
**Medical laboratories — Reagents
for staining biological material —
Guidance for users**

*Laboratoires médicaux — Réactifs pour coloration du matériel
biologique — Directives pour les utilisateurs*



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Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Acquiring reagents for <i>in vitro</i> diagnostic staining in biology.....	8
4.1 General principles.....	8
4.2 Manufacturer name.....	8
4.3 Identification of kit components.....	8
5 Information associated with the <i>in vitro</i> diagnostic reagent.....	8
5.1 Intended use.....	8
5.2 Instructions for use.....	9
5.3 Identification of the reagent for staining of biological samples.....	9
5.3.1 Reagent name.....	9
5.3.2 Description of IVD reagent for staining of biological samples.....	10
5.3.3 Batch code.....	10
5.3.4 Contents.....	10
5.4 Storage and handling conditions.....	10
5.5 Expiry date.....	10
5.6 Warnings and precautions.....	11
5.7 Additional information for specific kinds of reagents.....	11
5.7.1 Fluorochromes.....	11
5.7.2 Metal salts.....	11
5.7.3 Additional required equipment.....	11
5.7.4 Reagent preparation.....	11
5.7.5 Control procedure.....	11
5.7.6 Interpretation.....	12
5.7.7 Limitations of the examination procedure.....	12
5.7.8 Literature references.....	12
6 Validation and verification of biological stains.....	12
6.1 General Information.....	12
6.2 Validation for the intended use.....	13
6.3 Verification of the specifications.....	13
6.4 Certification of biological dyes.....	13
6.5 Acquisition of biological stains and dyes.....	13
Annex A (informative) Checklist for establishing or verifying specifications for biological stains and dyes.....	14
Bibliography.....	15

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword — Supplementary information](#).

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This Technical Specification addresses the need to use reagents in staining in biology that fulfill the criteria of ISO 19001, *In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*. This Technical Specification states the requirements for these reagents when used for diagnostic work in medical laboratory fields such as microbiology, molecular biology, cytology, histopathology, and haematology.

Introduction

This Technical Specification is based on ISO 19001, *In vitro diagnostic medical devices – Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*. It is written for medical laboratories that prepare their own *in vitro* diagnostic examination procedures from commercially available reagents that are not specifically intended for *in vitro* diagnostic use, as well as medical laboratories that use commercially prepared *in vitro* diagnostic reagents that are specifically intended for performing *in vitro* diagnostic examinations.

This Technical Specification describes the information that laboratories performing *in vitro* diagnostic staining in biology need to receive from the suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in biology. It also provides specific guidance for use of this information, which is a prerequisite for professional users in medical laboratories to achieve reproducible and comparable results in all fields of staining in biology.

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Medical laboratories — Reagents for staining biological material — Guidance for users

1 Scope

This Technical Specification provides requirements and guidance for selecting and assessing the quality of reagents to be used for *in vitro* diagnostic staining in biology.

This Technical Specification applies to the professional use of reagents for staining in biology by medical laboratories, and in particular, to those who are responsible for the requisition and evaluation of these reagents in medical laboratory disciplines such as clinical cytology, haematology, histopathology, microbiology, and molecular biology.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

ISO 19001, *In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*

3 Terms and definitions

For the purposes of this Technical Specification, the following terms and definitions apply:

3.1

batch lot

defined amount of material that is uniform in its properties and has been produced in one process or series of processes

[SOURCE: ISO 18113-1]

3.2

batch code lot number

distinctive set of numbers and/or letters that specifically identifies a batch and permits its manufacturing, packaging, labelling and distribution history to be traced

[SOURCE: ISO 18113-1]

3.3

blocking reagent

reagent that is used before staining to reduce the inherent background of a sample

[SOURCE: ISO 19001:2013, 3.2, Definition has been reworded to improve clarity.]

3.4

chromogenic reagent

reagent that reacts with certain chemical groups, present or induced, in cells and tissues with the formation of a coloured compound in situ

EXAMPLE Diazonium salt; Schiff's reagent.

[SOURCE: ISO 19001]

3.5

component

part of a finished, packaged and labelled IVD medical device

EXAMPLE raw material, substance, piece, part, software, firmware or labelling.

Note 1 to entry: Typical kit components include antibody solutions, buffer solutions, calibrators, and/or control materials.

