Joint Committee For Traceability in Laboratory Medicine

Was established in June, 2002

The aim of the Joint Committee is to support world wide comparability, reliability and equivalence of measurement results in Laboratory Medicine

It was Established as the result of a recognized need for internationally accepted reference systems and laboratories
JCTLM (cont.)

- Principle Promoters of the JCTLM
  - International Bureau of Weights and Measures (BIPM)
  - International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
  - International Laboratory Accreditation Cooperation (ILAC)
  - World Health Organization (WHO)
Some Other Key Stakeholders

- CRM producers (examples NIST, IRMM)
- IVD industry (AdvaMed, EDMA, JACR)
- EQA/PT Organizations, Regulatory Bodies
- EU
- ISO
Two Working Groups

- **WG 1** - Identify reference materials and procedures and endorse those appropriate to meet the requirements of the IC Directive….

- **WG 2** - Collect information on reference method laboratories (RML), encourage the formation of networks, establish a procedure for approval of RML on the basis of EN/ISO 15195
Since June, 2002

- WG 1 Has collected nominations for reference materials and methods
- Based on EN 12286/ ISO 15193 and EN 12287/ISO 15194, has developed provisional recommendations for Electrolytes, Metabolites and Substrates, and Drugs. These lists will be published in the fall.
- Low molecular weigh hormones, proteins, coagulation factors, and Nucleic Acids are more complex and will continue to be developed.
Since June 2002

- WG 2 has collected nominations for laboratories.
- These laboratories are currently under review with respect to EN/ISO 15195
- Comparative studies are under development with EQUAS Samples to be sent this fall
JCTLM Recognition

- The JCTLM is a collection of experts supported by the organizations listed before.
- It has no legal standing with the EU.
- EN/ISO 17511 and 18153, however, are harmonized and do recognize the value of international endorsement of materials, methods and laboratories. The output of the JCTLM meets that need.
• It is not yet recognized how or if the EU will accept the work products of the JCTLM.

• At minimum the evaluation of the resources involved, compared with the appropriate EN/ISO standards, reduces the work an IVD manufacturer must do as it attempts to meet the requirements of the IVD Directive