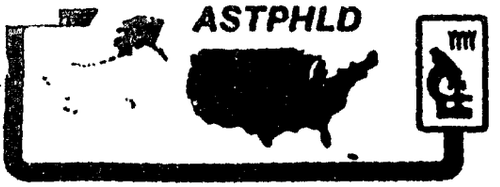

REPORT

NINTH ANNUAL CONFERENCE ON HUMAN RETROVIRUS TESTING

Reno, Nevada
March 1994

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Jeanne R. Cuff 10/6/94

PI - Signature Date

REPORT

NINTH ANNUAL CONFERENCE ON HUMAN RETROVIRUS TESTING

Reno, Nevada
March 1994

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CONFERENCE SUMMARY

The Ninth Annual Conference on Human Retrovirus Testing, held in Reno, Nevada on March 2-4, 1994 advertised the following purpose. "A forum on national and international laboratory-related retroviral issues which will allow for an exchange of information and ideas and encourage discussion of current issues". Judging from the presentations delivered during the plenary sessions and issues forums and the discussions they evoked both in the sessions, at the evening breakouts and in the halls, the purpose of the conference was met.

The conference was sponsored by the Association of State and Territorial Public Health Laboratory Directors. As in previous conferences, the Ninth Conference addressed many of the issues associated with retrovirus testing and again served as a vehicle for the disseminations of attendees' concepts and views germane to human retrovirus testing. Over three hundred participants attended the three day conference. Fifty poster sessions were presented and 14 exhibitors presented products related to HIV testing.

Mr. Charles Schable, Chief of the Serology Section, CDC, presented a well attended session on "The Basics of Retroviral Testing: the evening before the main conference program. The session gave participants an opportunity to brush up on their knowledge of retroviral testing and set the stage for the conference program over the next two days.

The first plenary session addressed the status of human retrovirus testing and covered pediatric AIDS, alternative CD4 technologies, current issues of HTLV testing and an international perspective on HIV testing. AIDS is of global concern and the international perspective on HIV testing presented by Dr. Ofelia Monzon was enlightening.

The issues forum on Wednesday continued the on going discussion of algorithms. This conference report contains a summary of the discussion and conclusions reached. On Thursday non-traditional HIV testing was the subject of Issues Forum II. Non-traditional testing continues to be controversial with the introduction of home testing. Regulatory affairs were covered in the Wednesday afternoon issues forum. Discussion on regulatory issues have a way of evoking strong opinions and this meeting was no exception. The fourth issues forum was on Western Blot False Positive and Issues of Testing in the Era of Vaccines. West blot false interpretation and the problems associated with the testing methodology continue to be a challenge. The forum attempted to address the problems associated with this testing and the problems that vaccines are presenting. A position paper derived from the session is included in this report.

The conference was concluded by the second plenary session. The session addressed systemic lymphoid response in early HIV infection, new horizons in molecular testing of HIV and a report on ASTPHLD's international training efforts.

PLEASE NOTE:

This conference did not address issues previously address in the first eight Conferences on Human Retrovirus Testing. Proceedings from those conferences may be obtained from: ASTPHLD, 1211 Connecticut Avenue, N.W., Suite 608, Washington, D.C. 20036

PLENARY SESSION SPEAKERS

Pediatric AIDS: correlates of Perinatal Transmission and Strategies for Interruption
Diane Wara, M.D.

Alternative CD_4 Technologies
Janet Nicholson, Ph.D.

The HTLVs: Current Issues
Jonathan Kaplan, Ph.D.

HIV Testing - An International Perspective
Ofelia Monzón, M.D.

Systemic Lymphoid Response in early HIV Infection
Ronald Turnicky, D.O., LTC, MC

New Horizons in Molecular Diagnostics
Helen Lee, Ph.D.

ASTPHLD International Training
David Carpenter, Ph.D.

ISSUES FORUM:
TESTING: HIV-1 AND HIV-2 ALGORITHMS

PANEL MODERATOR:

Jane Getchell, Dr.P.H., Associate Director, State Hygienic Laboratory, University of Iowa, Iowa City, Iowa

PANEL MEMBERS:

Barbara Werner, Ph.D., Director, Virology / Clinical Investigation Division, Massachusetts State Laboratory Institute, Jamaica Plain, Massachusetts

Robert Myers, Ph.D., Laboratory Scientist, Maryland Department of Health, Baltimore, Maryland

William Schalla, M.S., Chief, Model Performance Evaluation Program, Centers for Disease Control and Prevention, Atlanta, Georgia

Charles Schabel, M.S., Chief, Serology Section, Division of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

Hermann A.M. Mücke, Ph.D., Senior Vice President of Research and Development, Waldheim Pharmazeutika R&D Laboratory, Austria

In the U.S. all HIV testing algorithms consist of a screening test followed by a confirmatory test. Beyond this, no single sequence of testing is common to all laboratories. The specific algorithm used depends on the prevalence of infection in the population, the resources available to the laboratory, the volume of testing, the desired turnaround time, etc. IFA and WB are acceptable confirmatory tests. For any first time positive report on an individual, a request should be made to submit another sample for repeat testing. Tests used in resolving inconclusive confirmatory test results include antigen assays, recombinant and synthetic based assays, and PCR.

Testing for HIV-2 as part of the screening process results in a greater number of specimens requiring supplemental testing, few of which are actually confirmed as HIV-2. Screening for HIV-1 alone detects 60 to 90% of HIV-2 infections. As of March 1994, 49 cases of HIV-2 infection have been reported in the U.S. from 13 states. States that have tested specimens giving atypical HIV-1 WB patterns (gag and pol bands only) with HIV-2 specific assays have successfully identified HIV-2 infection.

