Australian Government

Department of Health

Therapeutic Goods Administration

Classification of IVD medical devices

Version 2.0, December 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Initial publication	IVD Section	16/08/2010
V1.1	Minor updates	Devices Conformity Assessment Section	November 2011
V2.0	Updated to reflect regulatory reforms	IVD Section	December 2015

Contents

Introduction

This guidance on the classification of in-vitro diagnostic medical devices (IVDs) is to assist manufacturers to classify their IVDs according to the Australian classification rules for supply in Australia.

Follow this guidance in conjunction with the legislative basis for classifying IVDs to gain the best possible understanding of the IVD classification framework.

These classification rules apply to both commercial and in-house IVDs.

Basis for classifying

The classification rules are based on a risk based approach to regulation, and IVDs are classified according to the health risk (either to the public or an individual) that may arise from an incorrect result.

- The higher the potential risk an incorrect result would pose, the higher the classification.
- The higher the risk class of a device, the higher the level of assessment and monitoring is required to demonstrate initial and ongoing compliance with the conformity assessment procedures.

Responsibility for classifying IVDs

The manufacturer is responsible for determining the class of the IVD by:

- using the classification rules in Schedule 2A of the in *Therapeutic Goods (Medical Devices) Regulations 2002*, and
- taking into consideration both the:
  - intended purpose of the device,
  - level of risk to the patient and public of an incorrect result.

Classifying IVDs

Classes of IVDs

Paragraph 3.3 (2)(b)

IVDs are classified into four risk classes on the basis of the manufacturer's intended purpose for the device:

IVD classification	Level of risk
Class 1	No public health risk **or** low personal risk
Class 2	Low public health risk **or** moderate personal risk
Class 3	Moderate public health risk **or** high personal risk
Class 4	High public health risk

Devices to be used in combination with other devices

Subregulation 3.3 (3)

If an IVD is designed to be used in combination with other IVDs, non-IVD medical devices, or accessories to medical devices, each device must be classified separately.

Accessories to medical devices are classified separately

Subregulation 3.3 (4)

Accessories are classified separately from the IVD that they are intended to be used with.

An accessory to an IVD is an item that its manufacturer specifically intends to be used together with an IVD to enable that IVD to be used as intended.

Software

Subregulation 3.3 (5)

If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

IVD software that is not intended to drive or influence an IVD instrument (or medical device that is not an IVD) is classified according to its intended purpose.

For more information, please go to Software as in vitro diagnostic medical devices (IVDs).

The highest classification determines the class of IVD

Subregulation 3.3 (7)

You must consider all of the classification rules to determine the correct class of an IVD.

If more than once classification rule applies to your IVD, apply the highest risk classification.

For example, identical devices may be classified differently if they have a different diagnostic purpose. This is why the manufacturer's intended purpose of the device is critical to determining the appropriate class.

Exceptions

There are exceptions, such as:

- Rule 1.5 specifies that IVDs that are non assay-specific quality control material are Class 2 IVDs
- Rule 1.6 specifies that instruments, specimen receptacles (other than a specimen receptacle for self-testing) and microbiological culture media are Class 1 IVDs
- Rule 1.8 specifies that export only IVDs are classified as Class 1 IVDs.

System or procedure pack

Subregulation 3.3 (7)

If one (or more) IVDs are supplied as part of a system or a procedure pack, the classification for the entire pack is the highest class of any individual IVD in the pack.

For example, if a procedure pack contains a selection of Class 1, 2 and 3 IVDs, then the entire pack is classified as a Class 3 IVD.

Packs containing IVDs and medical devices

Subregulation 3.3(9)

IVD and medical devices with different classifications

A system or procedure pack, that contains both IVDs and non-IVD medical devices which have different levels of classification, is classified according to the highest class of device in the pack. This will also determine if a system or procedure pack is to be included in the ARTG as an IVD medical device or a non-IVD medical device.

For example, a procedure pack contains:

- a portable prothrombin time meter (Class 1 IVD)
- test strips or cartridges for prothrombin time self-testing (Class 3 IVD)
- and a lancet for obtaining a blood specimen (Class IIa medical device).

The procedure pack would take on the highest classification of any individual component in the pack (in this case, Class 3 IVD), and is therefore required to be included in the ARTG as an IVD medical device.

