



IVDD and Genetic Testing

David E Barton,

National Centre for Medical Genetics

Dublin, Ireland

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Selected Relevant Directive Text

(9) **calibrators and control materials** needed by the user to establish or verify performances of devices *are in vitro* diagnostic medical devices”

1(b) 'in vitro diagnostic medical device` means any medical device which is a reagent, reagent product, **calibrator, control material...**

1(i) 'placing on the market` means the first making available in return for payment **or free of charge** of a device.....

Transfer of control materials between labs

Why?

- Many genetic disorders are very rare
- Particular mutations may be unique to a single family
- Family members may be living in different regions or countries
- Best practice is to run a positive control when testing for a specific mutation
- Such a positive control may only be available from another laboratory
- Labs do not charge each other for such materials

Scenario presented to Commission

Scenario on the exchange between testing labs of materials for use as controls developed and submitted to DG Enterprise:

Lab A sends DNA from the index case in a breast cancer family to Lab B for use as a positive control for a predictive test.

- Are such materials covered by the directive?
- Does it matter if the receiving lab is using an in-house assay or a CE-marked IVD?

NGRL approach to MHRA

- A. Plasmids containing mutations developed to determine the performance of mutation detection systems.
- B. Plasmids developed containing mutation controls for specific cancer genes

Questions:

1. For distribution or selling to European laboratories should these reagents be considered IVDs under the Directive, and thus require CE marking?
2. Would these reagents require CE marking if they were incorporated into UK or European external quality control assessment programs?

Professor Nick Cross, NGRL Wessex

MHRA Response

- EQA materials are excluded from the Directive
- Calibrators and control materials that are needed to establish or verify the performance of other devices are considered to be IVD's and will come within the remit of the regulations
- It will therefore depend on the intended purpose
- General control materials for specific genes with a diagnostic purpose made available outside an EQA scheme to establish or verify performance of devices are likely to be IVDs