ISSUES FORUM
NON-TRADITIONAL TESTING

PANEL MODERATOR:

Charles Schable, M.S., Chief, Serology Section, Division of HIV/Alds, Centers for Disease Control and Prevention, Atlanta, Georgia

PANEL MEMBERS:

J. Richard George, Ph.D., Chief, Developmental Technology Division, Division of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

Ms. Cynthia Cossen, Supervising Microbiologist, VRDL, CA Dept. of Health, Berkeley, CA

William Kassler, Ph.D., National Center for Prevention Services, Centers for Disease Control and Prevention, Atlanta, Georgia

Wanda Jones, Dr. P.H., Assistant Director for Science, Office of HIV/AIDS, Centers for Disease Control and Prevention, Atlanta, Georgia

The use of non-traditional specimens such as dried blood spots or saliva have been shown to be technically feasible. Research assays using EIA or WB specifically designed for, or modified for such specimens are clearly concordant with the standard serum testing algorithms. Unfortunately, licensed confirmatory procedures are currently not available and are an impediment to the routine use of non-traditional specimens. Hopefully this issue will resolve itself in the future as these products become licensed.

The use of rapid (<15 min) assays to detect HIV antibody in the clinic-based setting have yet to be proven themselves. Conflicting data exist as to whether clients will wait for their results from these rapid tests. ASTPHLD restates the position that persons should not be informed of a positive result unless it was confirmed by a more specific test such as WB or IFA.

There are several companies working with health departments and CDC to refine home sample collection devices. These are NOT home testing kits, but devices in which a specimen will be collected at home, mailed to a reference lab, and the client will then call at a later date for their result. On-going surveys suggest that these collection devices are technically feasible. However, since counseling is an integral part of HIV testing, the actual benefits of these devices is unproven.

ISSUES FORUM
WESTERN BLOT FALSE POSITIVE AND ISSUES OF TESTING IN THE ERA OF VACCINES

PANEL MODERATOR:

Michael Ascher, M.D., Chief, AIDS Support, VDRL, California Department of Health Services, Berkeley, California

PANEL MEMBERS:

J. Richard George, Ph.D., Research Microbiologist, Centers for Disease Control and Prevention, Atlanta, Georgia

Haynes W. Sheppard, Ph.D., Research Scientist, VRDL, California Department of Health Services, Berkeley, California

Keith Sayre, M.S., Product Manager, Ortho Diagnostics, Raritan, New Jersey

In the continuing evolution of screening tests for HIV capable of narrowing the "window period" and detecting the HIV-2 variant, problems with nonspecificity of the EIA assays have occured. The false-positive samples arising from this situation are samples that come from uninfected individuals but which test positive on one or more screening assays and have a positive confirmatory test result. The Western blot patterns are incomplete suggesting seroconversion consisting of either envelope-only reactions at the regions of gp41, gp120 and gp160, or the coincidence of such envelope band(s) with the occurrence of a false positive gag reaction, typically at p24. These samples contain no other bands and they fail to progress over time to a more complete pattern of bands on Western blot. Some of these samples are also positive on IFA. A positive antigen test can be useful in resolving such samples. Recombinant and sythetic peptide EIA tests give variable reactivity on these samples. A negative result using either test on an apparent seroconvertor should be a "red flag" for further studies.

These samples first began to be described with the 1990 enhancement of EIA tests and have increased further with the use of newer generation combi HIV 1 2 tests.

Current recommendations establish that failure to progress at six months is definitive for lack of HIV infection. However, in most cases, the resolution of such samples can be made by examining a followup sample for progression of band pattern at a one to three month interval.

It is therefore recommended that all samples having the appearance of a minimal seroconversion on blot (with no other bands) can be reported as positive but that the written result should include a note that such results can be nonspecific and that a followup sample is recommended to establish progression to a more complete pattern. The time limit for defining absence of infection should be stated.

Samples from those who have participated in HIV vaccine trials may give unusual patterns, resulting in erroneous interpretations. Studies to differentiate such specimens from true positives are in progress.

ROUND TABLE: INTERNATIONAL PERSPECTIVES

MODERATOR:

William J. Hausler, Jr., Ph.D., Director, University Hygienic Laboratory, University of Iowa.

PANEL MEMBERS:

Elizabeth M. Dax, M.D., National HIV Reference Laboratory, Australia

Ofelia Monzón, M.D., Consultant, ADS Research Group, Research Institute for Tropical Medicine, Manila, Philippines.

The fundamental purpose was to discuss ways in which the ASTPHLD could provide its assistance or prescence in the international sphere of retrovirus testing.

Discussants made it very clear that the early consensus conferences did much to establish international recognition of standards of laboratory performance and reporting. Problems cited were inability to replicate USA laboratory environments, personnel, acquisition of reagents and specimen transport. In addition, many countries do not have sufficient regulations in force to prevent import and sale of reagents near or just beyond expiration date.

Countries outside the USA are not so much in need of training for relatively simple retrovirus laboratory diagnostic techniques as they are for assistance in guiding them to develop their own operational standards based on indigenous problems not encountered in the USA. The ASTPHLD was encouraged to become more active in assisting countries in the laboratory testing standardization process now that the WHO has significantly reduced its laboratory component.

The program committee is challenged to provide an international activities section within each Conference on Human Retrovirus Testing where laboratory scientists, manufacturers and program managers can meet and discuss issues of direct concern in human retrovirus testing in non-USA areas. The epidemic of HIV infection continues to expand and the ASTPHLD needs to maintain its public health laboratory leadership role.

ABSTRACTS

(Abstracts were reproduced in the conference program)

1 **Multisite Evaluation of the Murex SUDS® HIV-I Test for Detection of Antibody to Human Immunodeficiency Virus Type 1,** Richard C. Alexander, Dennis Ferrero, Bruce Fujikawa.

2 **HIV Study comparing the ability of serum, urine and saliva to Detect HIV seropositivity in known HIV-1 positive individuals,** M.A. Wilke, M.A. Baker, L.M. McIntosh, L.M. Killingsworth, L.R. Bernard.

