to producing viral DNA templates and for chromatographic purification of nucleic acid-containing compositions, in which the nucleic acid is quantified in chromatography fractions with the rapid detection of one or more nucleic acid sequences (*e.g.,* using real time RT-qPCR detection). In addition, the invention includes improved processes for production and purification of oncolytic poliovirus, such as PVSRIPO. Compositions generated using these methods are also described.

Potential Commercial Applications:

- Large-scale manufacturing for producing highly purified, live virus.
- Improved viral purification process that:
  - Increases the yield and/or purity of the resulting product, while decreasing the purification time;
  - is generally applicable to purification of any nucleic acid molecule-containing composition, such as virus-based composition, and can be used for the purification of live native or recombinant viruses necessary for clinical applications.
- Improved process for generating viral template plasmid (such as one that includes a DNA template for an RNA virus), which addresses the problem of genetic instability of the plasmids containing the viral genome (*e.g.,* of a recombinant polio virus) in host (*e.g.,* bacterial) cells, in which the plasmids are typically propagated.

Value Proposition:

- Cost- and time-effective means of producing highly purified virus-based GMP products, such as oncolytic viruses, for regulatory approval.

Development Stage: Clinical Phase I.

Inventor(s): Trevor Broadt (NCI), Samir Shaban (NCI), Yueqing Xie (NCI), Jianwei Zhu (NCI), George Mitra (NCI).

Intellectual Property: HHS Ref. No. E–267–2014/0–US–01, corresponding to US Provisional Patent App. No. 62/173,777, filed June 10, 2015, entitled ''Processes for Production and Purification of Nucleic Acid Containing Compositions.''.

HHS Ref. No. E–267–2014/0–PCT–02, corresponding to International Patent App. No. PCT/US2016/036888, filed June 10, 2016, entitled ''Processes for Production and Purification of Nucleic Acid Containing Compositions''.

Publications: Ouellette *et al., BioProcessing J.* 2005 4(2):31–38.

Related Technologies: HHS Reference #E–240–2015/0 entitled ''Methods of Analyzing Virus-Derived Therapeutics''.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: *john.hewes@nih.gov.*

Dated: August 16, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–20160 Filed 8–23–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report: 2014–2015; Availability of Report

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2014–2015. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3), describes activities and accomplishments from January 2014 through December 2015.

ADDRESSES: The report is available at *http://ntp.niehs.nih.gov/iccvamreport/2015/index.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background: The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare ''reports to be made available to the public on its progress under this Act.'' The eighth ICCVAM progress report is now available, which describes ICCVAM activities and accomplishments from January 2014 through December 2015.

Summary of Report Contents: Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- A computational approach that integrates several types of data to predict human skin sensitization hazard without using animals (ICCVAM)
- A plan to adopt high throughput assays and computational models for detecting and measuring estrogen receptor bioactivity as an alternative for three Tier 1 tests currently used in the Endocrine Disruptor Screening Program to assess estrogen receptor activity (U.S. Environmental Protection Agency [EPA])
- Establishment of a Communities of Practice webinar seminar series discussing relevant topics (ICCVAM)
- Evaluation of acute oral and dermal toxicity data to determine if oral toxicity tests are sufficient to assign U.S. EPA dermal hazard classifications, eliminating the need for separate acute dermal toxicity tests (NICEATM)
- A series of workshops that drafted recommendations on use of an *in vitro* test with potential to replace animal use for pertussis vaccine testing (NICEATM, U.S. Food and Drug Administration, other ICCVAM agencies).

Availability of Report: The report is available at *http://ntp.niehs.nih.gov/iccvamreport/2015/index.html.* Links to this report and all past ICCVAM annual and biennial reports are available at *http://ntp.niehs.nih.gov/go/iccvam-bien.*

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 15 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness and federal agency test method review, and optimize utilization of scientific

expertise outside the federal government. Additional information about ICCVAM can be found at *http://ntp.niehs.nih.gov/go/iccvam.*

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at *http://ntp.niehs.nih.gov/go/niceatm.*

Dated: August 16, 2016.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2016–20159 Filed 8–23–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850–9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850–9702, Tel. 240–276–5515 or email *ncitechtransfer@mail.nih.gov*. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Methods of Analyzing Virus-Derived Therapeutics.

Description of Technology: Researchers at the National Cancer Institute's Biopharmaceutical Development Program recently developed massively parallel sequencing methods for virus-derived therapeutics such as viral vaccines and oncolytic immunotherapies. The methods allow for the determination of micro-heterogeneity and quantitation of low frequency sequence variants, which have the possibility of supplanting monkey neurovirulence safety testing (MNVT), mutant analysis by PCR, and restriction enzyme cleavage (MAPREC) methods that are currently used to screen RNA virus-derived therapeutics.

Potential Commercial Applications:

- Improved methods for detecting mutations in GMP-manufactured virus-derived therapeutics, including viruses, viral template plasmids, or vaccines;
- The method allows for at least two different virus-derived therapeutics to be assayed simultaneously.

Value Proposition:

- Provides a cost- and time-effective means of assaying a virus-derived therapeutic, such as oncolytic viruses, for viral sequence variants, for regulatory approval;
- RNA virus preparation steps increase the amount of viral RNA obtained;
- Demonstrated superiority of massively parallel sequencing (''MPS'') over mutant analysis by PCR and restriction enzyme cleavage (''MAPREC'') analysis.

Development Stage: Clinical Phase I.

Inventor(s): Trevor Broadt (NCI), Michael D. Harwich (American International Biotechnology, LLC), William T. Budd (American International Biotechnology, LLC), Gregory A. Myers (American International Biotechnology, LLC).

Intellectual Property:

HHS Ref. No. E–240–2015/0–U.S.–01, corresponding to U.S. Provisional Patent App. No. 62/199,663, filed July 31, 201562/173,777, entitled ''Methods of Analysis of RNA Virus-Derived Therapeutics''

HHS Ref. No. E–240–2015/0–PCT–02, corresponding to International Patent App. No. PCT/US2016/044788, filed July 29, 2016, entitled ''Methods of Analyzing Virus-Derived Therapeutics''

Related Technologies: HHS Reference #E–267–2014/0 entitled ''Processes for Production and Purification of Nucleic Acid Containing Compositions''.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: *john.hewes@nih.gov*.

Dated: August 16, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–20162 Filed 8–23–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.