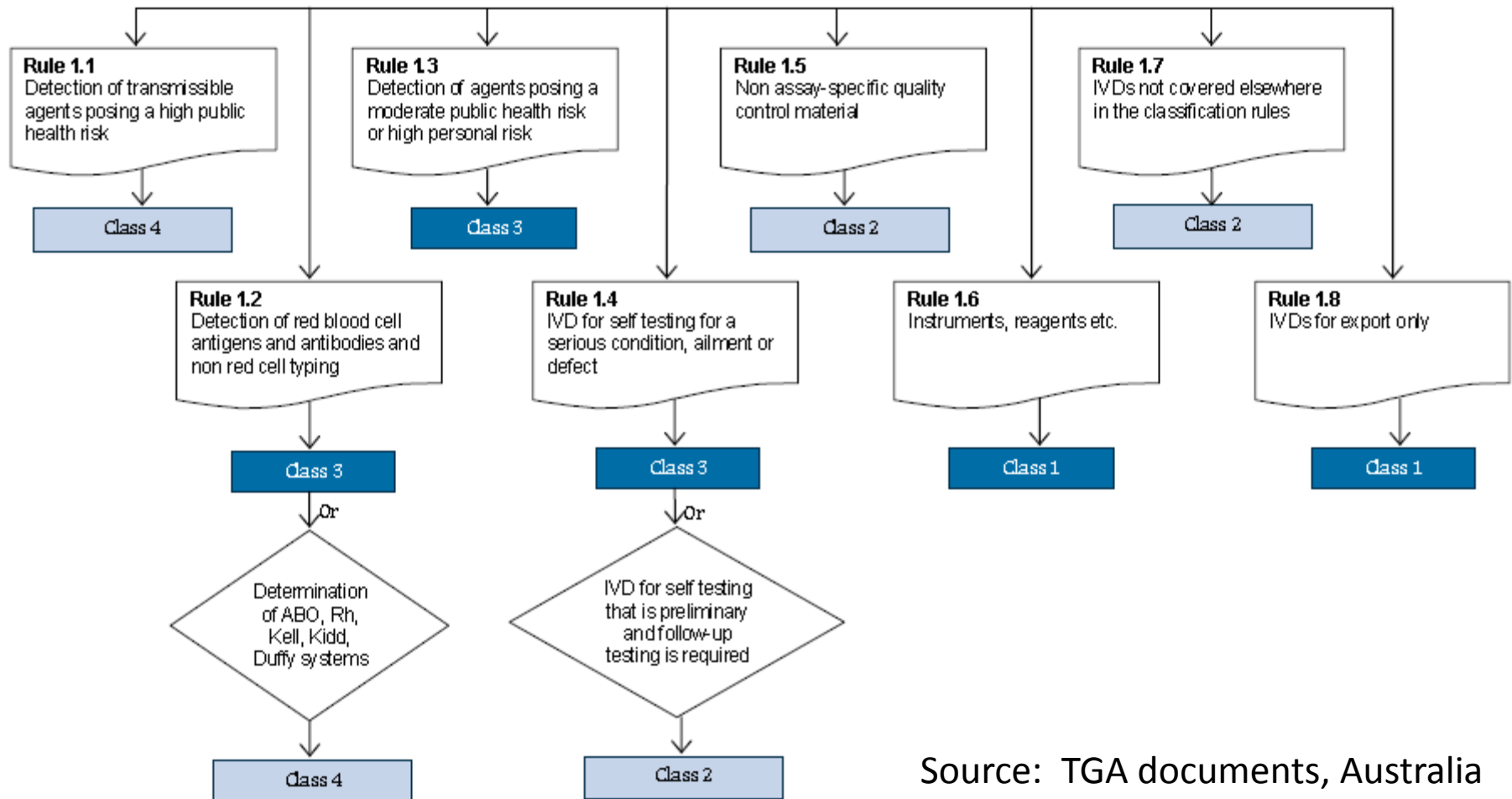


# IVD Classification Rules



Source: TGA documents, Australia

# GHTF Risk based Classification

CLASS	RISK LEVEL	EXAMPLES
<b>A</b>	<b>Low</b> Individual Risk and <b>Low</b> Public Health Risk	Stains, culture reagents
<b>B</b>	<b>Moderate</b> Individual Risk and/or <b>Low</b> Public Health Risk	Home use pregnancy tests, Urine test strips, <u>CD4, chlamydia serology</u>
<b>C</b>	<b>High</b> Individual Risk and/or <b>Moderate</b> Public Health Risk	Rapid tests for <u>rubella, malaria, Viral load, Early infant HIV diagnosis, TB</u>
<b>D</b>	<b>High</b> Individual Risk and <b>High</b> Public Health Risk	Blood screening tests: <u>HIV, HBV, HCV, HTLV</u>

# TB IVD classification

## US FDA:

**Class I** Reg. No. 886.3370; Product Codes GRT, NDZ, NJO

**Class I** Reg No.886.2660; Product Code JSY

**Class III** Product Code OJN (Enzyme-linked immunospot),  
MWA (NAAT), NCD (Immunity Test)

## EU:

IVDD Annex II, Non-List A, Non-List B

## Australia/Canada:

**Class C**; GHTF IVD Classification Rule No.3 (SG1-N45:2008)

**Class D**; GHTF IVD Classification Rule No.1 (SG1-N45:2008)

**Class B**; GHTF IVD Classification Rule No.6 (SG1-N45:2008)

## Japan:

**Class III**

