National Measurement System

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JCTLM: Nucleic Acid Review Team "Environment Scan – Standardisation Activity in NA measurement"

Helen Parkes, LGC UK

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Laboratory medicine and *in vitro* diagnostics

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NA Review Team:

- **Leader:** Ms Helen Parkes (LGC Ltd)
- **Members:**
- Dr Neil Almond [National Institute for Biological Standards and Control, NIBSC]
- Dr Joan Gordon [Maine Molecular Quality Controls, Inc]
- Dr Tomoshige Hori [Japan Bioindustry Association]
- Dr Lisa Kalman [Centers for Disease Control and Prevention, CDC]
- Ms Roberta M. Madej
- Dr Heinz Schimmel [Institute for Reference Materials and Measurements, IRMM]
- Dr Paul Wallace [Quality Control in Molecular Diagnostics, QCMD]

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What is the current status of entries in the JCTLM Database with respect to the existing standardized measurands in the field of your team's scope of activity?

RM procedures, limited – none registered in JCTLM

RMs – tabulated

- Does not reflect range of RMs
- Limited
- Entries
  - 6x BCRabl
  - 1x HIV
- Producers
  - JRC (IRMM)
  - NIBSC

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What are the missing materials, and methods and calibration services providers for standardized measurands?

Are there any key measurands for which Reference Measurement System Components exist that are not yet covered by JCTLM in your Review Team area?

YES…….
Significant effort – much duplication NMI's , initiatives, & industry
- no real co-ordination or awareness
Needs – sequencing, stratified medicine (&CDx), IVDs infectious disease & AMR molecular diagnostics,

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What are the new standardization projects underway in your field that could lead to JCTLM Database entries in the future?

GeT-RM – genetic testing RMs initiative – Lisa Kalman CDC US

The goal of the Genetic Testing Reference Materials Coordination Program (GeT-RM) is to coordinate a self-sustaining community process to improve the availability of appropriate and characterized reference materials for:

- Qu
- Prc

GeT-RM Genetic Testing Reference Materials PROGRAM

- Test development & validation
- Research
- The purpose of this program is:
- To help the genetic testing community obtain appropriate and characterized reference materials
- To facilitate and coordinate information exchange between users and providers of QC and reference materials
- To coordinate efforts for contribution, development, characterization and distribution of reference materials for genetic testing

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Quality Control for Molecular Diagnostics

- Quality Control for Molecular Diagnostics (QCMD) is an independent International External Quality Assessment (EQA) / Proficiency Testing **(PT) organisation. QCMD provides a wide-ranging quality assessment service primarily focused on molecular infectious diseases to over 2000 participants in over 100 countries.**
- **QCMD is dedicated to advancing the quality of molecular diagnostics through External Quality Assessment (EQA), Proficiency Testing (PT) and other supporting quality initiatives.**

- **Paul Wallace – CSO NA review team**

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NMI activity:

- EMPIR/LGC – BioSITrace, NeuroMET,AntiMicroResist, INFECTMET
  - Outputs RMs and Reference procedures
  - digitalPCR
  - AMR - TB & HIV
  - KRAS panel
  - Metagenomics standards panel (NGS)
- IFCC – C-MD
  - Collating PT schemes & RMs (Parvis DE, LGC)
- NIST
  - Joint Initiative Metrology in Biology
  - Genome in a bottle NIST /Stanford
  - BRAF
- NMIA - BRAF …
- NIMC – KRAS
- NIBSC – KRAS etc /
  - SOGAT (standardisation of gene amplification tests)

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Contact list for reference material producers, developers of measurement procedures, providers of reference measurement services to be targeted/contacted by JCTLM with regard to the missing, and new nominations?

horizon

HDx™ Reference Standards

- Horizon is a leading provider of genetically defined, human genomic reference standards, including Formalin-Fixed Paraffin-Embedded (FFPE) cell line sections and purified genomic DNA (gDNA). HDx™ Reference Standards offer a sustainable source of reference material to laboratories, proficiency schemes and manufacturers, providing an unprecedented level of control.
- https://www.horizondiscovery.com/reference-standards/
- UK , LGC – joint projects

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- Maine Molecular Quality Controls, Inc. (MMQCI) designs and markets molecular controls for use in inherited disease testing, infectious disease detection, and pharmacogenetics.

MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.

  - As experts in quality assurance of laboratory medicine, MMQCI produces high caliber controls uniquely suited to monitor all phases of molecular testing as required by best practice and regulations. MMQCI controls provide confidence in test results.
  - MMQCI continues to design and produce innovative, high-quality control products as needed for emerging nucleic acid technologies as they come into use by the molecular diagnostic community. Custom orders from in vitro diagnostic manufacturers are always welcome at MMQCI's cGMP facility

- Joan Gordon, CEO – NA review team

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Summary

- The NA review team represents very well RM producers in this field, and RM procedure developers
- We need to be more proactive in encouraging submissions to JCTLM – but WGs feel “disengaged”

BUT

- Need to be more on message
- What is benefit?
- Difficulty in compliance with JCTLM dbase entry requirements
- “Higher order” – or “fit for purpose”

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