IVD and a medical device with comparable classifications

Subregulation 3.3(10)

When a system or procedure pack contains both an IVD and a non-IVD medical device which have a comparable risk classification, the pack is classified according to its primary intended purpose. This will also determine whether the pack is included on the ARTG as an IVD or a non-IVD medical device.

Related information and guidance

Section 16 Systems and Procedure packs; Australian Regulatory Guidelines for Medical Devices

Applying the classification rules

Ensure the classification is consistent with the intended purpose you assign to your IVD as indicated by the packaging and information supplied with the device (e.g., instructions for use or advertising material).

We have provided some classification examples to help you, if required.

Rule 1.1 – Detection of transmissible agents posing a high public health risk

IVDs captured by this rule pose a high public health risk due to the significant impact incorrect results would have for public health, and are therefore Class 4 IVD medical devices or Class 4 in-house IVDs.

Rule 1.1 is presented in two parts:

- **1.1 (a)** applies to IVDs that are intended to be used to establish the safety of blood and blood components for transfusion, or cells, tissues and organs for transplantation.
- **1.1 (b)** applies to IVDs that are intended to be used to diagnose clinical infections that cause serious diseases with a high risk of transmission within the Australian population.

Classification Rule 1.1 (a)

This rule applies to all assays intended to be used to determine suitability for transfusion or transplantation as part of the laboratory's infectious diseases donor screening algorithm, which includes:

- front-line or screening assays
- confirmatory assays
- supplemental assays
- IVDs that detect structural components or surrogate markers of transmissible agents that cause serious disease.

In most cases, a positive result is a major determinant as to whether the donation or product will be used.

Classification Rule 1.1 (b)

This rule applies to IVDs that are intended to detect infectious agents capable of causing serious disease which:

- could result in death or long-term disability
- are often incurable or require major therapeutic interventions
- and where accurate diagnosis is vital to mitigate the public health impact of the disease.

Some IVDs are only intended to be used in a diagnostic setting, but are identical to those intended to be used for screening blood and tissue donations.

If rule 1.1 (b) does not apply

If rule 1.1 (b) does not also apply to these devices, they may be classified according to other rules, provided the IVD is marketed in accordance with the alternate classification.

For example, a syphilis assay is classified as a Class 4 IVD if it is intended to screen blood and tissue donations, but is a Class 3 IVD as per rule 1.3 (1) (a) if it is intended for diagnostic purposes only.

Recommendation from expert advisory panel

To avoid uncertainty about the classification of IVDs as Class 4 under rule 1.1 (b), TGA consulted with an expert advisory panel on which transmissible agents could be considered to cause serious disease with a high risk of propagation in Australia.

Please note

Tests for other transmissible agents would only be considered Class 4 IVDs on the basis of further expert advice.

IVD classification examples for Rule 1.1.

Rule 1.2 – Detection of red blood cell antigens and antibodies and non-red cell typing

IVDs captured by this rule pose a high public health risk, or a high personal risk due to the significant impact incorrect results would have on public health and patient outcomes.

Classification rule 1.2 divides blood grouping IVDs into two subsets depending on:

- the nature of the blood group marker the IVD is designed to detect
- its importance in a transfusion or transplantation setting.

Which class applies?

Class 3 IVDs

All IVDs which:

- test for antigens, antibodies or genetic markers specific to any of the red blood cell markers not identified in rule 1.2 (2)
- are intended to be used in tissue typing to test for human leukocyte antigens and antibodies or platelet markers.

Class 4 IVDs

All IVDs which test for antigens, antibodies or genetic markers specific to any of the high risk blood groups identified in rule 1.2(2). Red blood cell markers captured by this rule are critical to ensuring safe transfusion of blood and blood components, or transplantation of cells, tissues and organs.

IVD classification examples for Rule 1.2.

