consumable used to hold material for forensic analysis, and which once sealed cannot be readily reopened or its contents otherwise accessed or its identification compromised, without attempts to do so being evident

3.1.25 validation

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 *The term "validated" is used to designate the corresponding status.*

NOTE 2 *The use conditions for validation can be real or simulated.*

[SOURCE: BS EN ISO 9000:2015, **3.8.13**]

3.1.26 verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 *The term "verified" is used to designate the corresponding status.*

NOTE 2 *Confirmation can comprise activities such as:*

a) performing alternative calculations;

b) comparing a new design specification with a similar proven design specification;

c) undertaking tests and demonstrations; and

d) reviewing documents prior to issue.

[SOURCE: BS EN ISO 9000:2015, **3.8.12**]

3.2 Abbreviated terms

For the purposes of this PAS, the following abbreviations apply.

DNA	deoxyribonucleic acid
PCR	polymerase chain reaction
STR	short tandem repeat

4 Risk assessment

The organization shall establish and document a product-specific risk assessment of the manufacturing/assembly processes, which shall be reviewed when an incident occurs and/or at defined specific intervals.

NOTE 1 *Personnel conducting the risk assessment should be suitably qualified, experienced and familiar with the manufacturing/assembly process being assessed.*

The risk assessment shall identify and evaluate any risks of contamination and quality failure in the manufacturing/assembly process, and the actions to mitigate and control these risks.

NOTE 2 *This is so that risks to users, customers, employees, other equipment and the manufacturing environment are evaluated and mitigated.*

NOTE 3 *Risk analysis should draw from a variety of data sources (e.g. customer complaints and/or past experience with similar products, field data, risks identified during the development process) and may use a range of suitable assessment methodologies, for example hazard analysis critical control points (HACCP) and failure mode and effects analysis (FMEA).*

The risk assessment shall cover supply chain continuity, site boundaries, infrastructure, equipment, materials, substances, physical conditions, handling practices, management practices and past incident information on contamination.

The risk assessment shall include, where appropriate:

a) equipment;
   1) maintenance; and
   2) protection;
b) high risk areas;
   1) material handling during manufacture/assembly;
   2) location of connection and transfer points;
   3) air quality; and
   4) dust and particulate generation; and
c) procedures and processes;
   1) material receipt;
   2) loading and unloading procedures;
   3) specification and assessment of the quality of raw materials;
   4) manufacture procedures;
   5) assembly procedures;
   6) packaging and labelling procedures;
   7) storage procedures; and
   8) cleaning procedures.

The risk assessment shall be used to inform and define the manufacturing/assembly process(es) and equipment.

The organization shall maintain records which document and track the analysis and mitigation of identified risks.

NOTE 4 *For DNA consumables, BS ISO 18385: 2016, Clause **6** provides requirements for human DNA contamination risk management.*

To demonstrate control of its personnel, processes, equipment and management of risk, organizations shall operate a documented quality management system.

NOTE 5 *Annex A provides guidance on quality management for users of this PAS.*

NOTE 6 *Organizations are advised to consider the desirability of quality management system and registration against the appropriate standard, such as BS EN ISO 13485 or the BS EN ISO 9000 series.*

5 Product requirements

5.1 General

Data to demonstrate that a consumable and kit meet the requirements specified in this standard shall be documented.

The limit of detection, the uncertainty of measurement at the limit of detection, and pass/fail criteria for the technique and technology used for testing shall be documented.

NOTE 1 *Limits of detection vary for different analytes and are based on the validated or modified validated methods that are used for the analysis and reporting of results for forensic casework samples.*

Information about the sensitivity and pass/fail criteria shall be provided. Information as to the consumable's specific use shall be provided. The suitability of these levels and conditions shall be evaluated.

NOTE 2 *It is the responsibility of both manufacturer and assembler to confirm this.*

For items that cannot be treated post-production, the organization shall select samples for testing that are representative of the range of the batch, i.e. from the beginning, middle and end, or as a justified random selection.

NOTE 3 *Guidance on sampling is given, for example, in BS ISO 3951-1, which describes an acceptance sampling system of single sampling plans for inspection by variables.*

Where the manufacture/kit assembler is aware of a change to the specification of a consumable/product/material, they shall notify and consult with appropriate end users of the consumable or reagent in question to obtain acceptance for the replacement.

