Serology Control Program Of the Venereal Disease Research Laboratory

By Ad Harris
and Hilfred N. Bossak, B.S.

THE SEROLOGY CONTROL program of the Venereal Disease Research Laboratory was evolved to assist State laboratories in attaining and maintaining a high level of efficiency in serologic testing. Through these State laboratories, the testing efficiency of all laboratories of this country performing serologic tests for syphilis may be favorably affected. This program has nine integrated segments, each of which is of little value as a separate entity, but which, collectively, have been effective in reaching the objective with a minimal expenditure of time and money. The serology control program has also served as a pattern of operation used by several States as a service to the laboratories within their jurisdictions. Available to the central laboratories of the 48 States, the District of Columbia, Alaska, Hawaii, Puerto Rico, and the Virgin Islands, the services of the program include:

Providing a laboratory manual prepared by the staff of the Venereal Disease Research Laboratory.

Providing reference-standard serologic reagents prepared by the staff of the Venereal Disease Research Laboratory.

Inspecting laboratory serology control programs.

Conducting scheduled training courses.

Conducting field refresher training courses or workshops.

Standardizing and supplying dehydrated control serum.

Conducting hemispherewide serologic evaluation studies on a continuing basis.

Participating as a control or co-control in intrastate serologic evaluation studies.

Offering a *Treponema pallidum* immobilization (TPI) testing service, nationwide, through the State and Territorial laboratories.

Mr. Harris is director of and Mr. Bossak is a bacteriologist with the Venereal Disease Research Laboratory, Public Health Service, Chamblee, Ga. *Their paper was presented at the First International Symposium on Venereal Diseases and the Treponematoses, Washington, D.C., May 28–June 1, 1956.*

Manual of Serologic Tests

A Manual of Serologic Tests for Syphilis has been prepared with the assistance of the authors of the tests and is revised at appropriate intervals. The manual contains general information about equipment; cleaning and care of glassware, antigens, and other reagents used in serologic tests; the effect of room temperature on test results; reporting of serologic test results; and laboratory control of test performances. Technique outlines, including recommendations for equipment, glassware, reagents, and step-by-step procedure for APHA reference, Hinton, Kahn, Kline, Kolmer, Mazzini, Rein-Bossak, and VDRL tests, are contained in the 1955 edition (*1*). Instructions are given in the appendix for the collection and preservation of sheep red cells, preparation and preservation of complement, use of merthiolate as a bacteriostat for spinal fluid, and a recommended method for quantitative determination of spinal fluid protein. This manual has been revised at approximately 5-year intervals in order to stay abreast of acceptable changes in the field of serology. The 1955 edition is the latest revision.

Services to Laboratories

Standardized antigens and other reagents for the tests listed in the Manual of Serologic Tests for Syphilis are prepared and made available for check-testing purposes to commercial or State laboratories that manufacture or purchase these reagents. During past years, the older type, lipoidal antigens were standardized and distributed for use in check-testing but this activity is now confined to the cardiolipin-type antigens. Verification testing of antigens prepared by State laboratories is also done on request. Agreements have been reached under which samples of VDRL antigen are submitted to the Venereal Disease Research Laboratory for check-testing and approval before sale by commercial laboratories in this country.

State laboratories are visited on request for consultation and for reviewing their serology program (testing, laboratory control, training, and laboratory visitation). Written reports of observations, commendations, and recommended changes, if any, are submitted to the State laboratory director and the State health officer. This service will be more fully described in a later paper.

Training Courses

Training courses are regularly scheduled at the Venereal Disease Research Laboratory. Nine 2-week courses were scheduled during the fiscal year 1956; 10 courses were held. Applications from this country for these 2-week courses must be signed by the State health officer or the State laboratory director, unless the applicant is an employee of the Public Health Service, in which case the application must be approved by the medical officer in charge of the laboratory where the applicant is employed. Trainees are accepted from Armed Forces installations in this country and from the World Health Organization, the Pan-American Sanitary Bureau, and employees of central laboratories in other countries. Schedules of courses for each fiscal year are distributed before July 1, and reservations are made as soon as applications are received. Application lists are closed 1 month before the dates the courses are to start.

Five courses titled "Serology of Syphilis" were scheduled for the fiscal year beginning July 1956. These courses provide refresher training to senior operating personnel of State and Public Health Service laboratories. They are composed of lecture, demonstration, and participation periods covering the most widely used American methods for the serodiagnosis of syphilis, with references to latest developments in this field.

