

Laboratory-based Evaluation of Rapid Syphilis Diagnostics

Manual of Operations

The Sexually Transmitted Diseases Diagnostics Initiative (SDI)

**UNDP/World Bank/WHO Special Programme for Research and Training in
Tropical Diseases (TDR)**

Geneva, Switzerland

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1. STUDY OBJECTIVES

1. To compare the performance of rapid treponema-specific tests against current reference standard tests such as the *Treponema pallidum* Particle Assay (TPPA)
2. To assess the operational characteristics of rapid treponema tests, including the ease of use, technical complexity and inter-reader variability
3. To provide data for the selection of a limited number of tests for evaluations in field settings in developing countries.

2. BACKGROUND

The Sexually Transmitted Diseases Diagnostics Initiative (SDI) is a programme within the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). At a recent joint SDI-Wellcome Trust meeting on rapid STI diagnostics for use in primary health care settings in developing countries, the evaluation of the performance and reliability of rapid syphilis diagnostics was identified as an important priority for SDI.

Serologic tests are the diagnostic test of choice for syphilis. Simple flocculation type tests, such as the rapid plasma reagin (RPR) test, are widely used for screening of asymptomatic patients. Since the RPR antigen is cardiolipin, these tests are not specific for *Treponema pallidum* and false positive results are often encountered, especially in pregnant women, leading to over-treatment. Positive RPR results therefore need to be confirmed with a treponema-specific tests such as the TPPA. However, these confirmatory tests are technically demanding and not widely available in most developing country settings outside of reference laboratories. Simple, rapid, point-of-care type treponema-specific tests are now commercially available. These tests may be suitable for use in primary health care settings for the diagnosis of syphilis, but there is limited data on their performance characteristics. Evaluating the performance of these tests, their utility in a disease control programme and acceptability to patients and health care providers will improve the diagnosis of syphilis in primary health care settings in developing countries and reduce over-treatment.

There are over 20 rapid syphilis tests currently commercially available. Given the high cost of field trials, a triage step is necessary to select a limited number of the most promising tests for field trials. Hence the SDI rapid test evaluations will be carried out in two phases: 1) a laboratory-based evaluation of test performance and reliability using archived serum specimens from diverse geographic locations; 2) field trials of test performance, utility in disease control and prevention, and acceptability to patients and care providers. This protocol describes the evaluation process for the first phase only.

3. **STUDY PLAN**

3.1. General principles of diagnostic test evaluation

The evaluation will be conducted according to the following guiding principles:

1. A diagnostic test should be evaluated for a clearly defined indication
2. A diagnostic test should be evaluated using the methods and equipment fit for that purpose
3. Staff performing the evaluation should be qualified and competent to undertake the task and demonstrate that they can perform the test properly
4. There should be a regular independent assessment of the laboratory performing the evaluations on compliance with the principles and practice of Good Laboratory Practice and with well-defined quality assurance/quality control procedures

3.2. Tests under evaluation

At the first meeting of the ad hoc SDI expert working group for laboratory-based evaluations, it was agreed that the tests to be included in this evaluation should have the following operational characteristics:

1. Rapid -- test result is available in less than 15 min.
2. Simple-- test can be performed in a single or 2 steps, requiring minimal training and no equipment
3. Easy to interpret --card or strip format with visual readout

A letter was sent from SDI to companies that manufacture and/or sell tests that fit the above inclusion criteria, to inform them of the SDI rapid diagnostics evaluation scheme. Companies interested in participating in the evaluation were asked to donate tests for evaluation and to sign an agreement for the results of these evaluations to be published in a WHO report and made available to health departments of WHO member states.

To date, six companies have agreed to participate in the SDI evaluation:

1. Abbott Laboratories, USA
2. Diesse Diagnostica, Italy
3. Fujirebio Inc., Japan
4. Omega Diagnostics, Scotland
5. Qualpro Diagnostics, India
6. Standard Diagnostics, Korea

A table summarizing the characteristics of the tests is on the next page.