3 **Does contact between Dried Blood Spots transfer HIV Seropositivity?** Carol J. Bell, Trudy L. Dobbs, and W. Harry Hannon.

4 **Comparative Performance of a Synthetic Peptide Assay as a Supplemental Test for HIV Antibody Detection,** S.B. Bennett, S. Fordan, S. Lampp, E.E. Buff, E.C. Hartwig, D. Frazier.

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10 **Evaluation of Laboratory Performance of T-Lymphocyte Immunophenotyping (TLI) in Support of HIV-1 Infected Patient Care and Management,** C.D. Cross, W.O. Schalla, R.N. Taylor, J.H. Handsfield.

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INDEX TO ABSTRACT AUTHORS

CONFERENCE ATTENDEES

Sandra Aarnaes
Supervisor, Microbiology, University of CA, Irvine Medical Center, Rt. 19, 101 City Drive, Orange, CA 92668

Al Absher
Organon Teknika,100 Akzo Avenue, Durham, NC 27712

Richard C. Alexander
Laboratory Director, San Bernardino County, Public Health Department, 799 E. Rialto Avenue, San Bernardino, CA 92415-0011

Thomas S. Alexander Ph.D.
Immunologist, Summa Health System, 525 E. Market Street, Dept. of Pathology, Akron, OH 44309-2090

Kim Anderson
HIV Lead Tech, Osborn Laboratories, 14901 W. 117th St., Olathe, KS 66062

Michael Ascher M.D.
Deputy Chief, Viral and Rickettsial Disease Lab, California Dept. of Health Services, 2151 Berkeley Way, Berkeley, CA 94704

Farah Babakhani
Branch Supervisor, Medical Serology, Texas Department of Health, 1100 West 49th Street, Austin, Texas

Mary Beth Baker
Virology Supervisor, Pathology Associates Medical Laboratories, E. 11604 Indiana, Spokane, WA 99206

Lawrence A. Baker
Research Manager, CIBA-Corning Diagnostics, 333 Coney St., E. Walpole, MA 02032-1597

Elizabeth Baylis
Virologist, Public Health Foundation, California, 2151 Berkeley Way, Berkeley, CA 94801

Carol J. Bell
Project Administrator, ISQAL, Centers for Disease Control/Prevention, 4770 Buford Highway NE (MS-F19), Chamblee, GA 3-0341-3724

Spencer B. Bennett
Retrovirology Supervisor, Florida HRS Office of Lab Services, 1217 Pearl St., Jacksonville, FL 32202

Christopher Bentsen
Director-Regulatory, Quality and Clinical Affairs, Genetic Systems / Sanofi Diagnostics Pasteur, 6565 185th Avenue, N.E., Redmond, WA 98052

Richard Berman
Director Clinical Microbiology, Pennsylvania State Public Health Lab., P.O. Box 500, Exton, PA 19341-0500

Beth Billyard
Research Scientist, Gen-Probe, 9880 Campus Point Drive, San Diego, CA 92121

William Black
R & D Project Manager, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

James W. Blaine Ph.D.
Assistance Bureau Director, Virginia Consolidated Laboratory Services, One North 14th Street, Richmond, VA 23219

Sharon Blumer M.S.
Centers for Disease Control and Prevention, 4770 Buford Hwy, NE Mailstop, Atlanta, GA 30341

John A. Boffa
Vice President, Technical Service GIB Laboratory, 41 Spring Street, New Providence, NJ 07974

Robin Botchlet
Supervisor Immunology, Public Health Laboratory, Oklahoma State Dept of Health, P.O. Box 24106, Okla City, OK 73124-0106

Richard M. Braun
Boston Biomedica, Inc., 375 W. Street, W. Bridgewater, MA 02379

Timothy J. Brosz
Microbiologist, ND State of Dept. of Health & Consolidated Laboratories, 1205 Ave. A West, P.O. Box 5520, Bismarck, ND 58502-5520

Dr. Arthur Brown
Walter Reed Army Institute of Research, 13 Taft Court, Suite 201, Rockville, MD 20850

Mark A. Cannon
Laboratory Manager, U.S. Army, 13 Taft Court Suite 201, Rockville, MD 20850

David F. Carpenter Ph.D.
Director, Division of Laboratories, IL Department of Public Health, 825 N. Rutledge, P.O. Box 19435, Springfield, IL 62794

Julie Ann Chalmers
Medical Technologist, Immunology Lab University Hospital, University of Virginia, Charlottesville, VA 22908

Jerome R. Cordts, M.Ed.
Executive Director, ASTPHLD, 1211 Connecticut Avenue, N.W., Suite 608, Washington, D.C. 20036

Coleman Chuen
Abbott Diagnostics, Dept. 2TN/AP6C, Abbott Park, IL 60064

Gabrielle Cloutier
Lab Technologist, Blood Center of S.E. Wisconsin, 626 S. 66th Street, Miwaukee, WI 53214

Patrick F. Coleman M.D.
Director, R&D, Genetic Systems, 6565 185th Ave., N.E.. Redmond, WA 98052

Greg Coleman
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

Jeanne Connelly
Product Mgr., Worldwide Commercial Development, Ortho Diagnostics Systems, Inc., 1001 US Hwy 202, P.O. Box 350, Raritan, NJ 08869-0606

James M. Conroy
Research Scientist, New York State Department of Health, 120 New Scotland Avenue, David Axelrod Institute, Albany, NY 12201-2002

Dr. Niel T. Constantine Ph.D.
Director, Clinical Immunology, Univ. of Maryland, N2W65, 22 S. Greene St., Baltimore, MD 21201

Cynthia Cossen
Public Health Microbiologist, Viral & Rickettsial Disease Lab., California Public Health Laboratory, 2151 Berkeley Way, Berkeley, CA 94704