Rule 1.3 – Detection of transmissible agents or biological characteristics

(Posing a moderate public health risk or a high personal risk)

IVDs captured by this rule pose a moderate public health risk, or high personal risk, and often provide the critical or sole basis for correct diagnosis, and are therefore Class 3 IVDs. This rule applies to IVDs that are intended to be used for the detection of transmissible agents or biological characteristics:

- which cause diseases that, although often treatable, may result in death or long term disability if not treated in a timely manner
- where an incorrect result could lead to a patient management decision which has a significant impact on patient outcomes (e.g. result in death or severe disability)
- where an accurate diagnosis offers an opportunity to mitigate the public health impact of the condition
- Where they provide information that is critical for patient treatment

Please note

IVDs used to detect transmissible agents included in the Australian National Notifiable Diseases Surveillance System (NNDSS) were previously classified as Class 3 under now repealed classification rule 1.3(2).

The majority of IVDs to detect organisms included in the NNDSS continue to be Class 3 IVDs under classification rule 1.3(1) however there are some that are now considered to be Class 2 IVDs.

IVD classification examples for Rule 1.3.

Rule 1.4 – IVDs for self-testing

Self-testing IVDs are intended to be used by individuals with no scientific or technical expertise, or formal training in a medical field or discipline that the test relates to.

In general, Rule 1.4 classifies IVDs for self-testing as Class 3 IVDs if the condition, ailment or defect to which the test relates is considered to be:

- inappropriate to be diagnosed or treated without consulting a health professional
- beyond the ability of the average person to evaluate accurately, or treat safely without adequate supervision.

Relevant definitions

Regulation 1.3 defines an **IVD medical device for self-testing** as one intended to be used:

a. in the home or similar environment by a lay person; or

b. in the collection of a sample by a lay person and, if the sample is tested by another person (e.g. a laboratory) the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the test relates.

TGA interprets **direct supervision** as written or verbal communication from a health professional that is able to:

- explain the significance of the test **and**
- answer questions that the person may have regarding the interpretation of the result.

This applies regardless of the nature of the result, e.g. positive, negative, quantitative value.

Other classification rules can apply

If the self-test does not determine a serious condition, or the result is preliminary and follow-up testing is required, other classification rules apply. The instructions for use provided with the test should clearly advise the patient that follow-up testing with a medical practitioner is required.

Self-testing IVDs that cannot be supplied in Australia

Certain types of self-testing IVDs cannot be entered on the ARTG, and therefore cannot be legally supplied in Australia, including:

- tests for pathogenic organisms or transmissible agents (including notifiable infectious diseases except HIV)
- genetic tests
- tests for serious disorders (such as cancer or myocardial infarction)

A full description of IVDs that are excluded from ARTG entry can be found within the *Therapeutic Goods (Excluded purposes) Specification 2010* made under section 41BEA of the Act.

Please note

The *Therapeutic Goods (Excluded purposes) Specification 2010* does not apply if the IVD:

- is used as part of a government-sponsored screening program, or
- monitors a previously diagnosed disease, or
- is for export only.

IVD classification examples for Rule 1.4.

Rule 1.5 – Non-assay specific quality control material

IVDs captured by this rule pose a low public health risk, or moderate personal risk.

This rule classifies non-assay specific quality control material as Class 2 IVDs, despite classification rules 1.1 to 1.4.

Non assay-specfic quality control material

Quality control material is taken to be controls, calibrators and standards. As a subset of this non assay-specific quality control materials is control material that is:

- not intended to be used with a specific IVD(s), and
- used to monitor the overall performance of a device.

It is not control material that is intended by the manufacturer to be used on its own to validate and/or release results for a particular IVD(s). If representative values are provided as examples of typical results when used with certain assays:

- the wording in the IFU would need to reflect that it is indicative only, and
- the end user must establish expected results for their particular assay(s).

Assay-specific control material

Classification Rule 1.5 does not apply to assay-specific control material which is control material intended to be used:

- with a particular IVD(s), and
- for the validation and/or release of results.

Assay-specific control materials are classified in accordance with Classification rules 1.1 to 1.4, and can be either Class 2, 3 or 4 IVDs depending on the classification of the assay it is intended to be used with.

IVD classification examples for Rule 1.5.

Rule 1.6 – Reagents, instruments

IVDs captured by this rule pose no (or minimal) public health risk, or low personal risk.

This rule classifies general laboratory products (reagents, instruments, apparatus, equipment or system) that are manufactured, sold or represented for use for in vitro diagnostic examinations as Class 1 IVDs.