[SOURCE: ISO 18113-1]

3.6

control material

substance, material or article intended by its manufacturer to be used to verify the performance properties of an IVD medical device

Note 1 to entry: For staining in biology, control material may also include previously diagnosed patient samples (cellular or tissue).

[SOURCE: ISO 18113-1:2009, 3.13, The term *performance characteristics* has been changed to *performance properties*.]

3.7

dye

coloured organic compound that, when dissolved in a suitable solvent, can impart colour to a material

[SOURCE: ISO 19001]

3.8

examination

set of operations having the purpose of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g. microbiology), an examination can be the total activity of several examinations.

[SOURCE: ISO 18113-1:2009, 3.16, Note 1 to entry has been modified for clarity.]

3.9

expiry date

expiration date

upper limit of the time interval during which the performance properties of a material stored under specified conditions can be assured

[SOURCE: ISO 18113-1:2009, 3.17, The term *performance characteristics* has been changed to *performance properties*.]

3.10

fluorochrome

reagent that emits visible light when irradiated with excitation light of a shorter wavelength

[SOURCE: ISO 19001]

3.11**hazard**

potential source of harm

[SOURCE: ISO/IEC Guide 51:1999]

3.12**information supplied by the manufacturer
labelling**

written, printed, or graphic matter

- affixed to an IVD medical device or any of its containers or wrappers, or
- provided for use with an IVD medical device, related to identification, technical description, and use of the IVD medical device, but excluding shipping documents

EXAMPLE Labels, instructions for use.

[SOURCE: ISO 18113-1]

3.13**instructions for use**

information supplied by the manufacturer to enable the safe and proper use of an IVD medical device

Note 1 to entry: Includes warnings, precautions, and directions supplied by the manufacturer for the use, maintenance, troubleshooting and disposal of an IVD medical device.

[SOURCE: ISO 18113-1]

3.14**intended use****intended purpose**

objective intent of an IVD manufacturer or the laboratory user regarding the use of a product, process or service as reflected in the specifications, instructions and information supplied by the IVD manufacturer or specified by the laboratory user

[SOURCE: ISO 18113-1:2009, 3.31; Definition has been expanded to include intent of laboratory users.]

3.15***in vitro* diagnostic medical device****IVD medical device**

device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of primary samples derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1]

3.16***in vitro* diagnostic reagent****IVD reagent**

chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as an IVD medical device

[SOURCE: ISO 18113-1]

3.17

kit

set of components that are packaged together and intended to be used to perform one or more specific IVD examinations

Note 1 to entry: Kit components can include reagents (such as antibodies, enzymes, buffer and diluents), calibrators, controls and other articles and materials.

[SOURCE: ISO 18113-1]

3.18

label

printed, written, or graphic information placed on a medical device or its container

[SOURCE: ISO 18113-1]

3.19

lectin

protein of non-immunogenic origin with two or more binding sites that recognize and bind to specific saccharide residues

[SOURCE: ISO 19001]

3.20

manufacturer

natural or legal person responsible for the design, manufacture, fabrication, assembly, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on his or her behalf by a third party

[SOURCE: ISO 18113-1]

3.21

medical device

instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of *in vitro* examination of primary samples derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its intended function by such means

Note 1 to entry: The concept medical device includes *in vitro* diagnostic medical device.

[SOURCE: ISO 18113-1:2009, 3.47, Note 1 to entry has been added for emphasis.]

3.22**precaution**

statement that alerts users to special care or activities necessary for safe and effective use of an IVD medical device or to avoid damage to the IVD medical device that could occur as a result of use, including misuse

Note 1 to entry: The distinction between warnings and precautions is a matter of degree, considering the likelihood and seriousness of the hazard. See the definition of *warning* (3.38).

[SOURCE: ISO 18113-1]

3.23**primary sample specimen**

discrete portion of a body fluid or tissue taken for examination, study or analysis of one or more quantities or properties to determine the property of the whole

[SOURCE: ISO 18113-1:2009, 3.54, Non-relevant notes to entry have been deleted.]

3.24**product certification**

third-party attestation that specified requirements relating to a product are fulfilled

[SOURCE: ISO/IEC 17000:2004, 5.5, Definition has been made specific for the product.]