Rodger Counderson
Coulter Corporation, P.O. Box 169015, Miami, FL

Chuck Crampton
Organon Teknika, 100 Akzo Avenue, Durham, NC 27712

Terry C. Crockett
Laboratory Scientist Supervisor, LA State Dept. of Health, 325 Loyola Ave., Rm. 709, New Orleans, LA 70112

G. David Cross
Health Scientist, Centers for Disease, Control & Prevention, 1600 Clifton Rd., N.E., Mailstop G23, Atlanta, GA 30333

Norman Crouch Ph.D.
Minnesota Department of Health, 717 Delaware Street, S.E., Minneapolis, MN 55440

Pat Cruse
Deputy Director, USAF HIV Testing Services, AL/AOELH 2601 West RD STE 2, Brooks AFB TX 78235-5241

Marilou Cruz
Medical Technologist, Kaiser Medical Group, 22040 Ballinger Street, Chatsworth, CA 41311

Terry Cummings
Laboratory Supervisor, Alpha Therapeutic Corporation, 5700 Pleasant View Road, Memphis, TN 28134-6503

Barbara Daanen
Asst. Scientist, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

Linda Davis
Medical Technologist, Fort Wayne Regional Laboratories, 328 Ley Road, Fort Wayne, Indiana 46825

Phill Davis
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

Elizabeth M. Dax M.D.
National HIV Reference Laboratory, Australia, Fairfield Hospital, Fairfield 3078, Melbourne, VK Australia

Stephen P. Day Ph.D.
Chief, Molecular Biology, Wisconsin State Laboratory of Hygiene, 465 Henry Mall, Madison, WI 53706

Gloria Echeverria De Perez M.D.
Institute of immunology, Caracas, Venezeula, Apartado 50109, Caracas, OF 1050A Venezuela

Stephen R. Delaney Ph.D.
Abbott Laboratories, One Abbott Park Rd., Bldg. AP-8B, Dept. 09YH, Abbott Park, IL

Susanne Desrosiers
Laboratory Scientist, New Hampshire Public Health Laboratory, 6 Hazen Drive, Concord, NH 03301

Mark Destree
Blood Center of S.E. Wisconsin, 4865 S. Katelyn Circle, #104, Greenfield, WI 53220

Patti Dewey
Organon Teknika, 100 Akzo Avenue, Durham, NC

Arthur F. DiSalvo M.D.
Director, Nevada State Health Laboratory, 1660 N. Virginia Street, Reno, Nevada 89503

Roger Dodd Ph.D.
Head, Transmissible Diseases Department, American Red Cross, Holland Laboratory, 15601 Crabbs Branch Way, Rockville, MD 20855

P. David Dotson, Jr.
Chief Virology/Immunology, Indiana State Department of Health, 1330 W. Michigan St., Indianapolis, IN 46206-1964

James Douglas
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

Harold Dowda Ph.D.
Director, Bureau of Laboratories, South Carolina Department of Health, 8231 Parklane Road, Columbia, SC 29223

Evelyn Edwards
Medical Technologist, South Caroline Department of Health & Environmental Control /Laboratory, 8231 Parklane Road, Columbia, SC 29223

Richard Egan
Senior Director of Development, Direct Access Diagnostics, 440 Rt. 22 East, Bridgewater, NJ 08807

Jim Ellerdrock
Roche Diagnostic Systems, 1080 U.S. Highway 202, Branchburg, NJ 08876

Robert Falcon
Asst. Scientist, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

Dennis V. Ferrero
Laboratory Director, San Joaquin County, CA, P.O. Box 2009 1601 East Hazelton Avenue, Stockton, CA 95201

John Fitchen
Epitope, 8505 SW Creekside Place, Beaverton, OR 97005

Steve Fitzwilliam
Roche Diagnostic Systems, 1080 U.S. Highway 202, Branchburg, NJ 08876

Colleen M. Flood
Senior Bacteriologist, New York State Dept. of Health, WCL&R/David Axelrod Institute for Public Health. Albany, NY 12201

Dr. Bagher Forghani
Research Scientist, VRDL, CA Dept. of Health Services, 2151 Berkeley Way, Berkeley, CA 94704

Diane P. Francis
Program Administrator, Lab Assurance Program, Grad. Sch. of Public Health, San Diego State Univ., 5403 Alpine Blvd., Alpine, CA 91901-2315

Jack W. Frankel
Director, Tampa Branch Laboratory, Florida, 3952 W Martin Luther King, Jr. Blvd., Tampa, FL 33614-8404

Elizabeth A. Franko Dr. P.H.
Acting Director, Georgia Public Health Laboratory, 47 Trinity Ave., S.W. Room 13-H, Atlanta, GA 30334

Dwight E. Frazier
Director, Miami Branch Laboratory Florida, HRS, State of Florida, 1325 NW 14 Avenue, Miami, FL 33125

LaRonda Frazier
Medical Technologist, Kaiser Medical Group, 7027 Alvern Street, #115, Westchester, CA 90045

Sarah A. Fuller
Dept of Diagnostic Retrovirology, Walter Reed Army Institute of Research, 13 Taft Court, Rockville, MD 20850

J.L. Gallarda
Senior Research Biochemist, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

Rick Galli
Chief Tech, HIV Lab., Ontario Ministry of Health, Ontario Ministry of Health, 81 Resources Rd, Etobicoke, Ontario Canada M9P 3T1

Dana Gallo
Microbiologist, CA. State Dept. Health Services, 2151 Berkeley Way, Berkeley, CA 94704

J. Richard George Ph.D.
Chief, Dev. Technology Section, DHA, Centers for Disease Control & Prevention, 1600 Clifton Road, Atlanta, GA MSD12, Atlanta, GA 30333

Jane P. Getchell, Dr. P.H.
Associate Director, University Hygienic Laboratory, 102 Oakdale Campus #101 OH, Iowa City, IA 52242-5002