In addition, despite classification rules 1.1 to 1.4, the following devices are classified as Class 1 IVDs:

- instruments specifically intended for IVD procedures
- specimen receptacles (other than those intended for use in self-testing)
- microbiological culture media.

Reagents supplied separately

A separately supplied reagent, with a clearly defined purpose relating to its use, is classified according to the class of the analyte or parameter it is intended to be used with, for example, for use:

- to determine a specific analyte or parameter
- with a particular IVD
- with a group of similar or closely related tests

Products for general laboratory use that are not IVDs

These are not IVD medical devices unless the product is specifically intended by the manufacturer to be used for in vitro diagnostic examination.

For example, pipettes, test tubes, baths, centrifuges, balances and general consumables which are not specifically intended by the manufacturer to be used to perform a particular test, are not considered IVD medical devices.

IVD classification examples for Rule 1.6.

Rule 1.7 – Other IVDs are Class 2 IVD medical devices

IVDs captured by this rule pose a low public health risk, or moderate personal risk, and it is unlikely that an incorrect result will cause death or severe disability, or have a significant negative impact on patient outcomes.

The results obtained from devices captured by this rule rarely provide the sole determinant for the correct diagnosis. If it is the sole determinant, other information is available to guide the physician such as presenting signs and symptoms, or clinical information.

What devices are captured by this rule?

This rule applies to IVDs not captured by any of the other classification rules described in classification rules 1.1 to 1.6.

This classification also includes IVDs that detect infectious agents that are not easily spread in a population and/or cause 'self-limiting' disease, and are therefore considered to represent a low public health risk.

IVD classification examples for Rule 1.7.

Rule 1.8 – IVDs for export only

If the manufacturer of an IVD medical device only intends it to be exported from Australia (i.e. not supply it in Australia), it is classified as a Class 1 IVD medical device.

Legislative basis for classifying IVDs

The following provisions in the Medical Device Regulations describe the hierarchy of medical device classifications, and the relationship between the classification of IVD and non-IVD medical devices.

- Division 3.1 (particularly regulation 3.1 and subregulations 3.2(2) and 3.3(2)).
- Schedule 2A.

IVD classification examples

Detection of transmissible agents posing a high public health risk

Rule: 1.1 (a or b) **Class:** 4

Examples of IVDs captured by Rule 1.1(a)

- All tests intended to be used for blood, organ and tissue donor screening, including screening and confirmatory assays for:
  - Human immunodeficiency virus (HIV)
  - Hepatitis C virus (HCV)
  - Hepatitis B virus
  - HTLV I/II
  - Syphilis.
- Any additional assays used to screen donors on a supplementary basis, such as those used to determine Cytomegalovirus status or to screen for Malaria.

Examples of IVDs captured by Rule 1.1(b)

- Tests intended to be used to screen for HIV, either at the point of care or for self-testing.
- Tests intended for the diagnosis of infection with, or exposure to:
  - Severe acute respiratory syndrome-associated coronavirus (SARS-CoV)
  - Highly virulent pandemic influenza
  - Variola virus (Smallpox virus)
  - Viral haemorrhagic fevers, such as Ebola virus or Marburg virus.
- All tests intended for the diagnosis of infection with, or exposure to:
  - HIV 1 & 2
  - Hepatitis C virus
  - Hepatitis B virus*
  - HTLV I/II

Note: Applies to first-line assays, confirmatory assays and supplemental assays.

**Assays for Hepatitis B markers that are intended by the manufacturer to be used as an aid in the diagnosis of acute or chronic infection, or exposure to Hepatitis B, e.g.:*

- *Hepatitis B surface antigen (HBsAg)*
- *Hepatitis B core IgM antibodies (anti-HBcore IgM)*
- *Hepatitis B core total antibodies (anti-HBcore tot)*

- *Hepatitis B virus nucleic acid detection (HBV NAT)*
- *Other tests for Hepatitis B, including anti-HBs would be considered Class 4 IVDs if the manufacturer's intended purpose for the device included aiding in the diagnosis of Hepatitis B.*

Detection of red blood cell antigens and antibodies and non-red cell typing

Rule: 1.2 **Class:** either 3 or 4

Examples of Class 4 IVDs

IVDs intended for detecting red blood cell antigens, antibodies or genetic markers specific to the following high risk blood groups:

- ABO system - ABO1 (A), ABO2 (B), ABO3 (AB)
- Rhesus system - RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)
- Kell system - KEL1 (K)
- Kidd system - JK1 (Jka), JK2 (Jkb)
- Duffy system - FY1 (Fya), FY2 (Fyb).