The two courses in management and control of syphilis serology by the regional laboratory are designed for assistant laboratory directors and senior laboratory staff members and include review of interlaboratory serologic evaluation studies, laboratory inspection procedures, demonstration of antigen check-testing and standardization, and preparation of control serum.

Courses about tests for syphilis using the *Treponema pallidum* include lectures, demonstration of and class participation in the immobilization (TPI), agglutination (TPA), complement-fixation (TPCF), immune-adherence (TPIA), and other tests which use the virulent *Treponema pallidum* as an antigen source. The complexity of these tests requires that these classes be limited to small groups, so it has been necessary to schedule additional classes when large numbers of qualified applicants have applied. Applicants for these courses should have had adequate experience in the field of serology and be in supervisory positions.

Field refresher training courses are also held in cooperation with State department of health laboratories. On-the-job training is also accomplished during visits to Public Health Service laboratory facilities.

Control Serum

Dehydrated control serum for serologic tests for syphilis is offered to the State laboratories and to Public Health Service laboratories on a continuing basis. Twenty-six ampules of serum, considered to be a 6 months' supply when used at the rate of one ampule per week, are sent with a protocol showing the reactivity of each lot of serum in all of the tests performed at the Venereal Disease Research Laboratory. Continuous use of this control serum will allow the laboratories to determine the relative reactivity of their tests as compared with the same tests performed at the Venereal Disease Research Laboratory and, secondly, will show whether the reactivity of their tests is remaining at a constant level or is varying from day to day. The laboratories that use this serum do not report their findings to the Venereal Disease Research Laboratory, since this is not considered to be an evaluation service.

Serologic Evaluation Studies

The Public Health Service Serologic Evaluation Study is presently being conducted by distributing 20 samples of prepared sterile serum to each of 62 participating laboratories in each of 10 months of the fiscal year. During

the remaining 2 months, all reports are tabulated and an analysis of comparative results is issued. Laboratories participating in this study during the fiscal year 1956 included the central laboratories of the 48 States, the District of Columbia, Alaska, Puerto Rico, Hawaii, Mexico, and Canada, plus the Kahn, Kline, Kolmer, Hinton, Rein, and Mazzini laboratories and the Venereal Disease Research Laboratory. This type of serologic evaluation study produces data that may be used to ascertain relative efficiency of many laboratory performances of each type or kind of test as compared with the test-author results. In order to make available to the participating laboratories some comparative results before the yearly report is analyzed, a report of the results obtained at the Venereal Disease Research Laboratory each month, with all procedures, is sent to all participating laboratories as soon as their monthly report is received.

A similar, but smaller, serologic evaluation study is presently being conducted for the laboratories of Public Health Service facilities. In this study, 10 samples of prepared serum will be sent monthly for 5 months of this fiscal year to each of 26 Public Health Service laboratories. A report of the results obtained with the VDRL slide test and the Kolmer test at the Venereal Disease Research Laboratory is returned to the laboratories participating in this study as soon as their monthly reports are received.

Use of VDRL Services

The central laboratories of all 48 States, the District of Columbia, Alaska, Hawaii, Puerto Rico, and the Virgin Islands have received one or more of the services referred to in this report during the recent past. In the calendar year 1955, these laboratories utilized the services and control functions of the Venereal Disease Research Laboratory 264 times, in addition to submitting 2,875 serums for TPI testing. Additional services were given to the central laboratories of other countries either directly or through the function of the Venereal Disease Research Laboratory as a reference laboratory for the World Health Organization.

TPI Testing Service

The *Treponema pallidum* immobilization (TPI) test has been offered since January 1955 as an additional reference service, on a nationwide basis, through the laboratories of State health departments, by the Venereal Disease Research Laboratory. Criteria for acceptance of specimens for this testing are stipulated. Blood specimens are sent to State laboratories, where sterile serum is separated and forwarded to the Venereal Disease Research Laboratory. Each specimen of serum must be accompanied by a completed clinical data sheet containing statements about evidence or history of treponematosis; syphilis in the family; other venereal diseases; record of known STS; diseases other than treponematosis especially those presumed to elicit nonspecific reactions in STS; and the opinion of the attending physician regarding present diagnosis. Reports of TPI tests are sent to the respective State laboratories for forwarding to the submitting physician. During the first months of 1956, requests for this service were received at the rate of approximately 100 per week.

REFERENCES

(*1*) U. S. Public Health Service: Serologic tests for syphilis. 1955 manual. PHS Pub. No. 411. Washington, D. C., U. S. Government Printing Office, 1955.