Table 1. RAPID SYPHILIS DIAGNOSTICS UNDER SDI EVALUATION

Name	Determine Syphilis TP	Syphilis Fast	Espline TP	Syphicheck- WB	SD BIOLINE Syphilis 3.0	VISITECT Syphilis
Company	Abbott Laboratories Abbott Park, USA	DIESESE Diagnostica Senese SpA, Milan, Italy	Fujirebio Inc. Tokyo, Japan	Qualpro Diagnostics Goa, India	Standard Diagnostics, Inc. Kyunggi-do, Korea	Omega Diagnostics Ltd. Scotland, UK
Assay type	Immuno- Chromatography	Latex particle agglutination	immuno- chromatography	Immuno- chromatography	immuno- chromatography	immuno- chromatography
Antigen	TpN47	TpN15, TpN17	TpN15-17, TpN47	TpN17, TpN47	TpN15, TpN17, TpN47	?
Solid phase	Membrane strip	Card	membrane strip in cassette	Membrane strip	membrane strip in cassette	membrane strip
Specimen type	Whole blood/plasma / serum	Serum	serum/plasma	whole blood/plasma / serum	whole blood/plasma / serum	whole blood/plasma / serum
Number of tests per kit	10 tests/card	50	10x5	10 or 25/pack	30	25
Shelf life	2 years at 2-30°C	18 months reagents stable for 6 months at 2-8°C after reconstitution	9 months at 2-10°C	18 months at 4-30°C	18 months at room temperature	4°- 30°C duration?
Volume of sample + volume diluent	50 µl serum/plasma or 50 µl whole blood + 1 drop chase buffer	20 µl serum + 40 µl latex	25 µl serum/plasma	25 µl serum/plasma or 50 µl whole blood + 2 drops of diluent buffer	10 µl serum/plasma or 20 µl whole blood + 3 drops of assay diluent	50 µl whole blood or 25 µl serum/plasma + 50 µl diluent
Supplies required but not provided	Micropipette and tips for 50 µl; lancets for finger prick assay; EDTA capillary tubes	None	micropipette and tips for 25 µl	lancets for finger prick assay	micropipette and tips for 10 µl and 20 µl; lancets for finger prick assay	lancets for finger prick assay
Results available for reading	5 min. to 24 hours	8 min.	15 min.	15 min.	5-20 min.	15 min.
Price/test (US\$)	<US\$2.00	not available	US\$3.30	US\$ 0.75/test	US\$ 0.55/test	not available

3.3. Study sites

A request for applications for laboratories interested in participating in the evaluation of rapid syphilis diagnostics was posted on the WHO/TDR web site and distributed through the SDI mailing list. Applicants were asked to respond to a questionnaire regarding laboratory capacity and experience with diagnostics evaluation. Laboratories with relevant experience, facility and capacity for test kit evaluations were asked to send a qualifying panel of 20 sera along with the corresponding test results to the SDI Reference Laboratories for validation. The syphilis reference laboratories at the U.S. Centers for Disease Control and Prevention (CDC) and the Public Health Laboratory Service (PHLS) in the United Kingdom have agreed to act as SDI Reference Centres.

Eight laboratories from diverse geographic locations were selected for the SDI network based on their proficiency at performing syphilis serology, access to populations of moderate to high disease prevalence, capacity and ability to carry out evaluations in a timely manner and links to field sites for evaluation. The SDI laboratory evaluation sites selected are as follows:

SDI funded sites for laboratory-based evaluations of rapid syphilis diagnostics:

Site location	Institution	Principal applicant
AFRO region: Durban, South Africa Fajara, Gambia Mwanza, Tanzania	University of Natal MRC Laboratories National Institute for Medical Research	W. Sturm B. West J. Changalucha
SEARO/WPRO region: Nanjing, China Colombo, Sri Lanka	National Center for STD and Leprosy Control National STD/AIDS Control Programme	Y.P. Yin S. Mananwatte
AMRO region: Port au Prince, Haiti Birmingham, USA	Les Centres GHESKIO (Groupe Haitien d'Etude du Sarcome de Kaposi et des Infections Opportunites) University of Alabama	J.W. Pape D. W. Fitzgerald E. Hook III
EURO region: Moscow, Russia	Central Institute for Skin and Venereal Diseases	A. Kubanova E. Filatova