Where the constituent composition of a consumable or reagent is changed, the manufacturer/kit assembler shall verify that the change has not altered the properties and in turn invalidated any previous validation before the product is released.

The manufacturer/kit assembler shall notify and consult with appropriate end users of the consumable or reagent in question to obtain acceptance for the replacement.

5.2 Contamination

5.2.1 General

The packaging shall be designed so that it minimizes the risk of extraneous contamination during normal handling and storage.

The consumable/kit shall not have detectable levels of the analyte for which it is intended to be used.

NOTE *For a consumable, the absence of an analyte should be demonstrated where the sensitivity of the analyte assay technique employed is at least equal to the sensitivity of the analyte profiling technique for which the consumable is subsequently used.*

5.2.2 Consumable used in DNA sample analysis

The manufacturer/kit assembler shall have policies and procedures to control access to the production and assembly of consumables that will enter the DNA processing chain. Access shall be restricted to individuals covered by an adequate DNA elimination database for the purpose of detecting DNA contamination by those individuals.

A consumable intended for use in DNA analysis shall not have detectable human DNA or be described as forensic DNA grade by meeting the requirements set out in BS ISO 18385.

NOTE 1 *Laboratories with validated methods in the analysis of sample types encountered in forensic DNA cases (i.e. low quantity, degraded and compromised samples) should be used for testing. The most sensitive/enhanced autosomal DNA STR profiling method used to provide DNA casework profiles should be used. An additional PCR cycle to that recommended or validated for the method can be used to enhance profiling performance to provide added assurance of undetectable DNA to account for other more sensitive methods introduced or less frequently used, for example Y-STRs if that method is more sensitive than the autosomal DNA STR profiling method.*

For DNA consumables that can be ethylene oxide treated, the 1 000 DNA reduction factor shall be evidenced for each batch. This shall take the form of sealed spiked DNA samples with known quantities of DNA (minimum of 67 ng) located throughout the batch where the gas penetrates, and for those samples to be analysed post treatment. All spiked samples within the batch shall achieve a minimum 1 000-fold DNA dosage reduction.

For DNA consumables that cannot be ethylene oxide treated, such as water, lubricant gel and reagents, representative batch testing shall be conducted as per BS ISO 3951-1.

Where profiling methods are used for batch testing, all batch test samples shall pass or fail based on the criteria set out in Table 1.

NOTE 2 *If it is necessary to conduct further batch testing, this can be conducted by the original testing laboratory or another providing an alternative independent check.*

Table 1 – Testing criteria

Number of alleles detected	Action		Pass/Fail
0–1	No further analysis		Pass
2–3	Re-PCR	Alleles not replicated	Pass
		Some or all alleles replicated	Fail
4 or more	No further analysis		Fail

NOTE 3 *Alleles are represented by peaks in a DNA profile, which is a format used for the representation of an individual's genetic information. The allele peak height measured is above the analytical threshold determined by the validation of the method used.*

NOTE 4 *It should be noted that not all alleles are replicated when low levels of contaminating DNA are present, as demonstrated by Moore, et al. [3]*

NOTE 5 *If end users need to verify the batch testing, then the same criteria apply as set out in Table 1. However, one sample should suffice unless it fails, then a further four samples should be tested and pass prior to conducting an investigation into the suitability of the consumable batch.*

NOTE 6 *Batch testing using human-specific PCR testing can be used, as detailed in BS ISO 18385:2016, Annex A.*

5.2.3 Consumable used in gunshot residue analysis

A consumable intended for use in gunshot residue analysis shall not have detectable characteristic primer residue as determined by scanning electron microscopy, and/or propellant residue as determined by mass spectrometry.

NOTE *A consumable used in gunshot residue analysis might only be for the use of characteristic primer residue particles and others only for propellant residue.*

5.2.4 Consumable used in the analysis of alcohol (ethanol) in blood or other body fluids

A consumable intended for use in the analysis of alcohol (ethanol) in blood or other body fluids shall have a maximum concentration of alcohol of 0.1 mg/100 ml of body fluid, when calculated back to the concentration in the original body fluid.

5.2.5 Consumable used in the analysis of pharmaceutical or illicit drugs

A consumable intended for use in the analysis of pharmaceutical or illicit drugs shall not have any detectable drug/metabolite as listed in Table B.1.

