Welcome to the 2022 NIST Rapid Microbial Testing Methods Workshop

We will be using Slido for live polling during the workshop.

Please go to Sli.do #RMTM on your computer or mobile device.

Join at slido.com #RMTM
2022 NIST Rapid Microbial Testing Methods Consortium (RMTM) Workshop

Tuesday, April 19, 2022

11:00 AM to 3:30 PM (ET)

Join at slido.com #RMTM

Graphic Credit: Natasha Hanacek
Housekeeping

• This meeting is being recorded

• Please join the meeting with your full name and organization

• Please use the chat for comments/questions/feedback
Attendee Polls

Join at
slido.com
#RMTM
How to Join the Consortium

• Submit a letter of interest
• Review and sign the agreement sent by NIST
• Connect to the shared drive, join working groups, contribute!
NIST and Rapid Microbial Testing Methods (RMTM) Consortium Overview

Sheng Lin-Gibson
April 19, 2022
Building the Next Generation Biometrology and Engineering Biology Capabilities to support U.S. Biotechnology Enterprise and Bioeconomy

**Advanced Biometrology**
Unprecedented measurement capabilities to quantify complex *living* systems and processes

**Design-Build-Test-Learn**
Tools, platforms, and data/knowledge to predictively engineer biological systems to accelerate innovation in R&D and to advance biomanufacturing

**Standards**
Standards and related infrastructure to accelerate technology development and translation/clinical use
NIST measurement services

Reference Materials

Reference Data

Documentary Standards

Calibration Services
NIST has been working with FDA and SCB to develop standards to support a growing *regenerative medicine* and *advanced therapy* industry.
NIST Consortia: Public-Private Partnership to address pre-competitive challenges

- **NIST GENOME IN A BOTTLE (GIAB) CONSORTIUM**
  - Provides authoritative characterization of benchmark human genomes

- **NIST GENOME EDITING CONSORTIUM**
  - Develops measurement solutions and standards needed to increase confidence and reduce risks

- **NIST FLOW CYTOMETRY STANDARDS CONSORTIUM**
  - Accelerates the adoption of quantitative flow cytometry in biomanufacturing

- **NIST RAPID MICROBIAL TESTING METHODS CONSORTIUM**
  - Addresses measurements and standards needed to increase confidence in the use of rapid testing

https://www.nist.gov/mml/bbd
Advanced Therapy Products Need Modern Microbial Methods

Cell therapies (*Living drugs*)
- Decreased manufacturing time
- Short shelf-live
- Critically needed for seriously ill patients

**Manufacturing of advanced therapies, vaccines, and other biopharmaceutical products**

Product sterility testing
- USP <71> Based on culturing in broth for 14-21 days

21 days for sterility testing is too long!

Rapid manufacturing of non-activated potent CAR T cells

Cells generated within 24 h (vs 2 weeks)
Rapid Microbial Testing Methods (RMTM)

Example Rapid Methods
- Respiration (CO$_2$ detection)
- ATP
- Solid phase cytometry
- PCR
- Raman/IR spectroscopy
- Flow cytometry
- Mass spectrometry

Results in <24 h up to 2-7 days

- Rapid methods must be shown non-inferior to culture methods
- Challenging to validate and adopt RMTMs (no rule book)
RMTM Consortium Timeline

- **Jun 2020**: Federal Register Notice
- **Sep 2020**: Launch Workshop
- **Nov 2020**: First Consortium Meeting & subsequent monthly WG meetings
- **Jan 2022**: Initial results on commercial E. coli materials
- **Apr 2022**: Open Workshop to share progress and inform future plans
- **Jun 2022** (anticipated): Initiate interlaboratory study
Consortium Organization

NIST Team
- Scott Jackson
- Nancy Lin
- Tara Eskandari
- Sheng Lin-Gibson
- Jason Kralj
- Stephanie Servetas
- Kirsten Parratt
- Sandra Da Silva
- Joy Dunkers
- Monique Hunter
- Jennifer Dootz
- Shaswat Koirala

Standards Coordinating Body
- Dawn Henke
- Melody Sanders
- Katie Zander

WG01 Reference Materials
- Nancy Lin
- James Powell
- Brian Beck

WG02 Methods and Validation
- Scott Jackson
- Cynthia Martino
- Juan Diego Ospina

WG03 Interlab Design and Implementation
- Jason Kralj
- Huiping Tu
- Sathya Janardhanan
30 Consortium Members (CRADA, no fee)

• Agilent Technologies
• Allele Biotechnology and Pharmaceuticals, Inc.
• AlloSource
• American Type Culture Collection (ATCC)
• Apsis Healthcare Systems, LLC
• bioMérieux
• Bionique Testing Laboratories, Inc.
• Bristol Myers Squibb
• Defense Biological Product Assurance Office, CBRND-EB, JPEO, DoD
• EMD Millipore Corporation (MERCK Kommanditgesellschaft auf Aktien)
• EzBiome Inc
• Gentech Biosciences
• George Washington University - Computational Biology Institute
• Independent (Spencer Hoover)
• Independent (Vicki Barbur)
• Latham BioPharm Group
• Microbiological Consulting, LLC
• Microbiologics, Inc.
• Microbiology Consultants, LLC
• NIH Clinical Center - Center for Cellular Engineering
• National Institute for Biological Standards and Control (NIBSC)
• National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
• Sartorius Aktiengesellschaft
• Siolta Therapeutics
• SmartGene GmbH
• United States Pharmacopeial Convention
• University of Delaware (Udel)
• U.S. Food and Drug Administration
• Vericel Corporation
• Weill Medical College of Cornell University

5 Advanced Therapy Producers
10 Assay/RM Manufacturers
6 Consultants/CROs
4 Government
3 Academia
2 Non-profit/Other