3.4. Sources of Sera for Evaluation

Each laboratory site will assemble an evaluation panel from their collection of archived specimens as follows:

- 1) 50 TPPA positive specimens including:
 - 40 RPR+, TPPA+
 - 10 RPR-, TPPA+
- 2) 50 TPPA negatives specimens including:
 - 40 RPR-, TPPA-
 - 10 RPR+ TPPA-

3.5. Sample size calculations:

Each rapid test will be evaluated at 8 laboratories at diverse geographic locations using a locally assembled panel of 100 sera. For each test under evaluation, the use of 800 sera, of which 50% are positive, is an adequate sample size to determine the sensitivity and specificity of the test with a 95% confidence interval of $\pm 5\%$.

4. STUDY MANAGEMENT

4.1. Study team

The study team at each evaluation site shall consist of the principal applicant from each site, a technical supervisor and 2 technicians.

4.2. Responsibilities of study team members

The responsibilities of each member of the study team are as follows:

Principal applicant:

- participate in the development of the consensus evaluation protocol
- obtain ethical committee approval for the evaluation protocol and for the use of archived sera for the evaluation
- ensure the evaluation is conducted according to the consensus protocol as approved
- send data to SDI for collation with data from other sites
- participate in the overall analyses of the evaluation results

Technical supervisor:

- ensure all personal identifiers and data are unlinked from the serum specimens selected for rapid test evaluation
- ensure that both technicians are blinded to the reference test results for the evaluation panel by assigning the sera a study code (the sera should be numbered 1 to 100 with each number preceded by the two letters of the site

location e.g. the evaluation panel from the Durban site will be coded DU 1-100)

- supervise the pilot run and the performance of the rapid test evaluations
- ensure that the results of the rapid tests are read independently by technicians 1 and 2
- sign off the lab books of technicians 1 and 2 at the end of each day
- to collate the results from the two technicians and enter them into the Excel spreadsheet to be provided by SDI

Technician 1:

- perform rapid tests in accordance with manufacturers' directions
- record results in a laboratory record book
- place completed tests in a folder for technician 2 to read
- assess the operational characteristics of each rapid test according to the scheme provided

Technician 2:

- read results of rapid tests
- record results in a separate laboratory record book from that used by technician 1