5.2.6 Consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices

A consumable intended for use in the analysis of pharmaceutical or illicit drugs in biological matrices where low levels of the analytes are typically analysed (e.g. driving under the influence of drugs or drug-facilitated crime cases) shall not have any detectable drug/metabolite as listed in Table B.1.

NOTE 1 *Such analysis is usually carried out using combined techniques, such as gas or liquid chromatography-mass spectrometry, after extraction of the target compounds from the matrix and a concentration step, or steps. Any contamination in or on the consumable could therefore also become concentrated. Annex B shows a selection of drugs for which laboratories are recommended to be able to test in standard toxicology cases. Any contamination present should not result in drug concentrations greater than any legal limits when results are calculated back to the concentration in the original biological matrix. In some biological matrices, such as hair or oral fluid, detection limits and, therefore, the acceptable levels of contamination might be lower.*

NOTE 2 *Laboratories conducting the analysis of pharmaceutical or illicit drugs in biological matrices should conform with the requirements of ISO/IEC 17025 or BS EN ISO 15189, UKAS LAB 51 [4], and the appendix in the Forensic Science Regulator Code of Practice on "The analysis and reporting of forensic specimens for s5A of the Road Traffic Act 1988" [5]*

5.2.7 Consumable used in the detection and analysis of ignitable liquids

A consumable intended for use in the detection and ignitable liquid analysis shall not have detectable ignitable liquid and other volatile materials.

5.2.8 Consumable used in the detection and analysis of explosives

A consumable intended for use in the detection and analysis of explosives shall not have detectable levels using methods for specific explosive materials to be analysed.

5.2.9 Consumable used in the detection and analysis of particulates

A consumable intended for use in the detection and analysis of particulates (e.g. fibre lifting tapes) and that comes into direct contact with the material shall not have relevant particulate matter of suitable size that would impact on any analysis or results.

NOTE *This includes, as a minimum, glass, paint fragments, hairs and hair fragments, including eyelash and eyebrow, and fibres visible under low power microscopy.*

5.2.10 Consumable used for the collection and transportation of exhibits

A primary transport container shall not have detectable analyte for which the material is intended to be analysed, and shall not have particulate matter visible by the naked eye.

Primary packaging shall have no particulate matter visible by the naked eye.

5.3 Interference

5.3.1 General

It shall be demonstrated that the analyte is not compromised by any interferent (including the consumable itself) that could impact on the quality of analysis of the evidential material and interpretation of the analytical results.

5.3.2 Consumable used in DNA analysis

A consumable used in DNA analysis shall not have a detectable effect caused by:

a) polymerase chain reaction (PCR) inhibitors that affect the PCR amplification process;

   NOTE *Some integral components of collection/purification kits can inhibit PCR. However, these are reduced to a level that does not affect amplification, when used in accordance with the manufacturer's instructions.*

b) nucleases;

c) material that could interfere with the detection and analysis of fluorescently labelled PCR products, such as fluorescent dyes; or

d) substances that cause unintentional alteration to DNA electrophoretic characteristics (e.g. high salt concentration).

5.3.3 Consumable used in gunshot residue analysis

A consumable used in gunshot residue analysis for characteristic primer residues shall not have relevant particulate debris, including metallic particles that might impact on any analysis or results.

A consumable used in gunshot residue analysis of propellant residue shall not have detectable organic chemical characteristic of propellant residue.

5.3.4 Consumable used in the analysis of alcohol (ethanol)

A consumable used in the analysis of alcohol (ethanol) in blood or other body fluids shall not have detectable xylenes and other volatile substances that interfere with analysis of ethanol, determined by headspace gas chromatography (headspace GC).

5.3.5 Consumable used in the analysis of pharmaceutical or illicit drugs

A consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices shall not leach detectable levels of plasticizers (such as bungs in vials) that can interfere with gas chromatography-mass spectrometry (GCMS) and liquid chromatography-mass spectrometry (LCMS) analyses.

5.4 Traceability and continuity

5.4.1 Traceability

The source material, process and handling history of all materials shall be known, controlled and documented.

5.4.2 Continuity

A consumable used as a container shall be designed such that it can be labelled with sufficient detail to be fully traceable to the incident to which it relates.