Marcia Goldfarb
Lab Director, Anatek-EP, 17 Bishop St., Portland, ME 04103

Andrew Goldstein
Epitope, 8505 SW Creekside Place, Beaverton, OR 97005

Loretta Goodwin
Product Manager, Murex Diagnostics, Inc., 3075 Northwoods Circle. Norcross, GA 30071

Michael Grant
Product Develop. Mgr, Saliva Diagnostic Systems, 11719 N.E. 95th St., Vancouver, WA 98682

Rodger Gunderson
Coulter Corporation, P.O. Box 169015, Miami, FL

Steven Gutman M.D., M.B.A.
Director, Clinical Laboratory Services Div., Food and Drug Administration, 1390 Piccard Dr., Mail Code HFZ-440, Rm.150L, Rockville, MD 20850

Kenneth Hadlock Ph.D.
Scientist II, Genelabs Incorporated, 505 Penobscoe Dr., Redwood City, CA 94063

Nancy J. Haley Ph.D.
Director, Metlife Insurance Co., One Madison Ave., New York, NY 10010

Larry Hambleton
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

W. Harry Hannon Ph.D.
Chief, Clinical Biochem Branch, Centers for Disease Control & Prevention, 4770 Buford Highway NE (MS-F19), Chamblee, GA 30341--3724

William J. Hausler, Jr., Ph.D.
Director, University Hygienic Lab, Univ. of Iowa, 102 Oakdale Campus #101OH, Iowa City, IA 52242-5002

Dr. Patrick Hays
Senior Scientist, KS Health & Environment Laboratory, Forbes Building, 740, Topeka, KS 66620

Diane Hedger
Murex Diagnostics, Inc., 3075 Northwoods Circle Norcross, Georgia 30071

Sharon Henderson
Immunology/Virology Supervisor, Community Bld Center Kansas City, MO, 4040 Main, Kansas City, MO 64111

Denis R. Henrard Ph.D.
Abbott Laboratories, Dept. 9GJ, Bldg. AP8B One Abbott Park Road, Abbott Park, IL 60064

Cheryl Hermerath
Manager Serology/Virology, Arizona State Laboratory Services, 1520 W. Adams Street, Phoenix, AZ 85007

Sandra Gonzalez Hernandez
Senior Medical Technician, University of Miami, 1611 NW 12 Ave., JMH/East Tower Rm #2044, Miami, FL 33136

Sue Hocker
Epitope, 8505 SW Creekside Place, Beaverton, OR 97005

Gerald Hoff, Ph.D..
Epidemiologist, City of Kansas City, Missouri Health Department, 1423 E. Linwood Blvd. Kansas City, Missouri 64109

Lindsay F. Hofman Ph.D.
Laboratory Director, Saliva Diagnostic Systems, 11719 N.E. 95th St., Vancouver, Washington 98682

Barbara Hosein Ph.D.
Director, Diagnostic Research & Development, United Biomedical, Inc., 25 Davids Drive, Hauppauge, NY 11788

Tom Houston
Lab Technologist, Blood Center of S.E. Wisconsin, 4865 S. Katelyn Cir. #104, Greenfield, WI 53220

Kevin Huttman
Abbott Diagnostics, Dept. 2TN/AP6C, Abbott Park, IL 60064

Jay Hyman
Research Scientist, Organon Teknika, 100 Akzo Blvd., Durham, NC 27712

Sandra Irons
Supervisor Medical Microbiology, Nebraska State Health Laboratory, 3701 S. 14th Street, Lincoln, Nebraska

Jong-Ho Jean Ph.D.
Virologist, Delaware Public Health Laboratories, 30 Sunyside Road, P.O. Box 1047, Smyrna, DE 19977-1047

Joan Johnson
Abbott Laboratories, 1 Abbott Park Road, Dept. 93E AP10, Abbott Park, IL 60064

Wanda K. Jones
Assistant Director for Science, Office of HIV/AIDS, Centers for Disease Control & Prevention, 1600 Clifton Rd NE D-21, Atlanta, GA 30033

Laurie Jones
Center Director, Technical Services, Florida Blood Services, 445 31st Street North, St. Petersburg, FL 33713

Stephen L. Josephson Ph.D.
Director, Clinical Microbiology & Virology, Rhode Island Hospital & Brown University, APC 1136, Rhode Island Hospital, 593 Eddy St., Providence, RI 02903

Jonathan Kaplan Ph.D.
Asst. to the Dir. for Infectious Diseases, Centers for Disease Control & Prevention, 1600 Clifton Road., (Mailstop G29), Atlanta, GA 30333

William J. Kassler MD, MPH
Medical Epidemiologist, Centers for Disease Control & Prevention, 1600 Clifton Road Mailstop EO2/Div. of STD/HIV Prevention, Atlanta, GA 30333

Y. Glenn Kataoka
Assistant Laboratory Director, Colorado Dept. of Health, 4210 E. 11th Avenue, Denver, CO 80220

John W.D. Kay, Ph.D.
Program Director, HIV Organon Teknika Corporation, 100 Akzo Avenue, Durham, NC 27712

Rowena Kemp
Senior Technologist, Metlife Laboratories, 4 Westchester Plaza, Elmsford, NY 10523

Howard I. Kim
Technical Director, Damon Reference Laboratories, 1011 Rancho Canejo Blvd., Newbury Park, CA 91320

Renate F. Klein
Director, Pathology, Cornell Medical School, 1300 York Avenue, New York, NY 10021

Glenn Y. Kobayashi
Microbiologist, Hawaii State Dept. of Health, 1250 Punchbowl Street, Honolulu, Hawaii 96813

Jerry Kudlac
Director, Microbiology, Okla. State Dept. of Health, P.O. Box 24106, Okla. City, OK 73124-0106

Donald Kwalick M.D.
State Health Officer, Nevada Department of Human Resources

Mariano F. La Via M.D.
Medical University of South Carolina, 171 Ashley Ave., Charleston, SC 29425