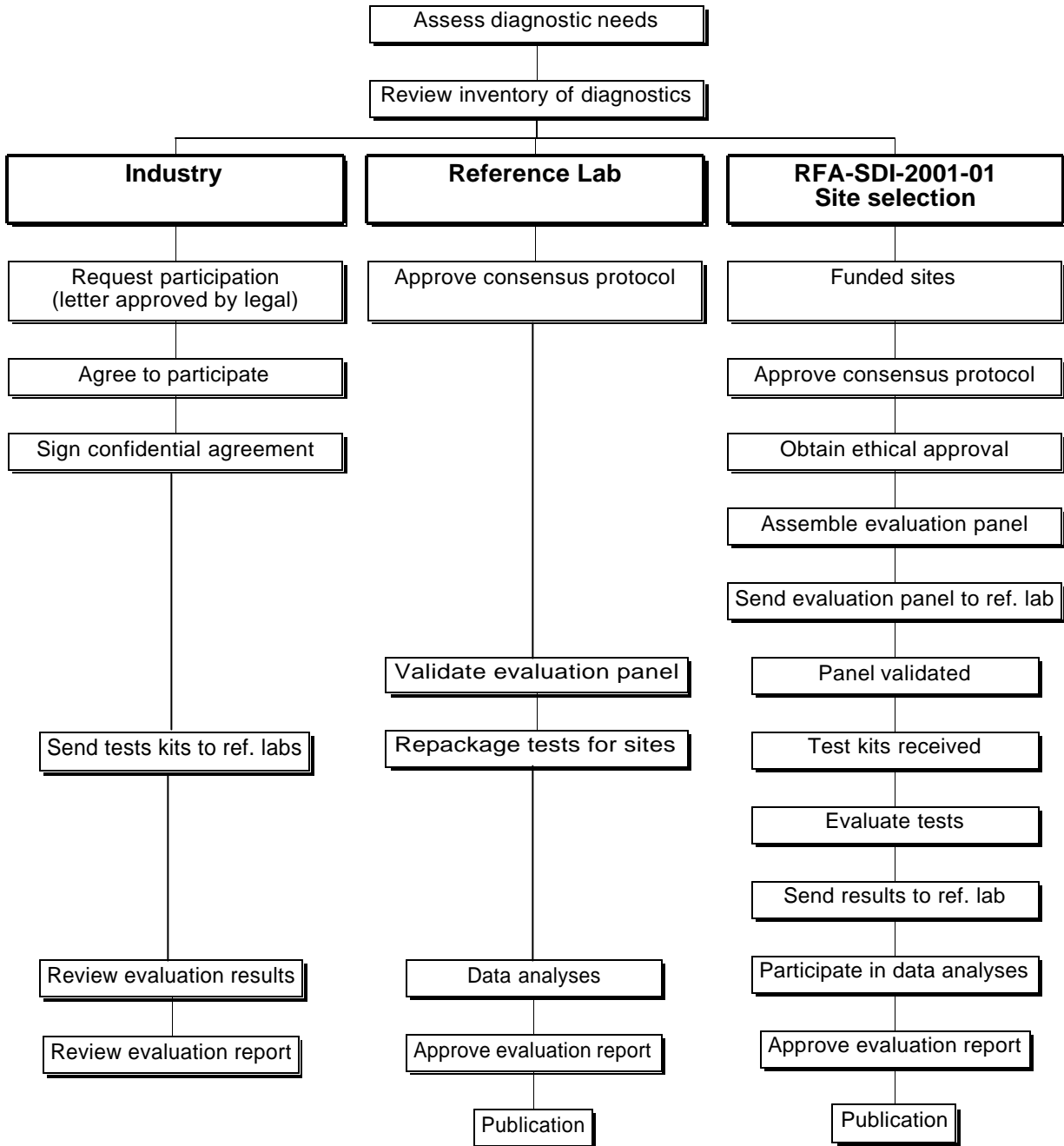
4.3. Management plan

SDI will coordinate the various components of the evaluation according to the plan as shown in Figure 1. Communications amongst sites and with reference laboratories are encouraged. Contact details for all the sites and the reference laboratories are contained in an appendix at the end of this manual. SDI will perform the data analyses in collaboration with the reference laboratories and send the results to the sites for comments and discussion before the selection process.

4.4. Trouble shooting

Sites encountering problems with the evaluation should contact Dr. Rosanna Peeling at SDI or Drs. Alan Herring at the PHLS, Bristol, UK and Ron Ballard at the CDC, Atlanta, USA.

Plans for the Laboratory-based Evaluation of Rapid Syphilis Diagnostics



5. STUDY SITE PREPARATION

5.1. Consensus protocol

All evaluation sites will use a single protocol for the evaluation although each site will assemble their own evaluation panel based on the characteristics described in section 3.4.

5.2. Ethical considerations:

Each evaluation sites must obtain institutional review board or ethics committee approval for performing the evaluations in accordance with this consensus evaluation protocol and for the use of unlinked archived sera in the evaluation panel. Each site should document, to the satisfaction of the local ethics committee, the mechanism whereby all personal identifiers and patient information are unlinked from the serum specimens so that the sera cannot be traced to individual patients. The letter of approval should contain the names and affiliation of all the members of the ethics committee and signed by the chair of the committee on behalf of the committee members.

5.3. Preparation and validation of evaluation panels:

Each site will assemble 100 sera according to the characteristics described in section 3.4. Each serum sample should be divided into two aliquots, one of which will be stored frozen on site and the other will be sent to the SDI Reference Centres for validation of test results obtained at the laboratory site.

5.4. Blinding to reference standard results

The laboratory supervisor at each site should ensure that the specimens are coded with the first 2 letters of the site location and numbered 1 to 100. He/she should ensure that all personal identifiers and data are unlinked from the serum specimens selected for rapid test evaluation. Both technicians should be blinded to the reference test results.

5.5. Piloting the study protocol

At each site, the technicians should perform each of the tests under evaluation with 2 positive and one negative sera from the evaluation panel under the supervision of the technical supervisor. The tests should be read by both technicians. If the results are invalid, the tests should be repeated with new devices. The supervisor and technicians should not proceed with the evaluation until they are confident regarding every aspect of the evaluation.