***NOTE** This can be through an integrated adhesive (e.g. bar code) or tie-on label large enough to bear appropriate details relating to the origin of the sample that are handwritten or printed with an indelible medium.*

5.5 Integrity

5.5.1 Freezing

For a consumable used in the collection of perishable materials that are frozen, the consumable shall have structural resilience to freeze-thaw cycles. Any adhesive used in sealing the consumable shall adhere and remain adhered within the expected range of freezing temperatures.

***NOTE 1** It might be necessary to freeze material (such as liquid blood) during transportation and storage to avoid degradation. General temperatures for freezing are –4 °C to –20 °C.*

***NOTE 2** For glass consumables, these storage conditions and transporting could lead to loss of integrity through breakage, subsequent risks to safety of personnel through physical injuries and exposure to biohazards, if the glass is not sufficiently robust to withstand freezing (–21°C), thawing and routine impacts through handling and transportation.*

5.5.2 Leaching

The structural integrity of a consumable used as a container shall be designed to safeguard that material so that it is not lost or compromised through substances leaching into or out of the container. The container shall be appropriate for its intended content.

***NOTE** This includes engineering aspects such as the fit of a screwed or push-on cap, and chemical resistance of the materials of construction to the sample contained within it.*

5.5.3 Tamper evident

Where a kit includes a consumable used as a tamper-evident container, the container shall have a seal or other mechanism that:

a) indicates that it has been sealed; and

   ***NOTE 1** This may be, for example, by a change of colour or by the removal of an identifiable strip.*

b) after being sealed, indicates if it has been opened or tampered with.

   ***NOTE 2** This may be, for example, by a permanent change in appearance following the opening of the container.*

5.5.4 Preservation of liquid materials for forensic analysis (kits)

A kit for body fluid collection and retention in liquid form shall include:

a) where preservatives are required, preservatives of appropriate concentration to be used to preserve the material immediately after collection, and during transportation and storage of the material; and

b) instructions on use of the kit, including information on how samples are correctly and stably stored during collection, and when transferred to the laboratory.

A kit for body fluid collection shall not compromise the preservation of the analyte during refrigerated storage.

***NOTE 1** A kit for body fluid collection used for testing alcohol in blood or urine should include sodium fluoride in sufficient quantity to provide a minimum of 1.5% w/v sodium fluoride in solution based on the effective volume when the container is full.*

***NOTE 2** A kit for body fluid collection used for blood sample collection should include an anti-coagulant, such as potassium oxalate, in sufficient quantity to provide a concentration of 1% w/v based on the effective volume when the container is full.*

5.6 Health and safety

Hazard warnings shall be provided for consumables, together with instructions as to storage, normal handling and disposal of consumables, where these pose a potential health and safety risk.

A consumable shall not become physically compromised during storage and normal handling.

***NOTE 1** Attention is drawn to the International Air Transport Association (IATA) Packing Instruction 650 [6] which applies to UN 3373 (i.e. biological substances transported for diagnostic or investigative purposes).*

***NOTE 2** Medical examination devices designed to assist in the recovery of evidence from human bodies should conform to BS EN ISO 13485.*

A consumable (including packaging) used for the transportation of sharp items shall be of appropriate design and of structural strength to minimize penetration and thus the risk of injury to personnel.

6 Consumable manufacture and kit assembly

6.1 General

For in-house manufacture/assembly and any subcontracted manufacture/assembly of components of consumables/kits, Clause **4** and Clause **5** shall apply.

6.2 Manufacturing, assembly process and equipment

The organization shall define and document:

a) the manufacturing/assembly processes and equipment to be employed to meet the requirements specified in Clause **5**;

b) the stages of the manufacturing/assembly process that pose a risk of contamination to a consumable/kit, and the necessary actions to implement in order to mitigate risks identified; and

c) the acceptance criteria for tests used to validate that the consumable/kit meets the requirements specified in Clause **5**.

The organization shall define and document in accordance with the risk assessment:

1) the manufacturing environmental conditions for each workspace;

2) the cleanroom standard in use;

3) the maintenance of air quality; and

4) documented procedures to clean, monitor and control manufacturing environmental conditions to avoid contamination.

