Impact of Traceability Requirements on the IVD Industry

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The Requirement...

Directive 98/79/EC
Annex I – Essential Requirement A.3

The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.
So what’s happened...

- Ten years of implementation experience with the regulatory requirement for traceability to reference materials of a higher order
- All CE marked IVDs will be traceable today though the traceability chain may be very short!
- Not all jurisdictions embrace the concept of traceability for value assignment (method comparison still required in some areas)
In theory...

1. Identify material higher order
2. Establish traceability chain (ISO 17511)
3. Assign values to trueness controls
In practice...

- Need to define materials
- Many areas simply do not yet have certified reference materials available

E.g.
Cardiac Markers (proBNP, Troponin T etc)
Genetic Markers
Manufacturers and reference materials

- IVD Manufacturers rely on certified reference materials in order to trace the values assigned to trueness controls
- However - IVD Manufacturers do not develop (and have very little impact on the development) of certified reference materials
- Area for improvement - better synergies can be developed
Impact of Accreditation to ISO 15189

ISO 15189 - Medical laboratories. Requirements for quality and competence.

Becoming more widely adopted in the clinical laboratory community - early adopters in Australia and France.

Imposes requirements on laboratories which in turn lead to questions for the manufacturers of IVDs.
Uncertainty

• Manufacturers will deliver the uncertainty associated with the values assigned to trueness controls.

• Laboratories aim to report uncertainty on the values they report following analysis

• But! Only the laboratories themselves can assign that uncertainty - work in ISO/TC 212/WG2 will help!
Traceability to results

• As clinical laboratories aim for ensuring comparable results they seek to extend traceability to the result of the sample analysis.

• Often an expectation that manufacturer may be able to provide traceability to the final lab result...

• In practice, this expectation cannot be met.
Comparing results

• Goal of comparing results across time and between testing platforms is still a great challenge.

• From a metrological point of view – hardest question to address has been how to prioritize commutability studies which will have the highest impact.
Conclusions

• Expectation that the regulatory requirements for metrological traceability would spur development of certified reference materials - to a large extent this has not happened but why?
• Mismatch between what the role and ability of a manufacturer to supply information and the needs of accredited clinical laboratories
• Traceability is having a greater impact on the work of clinical labs than ever before
Questions?

• Now is the time!