3.25**product certification body**

third-party organization that performs conformity assessment services and provides attestation related to products

[SOURCE: ISO/IEC 17000:2004, 2.5 and 5.5]

3.26**product qualification**

process of demonstrating whether a product is capable of fulfilling specified requirements

[SOURCE: ISO/IEC 12207:2008, 4.22, Definition has been made specific for the product.]

3.27**professional use**

designation that an IVD medical device is intended for personnel who are qualified to perform IVD examinations through special education and training

[SOURCE: ISO 18113-1]

3.28**safety data sheet****SDS****material safety data sheet****MSDS**

document prepared in accordance with regulatory requirements for occupational safety to convey information about a hazardous chemical substance

Note 1 to entry: A safety data sheet typically describes physical properties, health hazards, toxicity, fire and reactivity properties, and provides storage and handling precautions.

Note 2 to entry: Safety data sheets are not considered part of IVD medical device labelling.

Note 3 to entry: A globally harmonized system of classification and labelling of chemicals (GHS) contains classification criteria and hazard communication elements. [20, 21]

[SOURCE: ISO 18113-1:2009, 3.38, The preferred term “*safety data sheet*” and Note 3 to entry have been added.]

3.29

sample

one or more representative parts taken from a system that are intended to provide information on the system

[SOURCE: ISO 18113-1]

3.30

shelf life

period of time until the expiry date, during which an IVD reagent in its original packaging maintains its stability under the storage conditions specified by the manufacturer

Note 1 to entry: *Stability* (3.31) and *expiry date* (3.9) are related concepts.

[SOURCE: ISO 18113-1]

3.31

stability

ability of an IVD medical device to maintain its performance properties within the limits specified by the manufacturer

Note 1 to entry: Stability applies to

- IVD reagents, calibrators and controls, when stored, transported and used in the conditions specified by the manufacturer,
- reconstituted lyophilized materials, working solutions and materials removed from sealed containers, when prepared, used and stored according to the manufacturer's instructions for use, and
- measuring instrument or measuring system after calibration

Note 2 to entry: Stability of an IVD reagent or measuring system is normally measured with respect to time

- in terms of the duration of a time interval over which a metrological property changes by a stated amount, or
- in terms of the change of a property over a stated time interval

[SOURCE: ISO 18113-1]

3.32

stain

solution of one or more dyes at defined concentrations in a defined solvent used for staining

Note 1 to entry: The stain can be prepared by directly dissolving the dye in the solvent or by dilution of a stock solution with suitable agents.

[SOURCE: ISO 19001]

3.33

staining

impartment of colour to a material by means of reaction with a stain or chromogenic reagent

[SOURCE: ISO 19001]

3.34

stock solution of stain

stable defined solution of one or more dyes at a higher concentration or content than that used for staining

Note 1 to entry: Stability refers to constant properties of the dye even in the presence of other dyes.

[SOURCE: ISO 19001:2009, 3.14, The phrase "*or content*" has been added to the definition.]

3.35**validation**

verification, where the specified requirements are adequate for an intended use

Note 1 to entry: ISO 9000:2005, 3.8.5 defines validation as confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.^[1]

[SOURCE: ISO/IEC Guide 99:2007 (VIM), 2.45]

3.36**verification**

provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

Note 1 to entry: The item can be, e.g. a process, measurement procedure, material, compound or measuring system.

Note 2 to entry: The specified requirements can be, e.g. that a manufacturer's claims or specifications are met.

Note 3 to entry: Verification should not be confused with *validation* (3.35).

Note 4 to entry: In chemistry, verification of identity of entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007 (VIM), 2.44]

3.37**use error**

act or omission of an act that has a different IVD medical device response to that intended by the manufacturer or expected by the operator

Note 1 to entry: Use error includes slips, lapses and mistakes

Note 2 to entry: IEC 62366:2007, Annex B and D.1.3 give a discussion and examples of use errors.

[SOURCE: IEC 62366:2007]

3.38**warning**

statement that alerts users about a situation that, if not avoided, could result in hazards or other serious adverse consequences from the use of an IVD medical device

Note 1 to entry: The designation of a hazard alert as a warning is reserved for the most significant consequences.

Note 2 to entry: The distinction between a warning and a *precaution* (3.22) is a matter of degree, considering the likelihood and seriousness of the *hazard* (3.11).

Note 3 to entry: Use includes *use errors* (3.37) and reasonably foreseeable misuse. See ISO 14971 and IEC 62366 for discussions of these concepts.