James R. Lane
Project Director, SRA Technologies, 13 Taft Court, Rockville, MD 20850

Pat Langsdale
Vice President, Sales and Marketing, Viral Testing Systems, Inc., 600 Travis, Suite 6980, Houston, TX 77002-3005

Helen Lee Ph.D.
General Manager, Probe Diagnostic Unit, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064-3500

Stephanie Lee-Thomas
Microbiologist, Centers for Disease Control & Prevention, 1600 Clifton Road, MS-D12, Atlanta, GA 30333

Sadie Lehr
Microbiologist, Center for Public Health Laboratories, Oregon Health Division, 1717 SW 10th Ave., Portland, OR

Brian Louie
Senior Microbiologist, San Francisco Dept. of Public Health, 1396 S. Mayfair Avenue, Daly City, CA 94015

Dawn Madigan
Viral Testing Systems, Inc., 600 Travis, Suite 6980, Houston, TX 77002-3005

Fahmy A. Malak M.D.
Medical Consultant, Arkansas Dept. of Health, Public Health Laboratory, 4815 West Markham Street, Little Rock, AR 72205

Pamela Markwardt-Elmer
Microbiologist Senior, Wisconsin State Laboratory of Hygiene, 465 Henry Mall, Rm. 424, Madison, WI 53705

Jay R. Marshall MT(ASCP)
Reference Laboratory Manager, Cambridge Biotech Corporation, One Biotech Park, 365 Plantation Street, Worcester, MA 01605

Allyson May
Epitope, 8505 SW Creekside Place, Beaverton, OR 97005

Vincent C. Marsiglia DLM
Laboratory Administrator, Baltimore City Health Department, BDC Laboratory Rm. 237 1515 W. North Avenue, Baltimore, MD 21217

Robert Myers Ph.D.
Laboratory Scientist, Maryland Department of Health, P.O. Box 2355, Baltimore, MD 21203

Patsy McCarty MT(ASCP)
Division Director I, Mississippi Public Health Laboratory, 2423 North State St., Jackson, MS 39216

Jean McClure
Organon Teknika, 100 Akzo Avenue, Durham, NC 27712

J. Todd McPherson
Chief, Virology Section, North Carolina State Lab. of Pub. Health, 306 North Wilmington Street, Raleigh, NC 27609

Pat Meisner
T Cell Diagnostics, Inc., 38 Sidney Street, Cambridge, MA 02139

Jeffrey N. Meshulam
Executive Vice President, Cellular Products, Inc., 872 Main Street, Buffalo, NY 14202

Frank J. Michalski Ph.D.
Director Diagnostic Virology, METPATH, 1 Malcolm Ave., Teterboro, NJ 07608

Paul A. Mied Ph.D.
Acting Director, DTTD, Food & Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448

William S. Miller Ph.D.
William S. Miller, Inc., Consultant, 5618 St Albans Way, Baltimore, MD 21212

Daniel C. Mills Ph.D.
Area Resource Director, National Laboratory Training Network, ASTPHLD, 2151 Berkeley Way, Room 803, Berkeley, California 94704

Ofelia Monzón M.D.
Consultant, AIDS Research Group, Research Institute for Tropical Medicine, Manila, Phillipines

Richard C. Moody
Director, Serology Division, Alabama Dept. of Public Health, Bureau of Clinical Laboratories, 8140 University Dr. Montgomery, Alabama 36130-3017

Sallie Moore
Immunology Supervisor, Siena Nevada Labs, 888 Willow St., Reno, NV 89502

Romulo Morales
Virology Unit Manager, Georgia Public Health Laboratory, 47 Trinity Ave., S.W. Rm. 139-H, Atlanta, GA 30334

Ray Morrill
T Cell Diagnostics, Inc., 38 Sidney Street, Cambridge, MA 02139

Susan Mottice Ph.D.
Director, Bureau of Microbiology, Utah Division of Laboratory Services, 46 North Medical Drive, Salt Lake City, Utah 84113-1105

C. Roy Moulton
Virus Section Manager, State of Idaho, 2220 Old Pen. Road, Boise, ID 83712

Geoffrey H. Moyer M.D.
Medical Director, Damon Reference Laboratories, 1011 Rancho Conejo Blvd., Newbury Park, CA 91320

Hermann Mucke Ph.D.
Senior VP of Research and Development, Waldheim Pharmazeutika R&D Laboratory, Viral Testing Systems Corp., 600 travis, Suite 4750, Houston, Texas 77002

Darrell Muller
Roche Diagnostic Systems, 1080 U.S. Highway 202, Branchburg, NJ 08876

Kate Mulligan
Becton Dickinson Immunocytometry Systems, 2350 Qume Drive, San Jose, CA 95131

Michael Neal
Bacteriologist, New York State Dept. of Health, Wadsworth Ctr for Labs & Research/David Axelrod Institute, Albany, NY 12201

Lawrence W. Nelson
Technical Support Supervisor, Nevada State Health Laboratory, 1660 N. Virginia St., Reno, NV 89503

Sherian Nestor
Microbiologist, WV Dept of Health & Human Resource, 157 11th Avenue, Office of Laboratory Services, South Charleston, WV 25303

Richard H. Newhouse Ph.D.
VP Research, Clinical Studies, Serologicals, Inc., 780 Park North Boulevard, #120, Clarkston, GA 30021

Janet K.A. Nicholson Ph.D.
Center for Disease Control and Prevention, National Center for Infectious Diseases, MS-A25, 1600 Clifton Rd., N.E., Atlanta, GA 30333

Patricia Nix
Director, Laboratory Services, Alpha Therapeutic Corporation, 5700 Pleasant View Road, Memphis, Tennessee 38134-6503

Naziha Nuwayhid
Associate Director, VA Medical Center, 1400 Wallace Blvd., Amarillo, TX 79106