Examples of Class 3 IVDs

- IVDs intended for testing for red blood cell antigens or antibodies for:
  - Cw or V from the Rhesus system
  - Cellano (k) from the Kell blood group system
  - any markers from MNS or Cartwright blood group systems.
- All IVDs intended for use in tissue typing to detect antigens and antibodies for any human leukocyte antigens.
- IVDs intended for subtyping previously determined ABO system A group reactive patients (i.e. A_1, A_2, A_3 etc.).
- Tests intended for the **quantitative** determination of antibodies to Rhesus system blood group antigens (i.e. anti-D).

Detection of transmissible agents or biological characteristics

(Posing moderate public health risk or high personal risk)

Rule: 1.3 **Class:** 3

Examples of Class 3 IVDs

- Tests intended to detect the presence or exposure to a **sexually transmitted agent**, such as:
  - Neisseria gonorrhoeae
  - Chlamydia trachomatis

- Syphilis (Treponema pallidum)
- Donovanosis (Klebsiella (Calymmatobacterium) granulomatis)
- Herpes simplex virus 1 & 2
- Lymphogranuloma venereum (C. trachomatis L-1, L-2, L-3)
- Human papillomavirus
- Trichomoniasis (Trichomonas vaginalis).

· Tests intended to detect (in cerebrospinal fluid or blood) the **presence of an infectious agent that poses a high personal risk and has a risk of limited propagation**, including tests for the:

- direct detection of Cryptococcus neoformans antigens
- detection of N. meningitidis in CSF or blood
- detection of Haemophilus influenzae type B (Hib) antigen
- detection of IgM antibodies to malaria parasites
- detection of Prion diseases
- detection of Hendra virus.

· Tests that are intended to detect the **presence of an infectious agent and where an incorrect result could cause death or severe disability** to the individual or foetus being tested, such as tests to:

- confirm the presence or identity of methicillin-resistant *Staphylococcus aureus* (MRSA), either directly from a clinical specimen or from a cultured isolate.
- detect transmissible agents that cause serious infectious diseases such as influenza, typhoid fever and pertussis.
- specifically detect/identify Salmonella typhi, including serotyping reagents intended to identify Samonella typhi at the subspecies level (e.g., a serotyping kit intended to discriminate between S. typhi and S. paratyphi).
- detect Shiga toxin-producing E. coli or Verotoxin‑producing E. coli (STEC or VTEC) including serotyping reagents to specifically identify E.coli 0157:H7 (e.g., 0157 and H7 antisera).

· Tests to detect **Influenza A** including tests intended to:

- screen for influenza A (e.g., detection of matrix protein)
- detect or type an influenza A infection by different hemagglutinin subtypes and neuraminidase subtypes (e.g., H1 through H18 and N1 through N11 respectively)
- detect or type certain influenza A strains (e.g., H1N1, H5N1)

Only tests specifically intended to detect **highly virulent pandemic** strains that pose a high public health risk would be considered Class 4 IVDs.

· Screening tests intended to **determine prenatal immune status for infections** that may cause illness in pregnant women and birth defects, or serious infections in newborns, such as the detection of antibodies for:

- Toxoplasma gondii
- Rubella virus
- Cytomegalovirus (CMV)
- Herpes simplex virus 1 & 2
- Measles virus
- Treponema pallidum.

