

## Request for Applications

### **Laboratory-based Evaluation of Rapid Diagnostics for Syphilis**

RFA: RFA-SDI-2001-01

Diagnostics Research and Development/Sexually Transmitted Diseases Diagnostic Initiative

Release Date: July 28, 2001

The Sexually Transmitted Diseases Diagnostics Initiative (SDI) is inviting applications from laboratories interested in working with SDI on evaluations of rapid syphilis serologic tests.

The SDI is an initiative within the UNDP/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR). Its mission is to promote the development, evaluation and application of STI diagnostic tests appropriate for use in primary health care settings in developing countries. The major focus of SDI activities at present is the evaluation of commercially available rapid STI diagnostics for three priority diseases, syphilis, chlamydia and gonorrhoea.

In consultation with STI experts from developing countries, SDI has identified an urgent need for a rapid point-of-care screening test for syphilis that uses whole blood and can distinguish active syphilis from previous infection. This will be of particular value for screening antenatal clinic attenders in high prevalence settings to prevent congenital syphilis. Over twenty rapid syphilis tests are now sold internationally, but test performance data is limited, and it is not known if any of these tests meet disease control needs. SDI will be conducting a 2-stage evaluation of these rapid syphilis tests. Tests will be first evaluated in the laboratory using archived specimens for test performance, reproducibility, stability and ease of use. A few of the most promising tests from these laboratory-based evaluations will be selected for evaluation in field settings. SDI is seeking to establish a network of laboratories in diverse geographic areas for the first phase of this evaluation. Laboratories will be selected on the basis of:

- 1) Capacity and proficiency at performing standard tests for syphilis (RPR and TPHA), including number of tests/year and subscription to external quality assurance; applicants may be asked to send a panel of 20 sera to a designated reference centre for validation of test results obtained on site
- 2) Access to patient populations with high to moderate disease prevalence
- 3) Ease of specimen transport for reference testing/external quality assurance
- 4) Mechanism for institutional review of evaluation protocol and ethics approval
- 5) Ability to perform evaluations in a timely manner
- 6) Willingness to work in a team environment

Preference will be given to laboratories with strong links to field sites with patient populations of moderate to high disease prevalence and demonstrated experience with clinical trials.

### **How to Apply**

Please complete the appended questionnaire and return it, by email or fax, with the curriculum vitae of the principal applicant to Dr. Rosanna Peeling, WHO/TDR/SDI, 20 Avenue Appia, Geneva, Switzerland, Fax: 41 22 791 4854, Email: [peelingr@who.int](mailto:peelingr@who.int).

## Questionnaire

### Applications for Laboratory-based Evaluation of Rapid Syphilis Diagnostics

#### Part 1. Administrative information

1.1 Name of applicant and institutional affiliation  
(please enclose applicant's curriculum vitae)

Title:                                      Surname:                                      First name(s):

1.2. Full name of institution:

1.3. Full postal address of applicant:

1.4. Telephone:

1.5. Fax:

1.6. Email:

#### Part 2: Laboratory Site Information

2. General information:

2.1. Type of laboratory:

Public health/government \_\_\_\_\_ private \_\_\_\_\_ hospital \_\_\_\_\_  
University \_\_\_\_\_ other (specify) \_\_\_\_\_

2.2. Type of work performed in the laboratory:

diagnostic \_\_\_\_\_ research \_\_\_\_\_ both \_\_\_\_\_

2.3. Details of laboratory services:

STI tests offered: Please specify brand name, manufacturer and type of specimen used

Syphilis:

Screening: \_\_\_\_\_

Confirmatory testing: \_\_\_\_\_

Annual volume of syphilis tests and positivity rate:

pre-natal screening \_\_\_\_\_, approx. \_\_\_\_\_% positive;  
diagnostic testing \_\_\_\_\_, approx. % positive in men \_\_\_\_\_ in women \_\_\_\_\_

Average turn around time for test results: screening test \_\_\_\_\_ confirmatory \_\_\_\_\_

Diagnostic testing for other sexually transmitted infections: Please specify the type and number of specimens/yr submitted, the name and manufacturer of test kits (if applicable) and positivity rate by gender

*Chlamydia trachomatis* \_\_\_\_\_  
\_\_\_\_\_

*Neisseria gonorrhoeae* \_\_\_\_\_  
\_\_\_\_\_

*H. ducreyi* \_\_\_\_\_  
\_\_\_\_\_

Herpes Simplex Virus-2 \_\_\_\_\_  
\_\_\_\_\_

HIV \_\_\_\_\_  
\_\_\_\_\_

2.4. Laboratory capacity, facility, and management:

Number of scientific staff and qualifications

Professional: \_\_\_\_\_

Technical: \_\_\_\_\_

Clerical: \_\_\_\_\_

Are written standard operating procedures available for all laboratory procedures?

yes \_\_\_\_\_ no \_\_\_\_\_

Capacity of freezer storage currently available:

-20°C freezer \_\_\_\_\_; -70°C freezer \_\_\_\_\_

Is freezer back-up available in the event of a power failure? yes \_\_\_ no \_\_\_

Is a courier service for international specimen shipping available: yes \_\_\_ no \_\_\_

Are laboratory records computerized? yes \_\_\_\_ no \_\_\_\_; if yes, please specify the  
current software package used \_\_\_\_\_

Quality Assurance: participation in external regional, national or international

proficiency programs: yes \_\_\_\_ no \_\_\_\_

If yes, please specify \_\_\_\_\_

**Part 3: Research Activities (use additional pages if necessary):**

3.1. Previous experience with diagnostics evaluation: brief descriptions of tests evaluated, sample size, gold standard used, results (attach recent publications if applicable) and other relevant information.

3.2. Describe any links or ongoing collaborations with clinic sites where rapid STI diagnostics could be field tested. Please provide the name of collaborator(s) and a brief description of the field site with regard to distance from the laboratory site, patient population, experience with diagnostic evaluations, type of STI services (including diagnosis and treatment) offered and any other relevant information.

3.3. Brief description of other research activities:

3.4. Is a mechanism for ethical review of research involving human subjects available locally? If yes, approximately how long does the process take once the protocol is submitted?

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