

Regulation stage

# **In vitro diagnostic guide**

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# In vitro diagnostic

In vitro diagnostic (IVD) is a type of medical device, usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine. Examples include:

- pregnancy tests
- blood glucose monitors
- HIV test kits
- certain blood collection tubes
- immunoassays

IVDs are regulated by [Part IV of the UK MDR 2002](#) and all IVDs must be registered with the MHRA. There are four categories of IVDs, listed in order of perceived risk:

- general IVDs
- IVDs for self-testing which are intended to be used by persons in a home environment
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part III of Schedule 2A to the UK MDR 2002)
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part III of Schedule 2A to the UK MDR 2002)

General IVDs can be [self-certified](#), but all other IVDs need approval from a UK approved body or EU notified body before they can be registered with the MHRA and placed on the UK market. Find out more about [the IVD directive](#) and what [regulatory approval your IVD](#) needs to go through.