Thomas A. O'Brien Ph.D.
Product Director, Retroviral Products & Hepatitis B, Ortho Diagnostic Systems, Inc., 1001 US Hwy 202, P.O. Box 350, Raritan, NJ 08869-0606

Terri Ozegovich
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

Dr. William Pagels
Assoc. Director of Development, Direct Access Diagnostics, 440 Rt. 22 East, Bridgewater, NJ 08807

Mahen Park Ph.D.
Director, Disease Control Labs., Ind. State Dept. of Health, 1330 W. Michigan St., Indianapolis, Indiana 46206

Dr. John V. Parry
PHLS Virus Peference Division, Central Public Health Laboratory, London, 61 Colindale Avenue, London, United Kingdom NW9 5HT

Peter Parsons
Manager of Laboratory Integration, Class Development, 1018 Land's End Way, Virginia Beach, VA 23451

James L. Pearson Dr.P.H.
Director, Virginia Consolidated Lab Services, One North 14th Street, Room 234, Richmond, VA 23219

Chris Peter Ph.D.
Chief, Public Health Laboratory,San Diego County Public Health Laboratory,3851 Rosecrans St, P.O. Box 85222,San Diego, CA 92186-5222

Bruce H. Phelps
Mgr. Retrovirus R&D,Abbott Laboratories,One Abbott Park Road, D-93E AP10,Abbott Park, IL 60064-3500

Susan K. Phillips
Microbiologist, Centers for Disease Control and Prevention, 1600 Clifton Road NE Bldg-Room 2250, Atlanta, GA 30330

Mary M. Pollock
Microbiologist, VA Dept. of Health, One N. 14th Street, Richmond, VA 23219

Sylvia Posso
Viral Testing Systems Inc., 600 Travis, Suite 6980, Houston, TX 77002-3005

Sunny Powell
Coulter Corporation, P.O. Box 169015, Miami, FL

Richard A. Quattrocchi
President, Anonymous Test Services, Inc., 2550 W. Golf Road Suite 106, Rolling Meadows, IL 60008-4051

Steven Raia
Boston Biomedica, Inc., 375 W Street, W. Bridgewater, MA 02379

Michael T. Ramirez
Public Health Microbiologist, University (Iowa) Hygienic Laboratory, 102 Oakdale Campus #101 OH, Iowa City, IA 52242-5002

Barry Reed M.D.
V.P. Medical Underwriting, MetLife Insurance Co., One Madison Ave., New York, NY 10010

Andra Reneau
Viral Testing Systems Corporation, 600 Travis Suite 6980, Houston, TX 77002-3005

Lori Rhodes
Becton Dickinson Immunocytometry Systems, 2350 Qume Drive, San Jose, CA 95131

Donald G. Ritter
Microbiologist, State Virology Laboratory, Alaska, P.O. Box 60516, Fairbanks, AK 99706-0516

Claudia Rogers MT (ASCP)
Medical Technologist, Wyoming Public Health Laboratory, 517 Hathaway Bldg., Cheyenne, WY

Rosanna Rumbough
Serology Branch Head, N.C. State Laboratory of Public Health, 306 N. Wilmington St., Raleigh, NC 27609

Jeff J. Runyon
Supervisor, Quality Assurance, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

Christine Vogel Sapan Ph.D.
Director of Scientific Affairs, North American Biologicals, Inc. (NABI), 16500 N.W. 15 Avenue, Miami, FL 33169

Bob Sass
Zynaxis, Inc., 371 Phoenixville Pike, Malvern, PA 19355

Keith Sayre
Product Manager, Worldwide Commercial, Development, Ortho Diagnostic Systems, Inc., 1001 US Hwy 202, P.O. Box 350, Raritan, NJ 08869-0606

Charles Schabel, M.S.
Chief, Serology Section, Div. of HIV/AIDS, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E. D12, Atlanta, GA 30333

William Schaila M.S.
Chief, Model Performance Evaluation Program, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mail Stop G23, Atlanta, GA 30333

John Schilling
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Caska, MN 55318

Carol M. Schimek
Transfusion Transmitted Virus, Mayo Clinic, 200 First Street, S.W., Rochester, MN 55905

Nancy Schneider
Organon Teknika, 100 Akzo Avenue, Durham, NC 27712

Richard Schumacher
Boston Biomedica, Inc., 375 W. Street, W. Bridgewater, MA 02379

Mark Schwerzler
Chemist, TSRI, 305 South Street, Boston, MA 02130

Betsy R. Sears
Lab Manager, Osborn Laboratories, 14901 W. 117th St., Olathe, KS 66062

Eugene Seymour M.D., M.P.H.
CEO, Saliva Diagnostic Systems, 11719 N.E. 95th St., Vancouver, WA 98682

S.I. Shahied Ph.D.
Assistant Commissioner, NJ Division of Public Health NJ State Department of Health, CN360, Trenton, NJ 08625

Jacqueline M. Sheffield
Supervisory Medical Technologist, Infectious Diseases Division, 8901 Wisconsin Avenue, Bldg. 9 Room 1637, Bethesda, MD 20889-5600

Haynes W. Sheppard, Ph.D.
Research Scientist III, VRDL, Calif. Dept. of Health Services, 2157 Berkeley Way, CA

Ken Shockley
Murex Diagnostics, Inc., 3075 Northwoods Circle, Norcross, GA 30071

William Skillman
Product Director, Retrovirology, Ortho Diagnostic Systems, Inc., 1001 US Hwy 202, P.O. Box 350, Raritan, Raritan, NJ 08869-0606

J. Donnell Small, Jr.
Manager, Immunodiagnostics, Organon Teknika Corporation, 100 Akzo Avenue, Durham, North Carolina 27712

Thomas F. Smith Ph.D.
Chair Clinical Microbiology, Mayo Clinic, 200 1st Street, S.W., Rochester, MN 55905