Note: *If tests to detect immune status for these infections are not specifically intended for prenatal screening, they are classified according to other rules.*

- Tests intended to determine **infective disease status or immune status** where there is a risk that an incorrect result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient such as tests for the detection of CMV IgG in transplant patients.
- Tests that are intended to be used **to select patients for selective therapy and management**, such as:
  - Viral genotyping assays to establish a suitable course of therapy
  - Her2/neu testing to select patients with breast cancer for treatment using the drug Herceptin.
- Tests intended to **detect tumour markers, or to aid in the diagnosis of cancer**, such as:
  - free prostate specific antigen (free PSA)
  - carcinoembryonic antigen (CEA)
  - human chorionic gonadotropin (hCG)
  - cancer antigen (CA) 15-3, CA125.
- Pharmacogenetic tests intended to **predict metabolism of warfarin, or tests for other cytochrome P450 oxidative enzymes** which may be used to gauge the metabolism rate of drugs.
- All tests intended for **human genetic testing** (whether testing for an inherited or acquired genetic marker), including:
  - prenatal genetic screening
  - tests for detecting the Philadelphia chromosome
  - tests for Huntington's disease
  - test for cystic fibrosis
  - FISH probe to detect the BCR-ABL translocation.
- Tests intended for **therapeutic monitoring of immunosuppressive medicines** such as, cyclosporin and tacrolimus, due to the impact of an incorrect result on a patient and the potential for adverse transplantation outcome.
- Tests for **monitoring biological components** including acute cardiac markers such as, Troponin I, Troponin T and CKMB.

- Tests intended for the **management of life-threatening infectious disease** include viral load and genotyping assays for HIV and Hepatitis C virus.
- Tests intended for **screening of congenital disorders**, including tests for alpha-fetoprotein (AFP) when used in the detection of foetal open neural tube defects.
- **Software that is supplied as a 'stand-alone' IVD**, for example software for the interpretation of results obtained as part of a first trimester screening assessment to determine foetal risk of trisomy 21.

Examples of IVDs that are not captured by this rule

- Rule 1.3 (f) includes a note which clarifies the classification of tests used in the diagnosis or treatment of cancer, where a therapy decision is only made after further investigation, or that are used for monitoring.

  The following examples would therefore be considered Class 2 IVDs:

  – tests intended to be used for initial screening, such as a faecal occult blood screening test (FOBT) for bowel cancer, require further investigation if a positive result is obtained.

  – tests used only for monitoring disease status, such as a total PSA which may aid in the management of a prostate cancer patient.
- Chlamydia tests that are only intended to detect to the genus level (and not to the species level) are Class 2 IVDs under Rule 1.7.
- Individually supplied serotyping reagents to identify markers that assist in the characterisation of Salmonella at the species level, but do not in themselves specifically identify S. typhi, (e.g., monovalent and polyvalent O antisera and H antisera).

IVDs for self-testing

Rule: 1.4 **Class:** 3

Examples

- System for the self-monitoring of blood glucose.

  Each device is classified individually, with the highest class applying to the overall system:

  – the glucose meter is classified as a Class 1 IVD as per rule 1.6

  – the glucose reagent test strip is a Class 3 IVD because an incorrect result obtained when self-testing for blood glucose may lead to a life-threatening situation

  – the lancet is a Class IIa medical device
- Prothrombin time reagent test strips for the self-monitoring of the effects of anticoagulation therapy.

Examples of self-testing IVDs that are not captured by this rule

- Tests that do not determine a serious condition (and where the results are preliminary) are Class 2 IVDs:

  – Pregnancy and fertility self-testing kits

- Urine self-test strips to detect glucose and other general urine chemistry analytes

· A self-test for HIV is a Class 4 IVD as it is a screening test for a serious disease and Classification Rule 1.1b applies (i.e., higher classification rule applies).

Non-assay specific quality control material

Rule: 1.5 **Class:** 2

Examples

· Non-assay specific control plasmas for use in coagulation studies.

· Non-assay specific control serum containing multiple biochemical analytes.

· Non-assay specific control serum, intended for use as an independent control for HCV antibody assays.

· A DNA or RNA probe supplied for use as a non-assay specific normal control for in situ hybridisation (ISH).

Reagents, instruments

Rule: 1.6 **Class:** 1

Examples

· Microscope counting chambers, such as haemocytometers and chambered urinalysis slides labelled as being intended for the microscopic examination of urine and other body fluids.

Note: *Plain ground-glass microscope slides, although intended for an application related to microscopic analysis, are not IVDs unless specifically intended for diagnostic use.*

· Except for specimen containers intended for use in self-testing, evacuated or non-evacuated blood collection tubes and specimen containers intended for the collection of urine, faeces, cells or tissue specimens for subsequent in vitro examination.

