

enhance understanding of the psychology of participation and response, to develop better standards for project methodology and instrument design, or to improve data collection and other study procedures. Such research could take the form of experiments embedded within fielded surveillance or research projects or exploratory studies employing individual interviews or focus groups.

(4) *Research on utilizing computer-assisted instruments (including web-based technology) for HIV surveillance or research projects.* This research uses qualitative and quantitative data collection methods with volunteer respondents in order to assess the design and use of computer-assisted instruments.

(5) *Pilot interviews.* A limited number of pilot interviews are conducted using proposed instruments and data

collection methodologies. Sources of response error are identified through examination of pilot data, observation by methodologists, and techniques such as the coding of the interviewer-respondent interaction. Respondents for pilot interviews and interventions will be selected using the methods developed for the study that is being piloted.

(6) *Pilot testing of behavioral interventions.* Component testing will assess acceptability and feasibility of separate intervention activities. A limited number of pilot tests are conducted for behavioral interventions prior to being tested in a "full intervention trial."

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer-assisted development activities) are selected purposively from those who

respond to recruitment advertisements. In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project.

CDC estimates that an average of 1430 individuals will participate in HIV/AIDS methods, intervention, and instrument development activities in a given year and the average annual respondent burden is estimated to be 2135 hours. The estimates given below cover the time that each respondent will spend communicating with the recruitment staff, in answering survey questions and, in some cases, being debriefed about the decision and recall strategies they used. Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

| Types of data collection                                                          | No. of respondents | No. of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|-----------------------------------------------------------------------------------|--------------------|---------------------------------|----------------------------------------|-------------------------|
| (1) Methods, interventions, and materials development—individual interviews ..... | 250                | 1                               | 1                                      | 250                     |
| (2) Methods, interventions, and materials development—group interviews ...        | 450                | 1                               | 2                                      | 900                     |
| (3) Research on survey methodology .....                                          | 150                | 1                               | 1                                      | 150                     |
| (4) Research on human-computer interface .....                                    | 350                | 1                               | 1                                      | 350                     |
| (5) Pilot interviewing .....                                                      | 200                | 1                               | 1                                      | 200                     |
| (6) Pilot interventions .....                                                     | 30                 | 6                               | 2                                      | 360                     |
| Total .....                                                                       | 1,430              | .....                           | .....                                  | 2,210                   |

Dated: December 26, 2007.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Workshop on Acute Chemical Safety Testing: Advancing *In Vitro* Approaches and Humane Endpoints for Systemic Toxicity Evaluations

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Workshop announcement.

**SUMMARY:** The Interagency Committee on the Validation of Alternative

Methods (ICCVAM) and NICEATM announce the upcoming "Scientific Workshop on Acute Chemical Safety Testing: Advancing *In Vitro* Approaches and Humane Endpoints for Systemic Toxicity Evaluations." The goals of the workshop are to:

(1) Review the state-of-the-science and identify knowledge gaps regarding the key pathways involved in acute systemic toxicity.

(2) Recommend how these knowledge gaps can be addressed by collecting mechanistic biomarker data during currently required *in vivo* safety testing.

(3) Recommend how key *in vivo* pathway information can be used to develop more predictive mechanism-based *in vitro* test systems and earlier, more humane endpoints for *in vivo* test methods.

(4) Recommend how mechanism-based *in vitro* test systems and earlier, more humane endpoints can be used to further reduce, refine, and eventually replace animal use for acute systemic toxicity testing while ensuring the protection of human and animal health.

This workshop is open to the public with attendance limited only by the space available.

**DATES:** The workshop will be held on February 6-7, 2008.

**ADDRESSES:** The workshop will be held at the NIH, Natcher Conference Center, 45 Center Drive, Bethesda, MD 20892. A draft agenda and other information are available on the ICCVAM workshop Web site (<http://iccvam.niehs.nih.gov/meetings/AcuteToxWksp08/AcuteToxWksp08.htm>) and can be obtained from NICEATM (see **FOR FURTHER INFORMATION CONTACT** below).

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC-17, Research Triangle Park, NC 27709, (telephone) 919-541-2384, (fax) 919-541-0947, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

NICEATM and ICCVAM convened a peer review panel meeting in 2006. The panel was charged to determine the

usefulness and limitations of two *in vitro* cytotoxicity test methods for determining starting doses for two acute oral toxicity test methods, the Up-and-Down Procedure and the Acute Toxic Class method, in order to reduce the number of animals used in each of these *in vivo* tests. The panel's conclusions and recommendations are described in the *Peer Review Panel Report: The Use of In Vitro Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing* (available at [http://iccvam.niehs.nih.gov/methods/acute/tox/inv\\_nru\\_scpeerrev.htm](http://iccvam.niehs.nih.gov/methods/acute/tox/inv_nru_scpeerrev.htm)). The panel recommended that ICCVAM consider convening a working group to explore mechanisms of action for acute toxicity and to identify approaches for acquiring additional information on acute toxicity mechanisms when conducting required *in vivo* acute toxicity testing. The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) met by teleconference on August 3, 2006, and expressed support for the panel's recommendations (minutes of that meeting are available at <http://ntp.niehs.nih.gov/files/SACATMAug06MinutesVF081506.pdf>).

