The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

The use of the monoclonal antibody m912 (SM–101) as an antibody therapy for the treatment of pancreatic cancer, ovarian cancer, lung cancer, mesothelioma, and stomach/gastric cancer. The Licensed Field of Use explicitly excludes the use of the antibody in the form of an immunoconjugate, including, but not limited to, immunotoxins.

Upon the expiration or termination of the exclusive evaluation option license, Sanomab, Ltd. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 16, 2012 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; Email: lambertson@od.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelioma-expressing cancers, including mesothelioma, lung cancer, stomach/gastric cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated m912 (SM–101), which is a fully human monoclonal antibody against mesothelin. Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The m912 antibody can selectively bind to these cancer cells and induce cell death while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice. A previous notice for this license was published on 12 October 2011.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 24, 2012.

Richard U. Rodriguez,
Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–2213 Filed 1–31–12; 8:45 am]
BILLING CODE 4100–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories and Instrumented Initial Testing Facilities 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 and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The “Mandatory Guidelines for Federal Workplace Drug Testing Programs”, as amended in the revisions listed above, requires (or set) strict standards that Laboratories and Instrumented Initial Testing Facilities (IITF) must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies.

To become certified, an applicant Laboratory/IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a Laboratory/IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

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

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Instrumented Initial Testing Facilities (IITF)
Laboratories

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–677–7016, (Formerly: Bayshore Clinical Laboratory); ACM Medical Laboratory, Inc., 160 Elm Grove Park, Rochester, NY 14624, 585–429–2264;


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

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc.);


Baptist Medical Center—Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center);

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917;

Doctors Laboratory, Inc., 2906 Julia Ave., San Diego, CA 92104, 858–643–2083, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Beecham Clinical Laboratories; SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories); St. Anthony Hospital Toxicology Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS’ NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (Federal Register, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the Federal Register on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in Roche Biomedical Laboratory; Roche Compuchem Laboratories, Inc., A Member of the Roche Group);

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*, 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700, (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.);


MetroLab—Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295;

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088;

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515;

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory);

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory);

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7;

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555;

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories); Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/677–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories);


South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276;

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027;

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052;

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438;

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273;

Toxicology Testing Service, Inc., 5426 NW 79th Ave., Miami, FL 33166, 305–593–2260;

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

(Formerly: Roche Biomedical Laboratory; Roche Compuchem Laboratories, Inc., A Member of the Roche Group);

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); 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);
I. Public Participation and Request for Comments

All comments received will be posted, without change, to http://www.regulations.gov and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT’s “Privacy Act” paragraph below.

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (USCG–2011–0641), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means.

We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov and insert “USCG–2011–0641” in the “Keyword” box. Click “Search” then click on the balloon shape in the “Actions” column.

If you submit your comments by mail, hand delivery, submit them in an unbound format, no larger than 8 1/2 by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

B. Viewing Comments

To view comments, go to http://www.regulations.gov, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2011–0641” and click “Search.” Click the “Open Docket Folder” in the “Actions” column.

You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.