[SOURCE: ISO 18113-1]

3.39**working solution of stain**

prepared solution including part stock stain and part solvent, used for staining biological materials

[SOURCE: ISO 19001]

4 Acquiring reagents for *in vitro* diagnostic staining in biology

4.1 General principles

The user shall ensure that the staining reagents received from a vendor fulfill the necessary criteria for obtaining reliable and reproducible results. The requirements of ISO 15189:2012, 5.3.2 of apply to the reception, storage, acceptance testing and inventory management of reagents for *in vitro* diagnostic staining in biology.

The information supplied by the manufacturer accompanies the reagent and can usually be found in the following places:

- Outer container label;
- Immediate container label;
- Instructions for use.

Users shall evaluate reagents used for *in vitro* diagnostic staining in biology against the criteria of ISO 19001. The user may obtain information for the assessment from the manufacturer's labelling, or may need to assess the quality of staining prior to performing testing. A checklist is available in [Annex A](#) for the purpose of performing the assessment.

In vitro diagnostic reagents used for staining shall meet the requirements of ISO 19001, which includes the information required by the user to evaluate the reagent. Reagents that do not meet the requirements of ISO 19001 shall not be utilized for *in vitro* diagnostic staining.

To achieve fully identical dye solutions repeatedly, the amount of dye shall be given as pure dye and not dye powder.

NOTE Dyes and stains sold for staining in biology do not always fulfill the *in vitro* diagnostic criteria specified in ISO 19001. Some dyes and stains have been sold under an incorrect name, while other dyes and stains have either been contaminated or have significant variation in the content of the dye.

As the use of dyes and stains in medical laboratories is intended for diagnostic work, it is essential that these reagents fulfill the criteria for *in vitro* diagnostic reagents. Furthermore, to ensure the desired results are achieved, validated laboratory quality control procedures are required.

4.2 Manufacturer name

The name of the manufacturer shall be documented.

4.3 Identification of kit components

In the case of a kit, the identification of the kit components shall be documented. Each component should be identified by name, letter, number, symbol, colour or graphics in the same manner on all labels and in the instructions for use.

5 Information associated with the *in vitro* diagnostic reagent

5.1 Intended use

For *in vitro* diagnostic medical devices, the intended use(s) are specified by the manufacturer in the information supplied by the manufacturer. The intended use statement may be broad and nonspecific, or it may also indicate the property to be identified, the type of sample material, and whether the test is for monitoring, diagnosis, or screening.

For non-*in vitro* diagnostic medical devices, the laboratory shall confirm or define the intended use(s) for the reagent. The intended use may be indicated by the name of the reagent, or a general or specific

intended use statement may be indicated by the manufacturer in the instructions for use. If the intended use is not indicated, the laboratory shall define its intended use for the reagent.

If a laboratory uses a reagent for a purpose other than the intended use stated by the manufacturer, the laboratory shall define and validate the intended use.

EXAMPLE Whether cell or tissue samples or both can be used; whether frozen or chemically-fixed material or both can be used; protocol for tissue processing; which embedding media can be used.

5.2 Instructions for use

The laboratory shall follow the manufacturer's instructions for use for staining of biological material. The instructions for use should address the following information:

- a) handling and treatment of the primary sample before staining,
- b) details of a suitable reaction procedure used by the manufacturer for testing the reactivity of the dye, stain, chromogenic reagent, fluorochrome, antibody or lectin used for staining of biological material,
- c) result(s) expected when using the reaction procedure on the suggested type(s) of material in the way specified by the manufacturer,
- d) notes on suitable positive and negative control tissue and on interpretation of the result(s),
- e) references to published results obtained using the product in the way specified by the manufacturer, and
- f) benefits and limitations of the IVD medical reagent with respect to the intended use may be described, where appropriate.

NOTE 1 In ISO 19001, A.2 and A.3, detailed examples are given of how guidelines of this kind could appear for the procedure methyl green – pyronin Y (a combination of two dyes for the differential staining of DNA and RNA) and the procedure for the Feulgen – Schiff reaction (a chromogenic reagent used for both qualitative and quantitative staining of DNA)].

NOTE 2 In Reference [14, 15] further details are given on the use of antibodies for staining in biology.