NICEATM and ICCVAM included activities in their draft Five-Year Plan (2008–2012) (<http://iccvam.niehs.nih.gov/docs/5yearplan.htm>) to further reduce animal use and potential pain and distress associated with acute toxicity testing. These included organizing an international workshop to (1) identify predictive and more humane endpoints that may be used to terminate studies earlier in order to further reduce the severity and duration of pain and distress and (2) identify and standardize procedures for collecting mechanistic information from *in vivo* acute oral toxicity testing that will aid in developing batteries of predictive *in vitro* test methods that can further reduce and eventually replace animals for acute toxicity testing.

The ICCVAM Acute Toxicity Working Group subsequently organized this workshop in coordination with NICEATM, the European Centre for the Validation of Alternative Methods, and the Japanese Center for the Validation of Alternative Methods. The goals of the workshop are to:

(1) Review the state-of-the-science and identify knowledge gaps regarding the key pathways involved in acute systemic toxicity.

(2) Recommend how these knowledge gaps can be addressed by collecting mechanistic biomarker data during currently required *in vivo* safety testing.

(3) Recommend how key *in vivo* pathway information can be used to develop more predictive mechanism-based *in vitro* test systems and earlier more humane endpoints for *in vivo* test methods.

(4) Recommend how mechanism-based *in vitro* test systems and earlier, more humane endpoints can be used to further reduce, refine, and replace animal use for acute systemic toxicity testing while ensuring the protection of human health.

#### Workshop Attendance and Registration

The workshop will be held on February 6–7, 2008, at the NIH Natcher Conference Center, 45 Center Drive, Bethesda, MD 20892. Sessions will begin at 8 a.m. and end at approximately 5 p.m. on both days. Persons needing special assistance in order to attend, such as sign language interpretation or other reasonable accommodation, should contact 919–541–2475 voice, 919–541–4644 TTY (text telephone, through the Federal TTY Relay System at 800–877–8339), or e-mail [niehssoeeo@niehs.nih.gov](mailto:niehssoeeo@niehs.nih.gov). Requests should be made at least seven days in advance of the event. This workshop is open to the public with attendance being limited only by the space available. Individuals who plan to attend are encouraged to register in advance with NICEATM. Registration information, an agenda, and additional information are available on the workshop Web site (<http://iccvam.niehs.nih.gov/meetings/AcuteToxWksp08/AcuteToxWksp08.htm>) and upon request to NICEATM (see **FOR FURTHER INFORMATION CONTACT** above).

#### Preliminary Workshop Agenda

##### Day 1—Wednesday, February 6, 2008

- Opening Plenary Session—Welcome and Overview of Workshop Objectives.
- Session 1—Current Acute Systemic Toxicity Injury and Toxicity Assessments.
- Session 2—Key Pathways and Biomarkers for Acute Systemic Toxicity.
- Concurrent Breakout Group (BG) Discussions:
  - BG 1: Acute Systemic Toxicity Injury and Toxicity Assessments.
  - BG 2: Key Pathways and Biomarkers for Acute Systemic Toxicity.
  - Adjournment.

##### Day 2—Thursday, February 7, 2008

- Plenary Session—Discussion of Conclusions and Recommendations from Breakout Groups 1 and 2.

- Session 3—Developing Earlier Humane Endpoints for Acute Systemic Toxicity.

- Session 4—State of the Science: Using *In Vitro* Methods to Predict Acute Systemic Toxicity.

- Concurrent BG Discussions:
  - BG 3: Developing Earlier Humane Endpoints for Acute Systemic Toxicity Testing.
  - BG 4: Applying *In Vivo* Mechanistic Pathway Information to the Development and Validation of *In Vitro* Methods for Assessing Acute Systemic Toxicity.
  - BG 5: Partnering with Industry to Advance Acute Toxicity Alternative Test Method Development, Validation, and Use.

- Plenary Session—Discussion of Conclusions and Recommendations from Breakout Groups 3, 4, and 5.

- Workshop Adjournment.

#### Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (**Federal Register**, Vol. 67, No. 49, page 11358, March 13, 2002). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Dated: December 19, 2007.

**Samuel H. Wilson,**

*Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Mandatory Guidelines, "Certification of

Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016. (Formerly: Bayshore Clinical Laboratory)

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150.

Aegis Sciences Corporation, 345 Hill Ave., Nashville, TN 37210, 615-255-2400. (Formerly: Aegis Analytical Laboratories, Inc.)

Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783. (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239-561-8200/800-735-5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310.

Dynacare Kasper Medical Laboratories,\* 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.

Gamma-Dynacare Medical Laboratories,\* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823. (Formerly: Laboratory Specialists, Inc.)

Kroll Laboratory Specialists, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130. (Formerly: Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986. (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984.

(Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 13112 Evening Creek Drive, Suite 100, San Diego, CA 92128, 858-668-3710/800-882-7272. (Formerly: Poisonlab, Inc.)

Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206-923-7020/800-898-0180. (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MAXXAM Analytics Inc.,\* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700. (Formerly: NOVAMANN (Ontario), Inc.)