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U. S. DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Rapid Microbial Testing Methods Consortium

AGENCY: National Institute of Standards and Technology, Department of Commerce

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, in support of efforts to develop Standards for Regenerative Medicine and Advanced Therapies, is establishing the Rapid Microbial Testing Methods (RMTM) Consortium ("Consortium") for developing standards, including reference materials, related to rapid microbial testing for regenerative medicine products. The Consortium efforts are intended to advance rapid microbial measurement capabilities, provide measurement assurance strategies, support the development of microbial reference material(s), and collect data to support the development of best practices and standard methods. Participants will be required to sign a Cooperative Research and Development Agreement (CRADA). There is no cost for participating in the consortium.

DATES: The Consortium's activities will commence on September 15, 2020 ("Commencement Date"). NIST will accept letters of interest to participate in this Consortium on an ongoing basis. Acceptance of participants into the Consortium after the Commencement Date will depend on the availability of NIST resources.

ADDRESSES: Completed letters of interest or requests for additional information about the NIST RMTM Consortium can be directed via mail to Dr. Nancy Lin, Biosystems and Biomaterials Division of NIST's Material Measurement Laboratory, 100 Bureau Drive, Mail Stop 8543, Gaithersburg, Maryland 20899, or via electronic mail to rmtm@nist.gov, or by telephone at (301) 975-4935.

FOR FURTHER INFORMATION CONTACT: J'aime Maynard, CRADA Administrator, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to Jaime.maynard@nist.gov, or by telephone at (301) 975-8408.

SUPPLEMENTARY INFORMATION:

The safety and quality of advanced therapies for regenerative medicine, including cell therapy, gene therapy, and tissue engineered products, must be maintained prior to patient administration. The culture-based compendial methods currently used to assess product purity (specifically to ensure absence of microbial contamination) typically take weeks, which is inadequate for patients in urgent need of life-saving therapies. These methods are also incompatible with products that have a limited shelf-life and cannot meet good manufacturing practices required in

process control and release testing. Alternative rapid microbial testing methods are needed to ensure fit for purpose safety assessments for this broad class of advanced therapeutics.

NIST is establishing the RMTM Consortium to address this need. The Consortium's purpose is to develop solutions and standards to support the use of rapid microbial testing methods for regenerative medicine products. The Consortium efforts will focus on the following areas:

(1) Repository of Relevant Microorganisms

NIST intends to establish a repository of microorganisms relevant to regenerative medicine product contamination, including contaminants found in products, in manufacturing environments, and other relevant microorganisms. Sets of microorganisms from the repository will be selected for interlaboratory studies and for incorporation into a candidate reference material, based on input from the Consortium. The reference material will be designed to increase confidence in the use of RMTMs and is expected to consist of multiple microorganisms. There will be opportunities for Consortium members to contribute relevant microorganisms to the repository.

(2) Rapid Microbial Testing Methods

The NIST RMTM Consortium intends to develop an inventory of potential measurement methods and protocols for rapid microbial testing of regenerative medicine products. This inventory will include molecular methods and protocols that have been adopted successfully for rapid microbial detection as well as considerations for implementing test methods and approaches to validate protocols.

(3) Interlaboratory Studies

The NIST RMTM Consortium intends to organize at least one interlaboratory study based on candidate reference materials with the goal of utilizing a common material to collect reproducible data on rapid microbial testing methods in support of measurement assurance and standards development.

There is no cost for participating in the consortium.

Process: Interested parties with relevant rapid microbial testing associated capabilities (see below), products, and/or technical expertise to support this Consortium should contact NIST using the information provided in the ADDRESSES section of this notice. NIST will then provide each interested party with a letter of interest template, which the party must complete and submit to NIST. NIST will contact interested parties if there are questions regarding the responsiveness of the letters. NIST will select participants who have submitted complete letters of interest based on the capabilities listed below. Eligibility will be determined solely by NIST based on information provided by interested parties and upon the availability of necessary resources to NIST.

To participate in the NIST RMTM Consortium, the eligible applicant will be required to sign a CRADA with NIST.

Requirements: Each letter of interest should provide the following information:

(1) A description of the experience in development or use of rapid microbial testing methods or production of regenerative medicine products or related expertise.

(2) Topic areas of interest for participation.

(3) List of interested party's anticipated participants.

Letters of interest may not include business proprietary information. NIST will not treat any information provided in response to this Notice as proprietary information. NIST will notify each organization of its eligibility. NIST does not guarantee participation in the Consortium to any organization submitting a letter of interest.

Authority: 15 U.S.C. 272; 21 U.S.C. 356g

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