5.3 Identification of the reagent for staining of biological samples

5.3.1 Reagent name

The name of the reagent shall be documented.

When the name does not uniquely identify the reagent, an additional means of identification shall also be documented.

EXAMPLE Catalogue number, Chemical Abstracts Service (CAS)-Registry number or Colour Index (C.I.) number and name.

NOTE 1 CAS-Registry numbers are unique numerical code numbers assigned to chemical substances indexed by Chemical Abstracts.[17]

NOTE 2 The Colour Index gives a 5-digit number, the C.I. number and a specially constructed name to most dyes.[19]

NOTE 3 Colour Index numbers and names can for most dyes are found in Conn's Biological Stains.[18]

5.3.2 Description of IVD reagent for staining of biological samples

For reagents designated by the manufacturer for *in vitro* diagnostic testing according to ISO 19001, the information supplied by the manufacturer should include appropriate physico-chemical data accompanied by relevant data sheets for each batch. The data may contain the following information:

- a) Name;
- b) Chemical formula including solvent;
- c) Concentration or content;
- d) Colour index number;
- e) Expiry date;
- f) Warnings and precautions.

5.3.3 Batch code

A batch code, if provided, should be located on the reagent outer label.

If a kit contains different compounds bearing different batch codes, the batch code indicated on the outer container should enable the individual batch code of each component to be traced in the manufacturer's production record.

5.3.4 Contents

The mass, purity, volume, volume or mass after reconstitution and/or the number of examinations obtainable may be indicated.

5.4 Storage and handling conditions

The user shall store the reagent according to the storage conditions necessary to maintain the stability of the reagents, calibrators and control materials. Information for proper storage should be provided by the manufacturer. If not, the user shall determine the storage and handling conditions that are adequate for its intended use.

EXAMPLE 1 2 °C to 8 °C or 2...8 °C or graphical symbol;

-18 °C or below, ≤ -18 °C, or graphical symbol

Other conditions that affect stability may be indicated in the manufacturer's instructions.

EXAMPLE 2 Light, humidity.

Any other conditions that affect the handling or storage of the reagents, calibrators and control materials may be specified in the manufacturer's instructions.

EXAMPLE 3 Fragile.

5.5 Expiry date

The user shall ensure that reagents used for *in vitro* diagnostic examination are within their expiry date. An expiry date based upon the stated storage instructions may be indicated by the manufacturer. If not, the user shall ensure that the stability of the reagent is adequate for its intended use.

Expiry dates should be expressed by the year, month and, where relevant, the day (see ISO 8601).^[2]

EXAMPLE "YYYY-MM-DD" or ""YYYY-MM"

If only the year and month are given, the expiry date is the last day of the month indicated.

The label of the outer container indicates the expiry date of the component having the earliest expiry date, or an earlier date, where appropriate.

Reagents may have shorter expiry dates after opening (stock and in-use reagents). The user shall ensure that any opened reagent used for *in vitro* diagnostic testing is suitable for use.

5.6 Warnings and precautions

Information regarding whether an IVD reagent is considered hazardous may be found in the manufacturer's instructions or in the safety data sheet.

EXAMPLE Chemical, radioactive and biological hazards.

Statements or warning symbols for specific hazards may be required by local, national or regional regulations.

5.7 Additional information for specific kinds of reagents

5.7.1 Fluorochromes

Independent of the type of application, fluorochromes offered for staining in biology shall be accompanied by the following information:

- a) selectivity, i.e. a description of the target(s) which may be demonstrated using the conditions specified;
- b) excitation and emission wavelengths;
- c) for fluorochromes conjugated to antibodies, the ratio of fluorochrome/protein (F/P).

5.7.2 Metal salts

When offering metal compounds for use in metal uptake procedures in staining in biology, the following additional information shall be included:

- a) systematic name;
- b) purity.

5.7.3 Additional required equipment

Any special equipment required for proper performance and safe use but not provided by the manufacturer shall be listed

Information necessary to enable special equipment to be identified and connected for proper use shall be given.

5.7.4 Reagent preparation

All steps required for the preparation of the reagent(s) shall be described

EXAMPLES Reconstitution, mixing, incubation, dilution.

5.7.5 Control procedure

Adequate information about the performance of the reagent and a means to verify that it is performing within specifications shall be provided

Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

EXAMPLE Identification of acceptable control materials, frequency of examination of control materials.