Note: *General laboratory tubes that are used to contain reactions or to contain and store processed specimens are not considered to be specimen receptacles.*

· Manual, automated or semi-automated instruments intended for use as an IVD such as an enzyme immunoassay analyser, or an ESR analyser.

· Prepared (ready to use) microbiological culture media, including agar containing selecting agents, antimicrobials, chromogenic agents or chemical indicators for colony differentiation.

Note: *Dehydrated powders and agar bases are not considered to be IVDs.*

· Non-assay specific instrument consumable reagents, e.g. a wash solution for use on instrument XYZ. The wash solution is not specific to a particular analyte, however is specified for use on instrument XYZ.

Note: *Standard buffers (e.g. PBS) and saline solutions are not considered to be an IVD unless intended specifically for use as an IVD.*

Stains

Single staining solutions for diagnostic use can be classified as Class 1 IVDs under rule 1.6 (1) **only if** they are intended as general purpose reagents:

- e.g. grams iodine solution which is intended by the manufacturer for in vitro diagnostic use as a general purpose stain.

If staining solutions are supplied for a specific purpose, either individually or as a kit, the staining solution or kit must be classified according to the overall intended purpose of the stain or kit (see examples for Class 2 IVDs).

Stain powders or base ingredients used to prepare stains for use in a diagnostic setting are not considered to be IVDs because they are not finished products. However, once a powder or base ingredients have been made into a stain by a laboratory, the finished staining solution is an in-house IVD, and an appropriate risk classification must be applied according to the overall intended purpose of the stain.

Other IVDs are Class 2 IVD medical devices

Rule: 1.7 **Class:** 2

Examples

- A foetal cell staining kit intended for performing a Kleihauer stain to identify candidates required to receive more than one dose of anti-D immunoglobulin.
- A ready-to-use Romanowski staining kit intended for use in haematology for staining peripheral blood smears to perform white cell differentiation and evaluation of red cell morphology.
- A non-assay specific bacterial or viral RNA nucleic acid extraction kit intended for the extraction of pathogenic nucleic acid from a clinical specimen.
- Most biochemistry tests for blood gases, hormones, vitamins, enzymes, metabolic markers and substrates.
- IVDs for performing coagulation testing, including activated partial thromboplastin time (APTT), factor assays and prothrombin time testing (other than prothrombin time for self-testing, which is captured as a Class 3 IVD by rule 1.4).
- Cell culture lines for the culture of viruses present in clinical specimens.
- Pregnancy tests for self-testing.
- Tests to detect infection by:
  - Helicobacter pylori
  - Clostridium difficile
  - Adenovirus
  - Rotavirus
  - Giardia lamblia.
- Screening tests intended to presumptively detect Salmonella at the genus/species level such as individually supplied serotyping reagents that are not intended to identify an individual subspecies/serotype in their own right (e.g., polyvalent and monovalent O antisera).

The majority of individually supplied antisera would therefore be Class 2, even if the combination of results could lead, for example, to a diagnosis of S. typhi.

Note: *Confirmatory identification for microbiological culture using specific serotyping reagents, are classified according to the analyte being detected. For example, serotyping reagents to specifically detect/identify Salmonella typhi at the subspecies level (e.g., a serotyping kit intended to discriminate between S. typhi and S. paratyphi) or Haemophilus influenza serotype b are Class 3 IVDs.*

- Biochemical tests for establishing the presumptive identification of microbiological culture isolates, or for determining antimicrobial susceptibility of microbiological culture isolates.
- Tests used to detect transmissible agents that have public health importance but pose a moderate personal risk because they generally cause self-limiting disease:
  - Cryptosporidiosis
  - Campylobacter
  - Hepatitis A virus
  - Salmonella enteritidis
  - Mumps
  - Varicella zoster virus (unless intended for prenatal screening)
  - Barmah Forest virus
  - Chikungunya virus
  - Ross River virus
  - Ornithosis

Note: *IVDs to detect the above infectious organisms are included in the Australian National Notifiable Diseases Surveillance System (NNDSS) list and were previously classified as Class 3 IVDs.*

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
https://www.tga.gov.au

Reference/Publication #