



**Health Santé  
Canada Canada**

# **CANADIAN RULE BASED CLASSIFICATION SYSTEM (IVDD)**

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**Life Sciences British Columbia  
NRC-Industry Research Assistance Program**

**Health Canada Regulations on Medical Devices**

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# ***IN VITRO* DIAGNOSTIC DEVICES (IVDD)**

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- “*In vitro* diagnostic device” or “IVDD” means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.

# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 1- IVDDs used for donor screening

- An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as **Class IV**.  
(anti-HIV, HBsAg)



# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 2 - IVDDs used to determine disease status or immune status

- An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as **Class II**, (Hepatitis A virus, Influenza Virus A, B, C)

### EXCEPT:

- (a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Canadian population, in which case it is classified as **Class IV** (anti HIV-1 and/or HIV-2 EIA)



# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 2 - IVDDs used to determine disease status or immune status (cont.)

- (b) it falls into one of the following categories, in which case it is classified as **Class III**:
  - (i) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Canadian population,  
(Microbacterium sp. and Legionella)
  - (ii) it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent,  
(syphilis)

# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 2 - IVDDs used to determine disease status or immune status (cont.)

- (iii) it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or (Neisseria meningitidis, Haemophilus influenzae)
- (iv) there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring. (rubella virus, Streptococcus B)

# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 3 - IVDDs used for patient management purposes:

- An IVDD that is intended to be used for patient management is classified as **Class II**, (MIC (minimum inhibitory concentration) panels, DNA probe tests)

**EXCEPT** if it falls into one of the following categories, in which case it is classified as **Class III**:

- (a) it is intended to be used for the management of patients suffering from a life-threatening disease; or (p24 Ag HIV (prognosis only), IVDDs for the determination of drug resistance gene of HIV isolates)



# USE WITH RESPECT TO TRANSMISSIBLE AGENTS – RULES 1 - 3

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## Rule 3 - IVDDs used for patient management purposes (cont.):

- *(b)* there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

(CA15-3/CA125/CE/PSA/hCG (monitoring)  
for tumor outcomes)

# OTHER USES – RULES 4 & 5

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## **Rule 4 - IVDDs used for disease status and for patient management (cont.)**

- An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as **Class II**,  
(prostatic acid phosphatase, drugs of abuse, glucose)

**EXCEPT** if it falls into one of the following categories, in which case it is classified as **Class III**:

- (a) it is intended to be used in screening for or in the diagnosis of cancer;  
(automated PAP smear readers)

## OTHER USES - RULES 4 & 5

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### **Rule 4 - IVDDs used for disease status and for patient management (cont.)**

- (b) it is intended to be used for genetic testing; (testing for cystic fibrosis, breast cancer)
- (c) it is intended to be used in screening for congenital disorders in the fetus; (quantitative determination of serum or CSF levels of alpha foetoprotein in prenatal testing of spina bifida or Down Syndrome)



# OTHER USES - RULES 4 & 5

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## Rule 4 - IVDDs used for disease status and for patient management (cont.)

- (d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring;  
(IVDDs intended to be used for the screening of or diagnosis of late-onset disorders such as Huntington's disease or Alzheimer's disease)
- (e) it is intended to be used for disease staging; or  
(characterization of the nature or extent of a medical condition such as the degree of metastasis of a cancer tumour)



## OTHER USES - RULES 4 & 5

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### **Rule 4 - IVDDs used for disease status and for patient management (cont.)**

- (f) it is intended to be used to monitor levels of drugs, substances or biological components, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.

(IVDDs used to determine and monitor blood potassium (K<sup>+</sup>), blood gases and pH)

## OTHER USES - RULES 4 & 5

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### **Rule 5 - IVDDs for immunological typing:**

- An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as **Class III**.

(single reagents, kits or automated systems, used to ensure the immunological capability of donated blood, tissues, or organs)



# SPECIAL RULES

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- “Near patient *in vitro* diagnostic device” or “near patient IVDD” means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside.

# SPECIAL RULES – RULES 6 - 9

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## Rule 6 - Near-patient IVDDs:

- A near patient IVDD is classified as **Class III**.

(detection of Streptococcus, occult blood test kits, prothrombin time tests and blood glucose monitors)



# SPECIAL RULES – RULES 6 - 9

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## **Rule 7 - IVDDs specifically intended to used together:**

- In cases where an IVDD, including its analyzers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.

(sample buffers, dilution buffers, controls, coated microplates, etc. are classified in the same risk class as the associated test kit)

# SPECIAL RULES – RULES 6 - 9

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## Rule 8 - Class I IVDDs:

- If rules 1 to 7 do not apply, all other IVDDs are classified as **Class I**.

(general laboratory products (reagents, instruments, apparatus, equipment or system) for IVDD purposes → pipetters, specimen containers, microscopes, etc.)

# SPECIAL RULES – RULES 6 - 9

## Rule 9 - Special classification:

- Despite rules 1 to 8, an IVDD set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE		
Item	Column 1 IVDD	Column 2 Class
1.	Near patient <i>in vitro</i> diagnostic device for the detection of pregnancy or for fertility testing	II
2.	Near patient <i>in vitro</i> diagnostic device for determining cholesterol level	II
3.	Microbiological media used to identify or infer the identity of a microorganism	I
4.	IVDD used to identify or infer the identity of a cultured microorganism	I

# EXPERIENCE WITH THE RULES

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- High level of agreement (BMD and Sponsor) on device classification
- Most of the rules are clear, explicit and objective
- Problems occur when subjective opinion is possible
- Rule wording has caused some incongruous outcomes
- A couple of new rules would be beneficial

# RESOURCES ON THE INTERNET

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- Classification can be determined by comparing to similar devices already licensed
- Going to [www.mdall.ca](http://www.mdall.ca) allows you to search for licensed Class, II, III and IV devices
- MDALL (Medical Device Active Licence Listing) also has a section for Archived Licences
- It is possible to search by Company Name, Company ID, Licence Name, Licence Number, Device Name and Device Identifier