NOTE 1 *Interaction of personnel with production lines should be minimized through the use of automated processes.*

NOTE 2 *Manufacturers and assemblers should operate to cleanroom standards in accordance with the BS EN ISO 14644 series, so that the air quality of the workspace is appropriate for the consumable being handled. For example, for DNA consumables, Class 7 is recommended in BS EN ISO 14644-1:2015.*

Where access to a work environment has been identified as presenting a risk of contamination during the manufacture of a batch of consumables, this shall be recorded and access controlled accordingly

NOTE 3 *This includes controlling and recording access of personnel working on a regular basis in the production line, as well as any individual who accesses the workspace on occasion (e.g. an engineer). This data can be used when dealing with a contamination incident.*

For each batch of consumables/kit, the personnel involved in its manufacture/assembly shall be recorded.

A workspace for which a risk of contamination has been identified shall have a production line and layout that enables a unidirectional flow of the consumable/kit. It shall have air filters over air inlets to prevent the introduction of specified particle sizes according to the type of consumable being manufactured or kit assembled.

6.3 Cleaning regime and monitoring

A cleaning regime shall be specified for each workspace in accordance with the findings of the risk assessment and include a regular review of ongoing environmental monitoring, including as a minimum:

a) frequency of cleaning;

NOTE 1 *Frequency can vary for work surfaces, floors, manufacturing/assembly equipment and cleaning equipment.*

b) use of disinfectants and cleaning agents;

c) use of cleaning equipment;

d) use of barrier clothing;

e) cleaning procedures (work instructions);

f) cleaning procedures in the event of contamination of the workspace and/or the consumable/kit; and

g) practical experience and training required by personnel to undertake the cleaning.

NOTE 2 *As part of the validation of a cleaning regime, the organization may use decontaminants and decontamination procedures that have been proven by others to be effective against the substances which would constitute contamination. The initial research data should be included as part of the manufacturer's/assembler's documentation.*

An environmental testing regime shall be documented and implemented for each workspace based on risk assessment and monitoring, including as a minimum:

1) tests for detecting specific analytes as appropriate;
2) the frequency of those checks;
3) the pass/fail criteria for environmental tests; and
4) follow-up corrective actions for environmental test results that do not meet the pass criteria.

NOTE 3 *The pass/fail criteria should be based on limits of detection and background levels commonly agreed and accounted for by relevant technical specialists.*

6.4 Barrier clothing

The barrier clothing to be employed shall be specified and its efficacy shall be demonstrated.

NOTE 1 *Each workspace might have different barrier clothing requirements depending on the manufacturing/assembly activity being carried out and the level of automation of the process.*

A segregated area shall be provided for personnel to change into/out of required barrier clothing.

Where single-use barrier clothing is not employed, a cleaning regime shall be specified for the barrier clothing.

NOTE 2 *For reusable barrier clothing or personal protective equipment, there should be control measures in place to prevent carry-over or build-up of contaminants due to previous use.*

Personnel shall be given training in the use of barrier clothing and personal protective equipment, as well as the order to put on and remove, change, and dispose of such clothing and equipment.

NOTE 3 *For example, where gowns are specified for use in a defined workspace, personnel require training in gowning procedures.*

The use of barrier clothing or personal protective equipment and the implementation of the cleaning regime shall be recorded.

7 Personnel

Personnel shall provide consent or agree to the provision of a sample for the generation of a DNA profile for inclusion on one or more local and/or international DNA elimination databases for routine searching against casework-generated profiles, including data-sharing agreements to reduce sampling and profiling for each individual elimination database.

The organization shall identify and document the training and competency required by personnel to undertake the cleaning regime and the manufacturing/assembly activities.

Personnel shall be trained and authorized as competent for their role and duties in the cleaning regime and the manufacturing/assembly activities.

Personnel shall also be trained on the aspects of the risk assessment relevant to their role and duties, including measures to be taken to avoid introducing a potential contaminant or interferent to a batch of consumables/kits.

NOTE *Training provided depends on the consumable/kit being manufactured/assembled, the manufacturing environment, and level of interaction of personnel with the production line. For example, in the case of consumables for gunshot analysis, awareness training should be provided that includes risks of contamination posed by recreational use of guns, fireworks, and other activities that might create any exposure to a source of gunshot residue.*

Training received and other documentation to demonstrate that the specified knowledge, training and competency have been achieved before a person is authorized shall be recorded for all personnel.

8 Kit assembly

The organization shall establish and implement inspection or testing to verify that the individual consumables in the kit meet the requirements for performance, to conform to Clause **5**.