Edith S. H. Smith
Supervisory Health Science Specialist, Naval Central HIV Program, 8901 Wisconsin Avenue, P.O. Box 658, Bethesda, Maryland 20889-5600

Apryl Smith
Lab Technologist, Blood Center of S.E. Wisconsin, 5218 N. Lovers Lane Road #1, Miwaukee, WI 53225

Janet Sowka
Manager, South Bend Medical Foundation, 530 N. Lafayette Blvd., South Bend, IN 46617

John F. Stephens
Abbott Laboratories, 1 Abbott Park Road, Abbott Park, IL 60064

Susan Stramer Ph.D.
Section Manager, Retrovirus Research and Development, Abbott Laboratories, D93E, AP10, Abbott Park, IL 60064

Henry L. Strother
Public Health Labor. Scientist, Missouri State Public Health Laboratory, 307 West McCarty St., Jefferson City, MO 65101

Terre Sutherland
Lab Director, Community Bio-Resources, Inc., 1618 3rd Avenue N, Birmingham, AL 35203

Janet Teghtmeyer
Director, Processing Lab, Sacramento, CA Blood Center, 1625 Stockton Blvd., Sacramento, CA 95816

Ralph Timperi
Assistant Commissioner, State Laboratory Institute, Massachusetts, 305 South Street, Jamaica Plain, MA 02130

Chris Tornstrom
Zynaxis, Inc., 371 Phoenixville Pike, Malvern, PA 19355

Margaret Turano
T Cell Diagnostics, Inc., 38 Sidney Street, Cambridge, MA 02139

Ronald Turnicky D.O., LTC, MC
Diagnostic Retrovirology, Walter Reed Army Institute, Rockville, MD 20850

Howard Urnovitz Ph.D.
Founder & CSO, Calypte Biomedical, 1440 Fourth Street, Berkeley, CA 94710

Carol Valstyn
Becton Dickinson Immunocytometry Systems, 2350 Qume Drive, San Jose, CA 95131

Beth Vela
Supervisor, Quality Assurance, Abbott Laboratories, One Abbott Park Road, Abbott Park, IL 60064

Richard Walkenbach
Public Health Laboratory Scientist, Missouri State Public Health Laboratory, 307 West McCarty Street, Jefferson City, MO 65101

Diane Wara M.D.
Professor, Department of Pediatrics, Moffitt Hospital School of Medicine, University of California, San Francisco, California

Erik M. Warschauer Ph.D., MT
Supervisor, Clinical Reference Laboratory, Genetic Systems Corp., 6565 185th Avenue, N.E., Redmond, WA 98052

Barbara Weiblen
Boston Biomedica, Inc., 375 W. Street, W. Bridgewater, MA 02379

Barbara Werner Ph.D.
Director, Virology/ Clin. Invest. Division, Mass achusetts State Laboratory Institute, Department of Public Health, 305 South Street, Jamaica Plain, MA 02130

Judith Wethers MS
Director of Testing Retrovirology Laboratory, New York Department of Health, New York Department of Health, Box 509, Albany, NY 12201

Roxanne Whitesides
Immunohematology Supervisor, Kaiser Permanente, 16601 E Centre Tech Parkway, Aurora, CO 80011

Judith Wilber Ph.D.
Associate Director, Nucleic Acid Systems, Chiron Corporation, 4560 Horton Street, Emeryville, CA 94608

Bill Wong
Zynaxis, Inc., 371 Phoenixville Pike, Malvern, PA 19355

Jolene Wong-Lee
Product Manager, Diagnostics, Genelabs Diagnostics, USA, 505 Penobscot Drive, Redwood City, CA 94063

Norm Woods
Sanofi Diagnostics Pasteur, 1000 Lake Hazeltine Drive, Chaska, MN 55318

Hou Xinyue
Denver Disease Control Service, 605 Bannock Street, Denver, CO 80204

Raphael J. Yankey
Supervisor/Serology Lab, George Washington Univ. Med. Ctr., 901 23rd Street, N.W., Room 5353N, Washington, DC 20037

JoAnn Yee
Supervisor, Univ. of Calif. AIDS Virus Lab, Dept. of Medical Pathology, Davis, CA 95616

Elaine Yeh
Public Health Microbiologist, State of Calif. Virus Lab , CA Dept. of Health Services, 2151 Berkeley Way, Berkeley, CA 94704

Belinda Yen-Lieberman Ph.D.
Staff Scientist, Cleveland Clinic Foundation, Cleveland Clinic Fdn., Dept. of Clinical Path. L40, Cleveland, OH 44195-5140

Marc W. Yonker
Microbiologist, Indiana State Department of Health, 1330 West Michigan, Indianapolis, IN 46202

Sue Yoshino
Supervising Pub. Health Microbiologist, Public Health Laboratory, County of Orange, CA, 1729 W. 17th Street, Santa Ana, CA 92706

Judy Yost M.A. MT(ASCP)
Medical Technician Advisor, Bureau Director, HCFA, 6325 Security Blvd., 202 Meadows East Building, Baltimore, MD 21207

Madonna Young
Unit Supervisor, Serology Dept, Nichols Institute, 33608 Ortega Highway, San Juan Capistrano, CA 92690-6130

Susan Yu
Medical Technologist, Navy Central HIV Program, 12914 Autumn Dr., Silver Spring, MD 20904-3335

Susanne Zanto
Virology Supervisor, Montana Public Health, Laboratory, Cogswell Building, Helena, MT 59620

Minas Zartarian
Senior Specialist, University of California, Irvine, Medical Center, 101 The City Drive, Orange, CA 92668

Wojciech M. Zawada M.D., Ph.D.
Director, Immuno-Chemistry Section, Arkansas Dept. of Health, Division of Public Health Laboratories, 4815 W. Markham Street - Slot #47, Little Rock, AR 72205-3867