The organization shall establish and implement procedures for the assembly of the kit, in accordance with Clause **7**.

The organization shall develop a batch testing plan and procedure based on the risk assessment.

The test method used shall be validated and be sensitive enough to demonstrate conformity to this PAS.

NOTE 1 *Testing can be carried out by the assembler, the manufacturer or a third party. Where the manufacturer or third party carries out the testing, the assembler is responsible for obtaining verification that it has been tested.*

NOTE 2 *BS EN ISO/IEC 17025 provides guidance on the validation of test methods.*

9 Product release

9.1 General

The organization shall establish, document and implement a batch release procedure that includes testing of the product as appropriate.

9.2 Product documentation, packaging and labelling

Manufacturers/kit assemblers shall clearly identify when their products have been produced in accordance with this PAS.[1)]

NOTE 1 *An example of product identification/labelling is "PAS 377:2022 Forensic Grade".*

NOTE 2 *For DNA consumables produced in accordance with this PAS, identification/labelling can be "PAS 377 Forensic DNA Grade", "ISO 18385 Forensic DNA Grade" or "PAS 377/ISO 18385 Forensic DNA Grade".*

Products shall be packaged in a manner that maintains their integrity.

The product shall as a minimum be labelled with:

a) batch number or another unique identifier;
b) name of consumable/kit and product code;
c) expiry date; and
d) the storage conditions.

A product that includes multiple components shall be labelled as to be clear which components conform to this PAS.

NOTE 3 *Instruction sheets, labels, etc. that do not come into direct contact with the sampled material are not subject to the same requirements as consumables outlined in this PAS.*

9.3 Provision of information to the end user

9.3.1 General information

The manufacturer/kit assembler shall provide information with the consumable/kit which includes but is not limited to the following:

a) batch number or another unique identifier;
b) name of consumable/kit and product code;
c) expiry date and required storage conditions for consumables subject to deterioration over time or that require special storage conditions;
d) its intended use, and specific uses for which it is not intended or does not meet the specification; and
e) description of the quality tests carried out, the results of the quality tests, the acceptance criteria, and the limit of detection of the technique and technology used for the characteristics tested for.

NOTE *Testing certificates should be made available to end users.*

9.3.2 Further information

The organization shall make available to end users the following information:

a) technical description of the consumable/kit (e.g. technical specification);
b) an outline of anti-contamination measures taken; and
c) where applicable, the accreditation status of any third-party testing.

[1)] Marking PAS 377:2023 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third-party certification of conformity.

Annex A (informative) Quality management

A.1 General requirements

The organization should establish, document and maintain a quality management system that demonstrates control of its personnel, processes and equipment.

NOTE 1 *Users of this PAS are advised to consider the desirability of quality system assessment and registration against the appropriate standard, such as BS EN ISO 13485 or the BS EN ISO 9000 series, by an accredited third-party certification body.*

NOTE 2 *Laboratories accredited to BS EN ISO/IEC 17025 to assemble kits for clients do not require certification to BS EN ISO 9001, as the quality management system requirements are equivalent.*

A.2 Documentation

The quality management system documentation should include:

a) documented statements of a policy and objectives relevant to this PAS;

b) documents needed by the organization for the effective planning, operation and control of its processes;

c) for each consumable or kit, a record either containing or identifying documents defining product specifications and quality management system requirements for the complete manufacturing or assembly process, including quality assurance and quality control measures deployed;

d) traceable evidence of conformity to requirements for each batch of consumables or each consumable within a kit by means of quality control testing;

NOTE 1 *Testing may be carried out by the manufacturer, assembler or third party.*

e) evidence to support stated shelf life (expiry date) and storage instructions;

f) evidence of a continuous improvement ethos and openness to address quality issues; and

g) documented supplier approval process and an approved suppliers list with the manufacturer's requirements and specifications for the supplies.

The documentation should be reviewed at a minimum every four years.

NOTE 2 *Some documents might need to be reviewed more frequently.*

A.3 Record retention

Records should be maintained regarding the manufacture and testing of each batch of consumables for a period of time equivalent to or greater than the shelf life of the consumables.

Records should be retained for a minimum of five years. Where a batch of consumables has a shelf life that is greater than the recorded retention period, they should be retained for a period of time at a minimum equivalent to or greater than their shelf life. So that records can be used in appeals and cold case reviews, which in the latter instance can be many decades later, records should ideally be retained for a much longer period of time.

A.4 Monitoring

The characteristics of the consumable/kit should be monitored and measured to verify that consumable/kit requirements (Clause **5**) have been met. Evidence of conformity to the acceptance criteria should be maintained.

The manufacturer/kit assembler should maintain up-to-date staff elimination DNA profiles data on relevant and appropriate elimination databases.

All instances where a match against an elimination database profile is observed should be recorded as a non-conformance and be investigated.

NOTE *Depending on national and local elimination database operating models, it might be necessary to provide and maintain staff elimination profiles on more than one local, national and/or international DNA elimination database.*

A.5 Non-conforming consumable or kit

There should be a defined process for the control of non-conforming products. Where a non-conforming consumable or kit is identified, it should be controlled to prevent its unintended use and the end users impacted should be notified.

For any out-of-specification result, the nature of the issue, any subsequent actions taken, any additional testing performed and justification for how the product was determined to be conforming should be documented. Where a non-conforming consumable poses a risk to samples or sample analysis and impacts provision to the criminal justice system, this should be escalated to the Forensic Science Regulator.

NOTE 1 *Non-conforming products include those that do not meet the requirements of Clause* ***5*** *and Clause* ***6.***

NOTE 2 *Non-conforming products may be disposed of, quarantined and/or recalled.*

A.6 Continuous improvement

The organization should establish, document and maintain an improvement, corrective and preventative action process.

Documented procedures should be established to investigate quality issues identified through environmental monitoring, batch release testing, or customer complaints relating to product contamination. This should include recording the following:

a) nature and extent of the issue;
b) investigation to determine the root cause of the issue;
c) corrective and preventive action taken; and
d) review of the effectiveness of the corrective action.

NOTE *The organization should demonstrate continuous improvement in response to appropriate customer feedback, including complaints, and to instances of non-conformity. In addition, the organization should be proactive in improving its processes, for example through the assessment of risk, validation and product review.*

Annex B (informative)
Drug/Metabolite batch tested for in consumables

Table B.1 provides guidance on the drugs/metabolites that should be undetected in consumables used for any analysis of pharmaceutical or illicit drugs (**5.2.5** and **5.2.6**). The batch testing laboratory should provide the limit of detection for the method(s) used to test for the various drugs/metabolites.

Table B.1 – Drug/Metabolite analytes

Drug/Metabolite
Amphetamine, methamphetamine, methylenedioxyamphetamine (MDA), methylenedioxymethamphetamine (MDMA)
Cocaine, benzoylecgonine
THC-11-oic acid, THC, THC-OH and glucuronides
Morphine, morphine-3-glucuronide, morphine-6-glucuronide, diamorphine, 6-monoacetylmorphine, codeine (and glucuronide), dihydrocodeine (and glucuronide), pholcodine, methadone, EDDP (methadone metabolite)
Buprenorphine, norbuprenorphine
Lysergic acid diethylamide (LSD)
Diazepam, desmethyldiazepam, temazepam, oxazepam, chlordiazepoxide, alprazolam, phenazepam, flunitrazepam, lorazepam, midazolam, clonazepam, nitrazepam (and glucuronides), 7-aminoflunitrazepam, 7-aminonitrazepam, 7-aminoclonazepam
Ketamine, norketamine
4-Methylmethcathinone (mephedrone), 4-Methylethcathinone (4-MEC), methylone, butylone, MDPV
BZP, TFMPP, m-CPP
Amitriptyline, nortriptyline, dothiepin/dosulepin, duloxetine, fluoxetine, paroxetine, venlafaxine, fluvoxamine, citalopram, sertraline, trazodone, mirtazepine (and normetabolites)
Zopiclone, aminochloropyridine, zolpidem, zaleplon
Quetiapine, olanzapine, chlorpromazine, clozapine
Paracetamol, aspirin
Tramadol (and metabolites), oxycodone, dextropropoxyphene, norpropoxypheneamide
Fentanyl
Phenytoin, carbamazepine, lamotrigine, valproate
Diphenhydramine, chlorphenamine, hydroxyzine, promethazine
Propranolol, atenolol
GHB/GBL
Amobarbital, butobarbital, phenobarbital, pentobarbital, secobarbital
Sildenafil, tadalafil, vardenafil

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