6. THE EVALUATIONS

6.1. Performing the rapid tests

6.1.1. General guidelines on the use of test kits:

1. Note lot number and expiry date: a kit should not be used beyond the expiry date

2. Ensure correct storage conditions: if a desiccant is included in the package, do not use the kit if the desiccant has changed colour.
3. If test kits are stored in the refrigerator, they should be brought to room temperature (about 30 minutes) before use. The use of cold test kits may lead to false negative results.
4. Damaged kits should be discarded.
5. Use test kits immediately after opening the package.
6. Reagents from one kit should not be used with those of another kit.
7. Test should be performed exactly as described in the product insert

6.1.2. Preparing serum samples for testing:

If a precipitate is visible, the serum should be clarified by centrifuging at 12,000g for 5 minutes prior to testing. Avoid using hemolysed blood samples.

6.1.3 Biosafety guidelines:

- Treat all specimens as potentially infectious
- Wear protective gloves and laboratory gown while handling specimens
- Do not eat drink or smoke in the laboratory
- Do not wear open toe footwear in the laboratory
- Clean up spills with appropriate disinfectants e.g. 1% bleach
- Decontaminate all materials with an appropriate disinfectant
- Dispose of all waste, including test kits in a biohazard container

6.1.4. Order of Testing:

For the evaluation of multiple test kits, to avoid comparison of results between kits, it is important that each kit should be evaluated with the entire panel of 100 sera before evaluating another test kit. The order in which the various kits are evaluated is left up to each site. The dates of each evaluation for each serum sample should be noted.

For each test kit, it is recommended that the evaluation should be conducted in batches of 25 sera each. The evaluation should be conducted with the entire panel of 100 sera before any repeat testing should be considered.

6.2. Standard Operating Procedures (SOPs)

6.2.1. SOPs for test kits under evaluation:

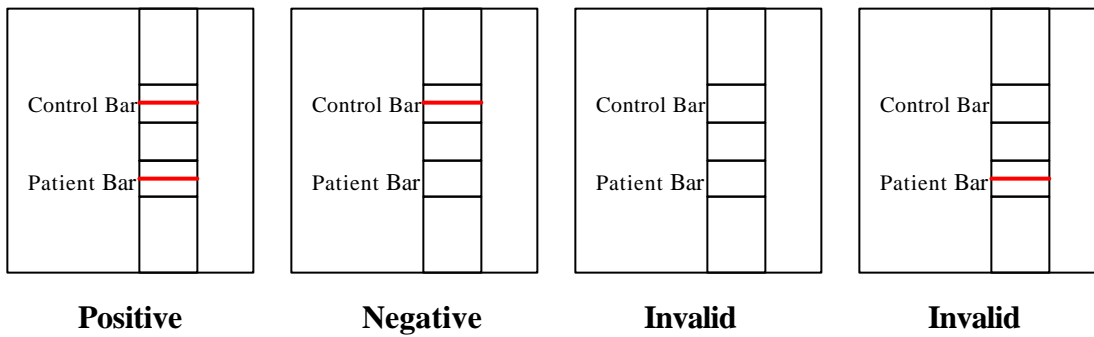
The following pages contain the SOPs for each of the tests. For any queries, please refer to the product insert for each test kit.

1. Abbott Laboratories: Determine Syphilis TP

Equipment required but not supplied: micropipette and tips, volume 50 µl

Standard Operating Procedure:

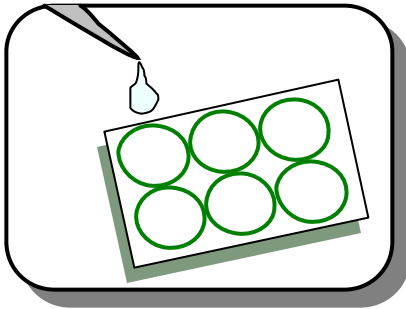
1. Remove the protective foil cover from each test
2. Using a micropipette, apply 50 µl of serum to the sample pad (marked by arrow symbol)
3. Wait a minimum of 15 minutes before reading the test result
4. Interpret test results as follows:



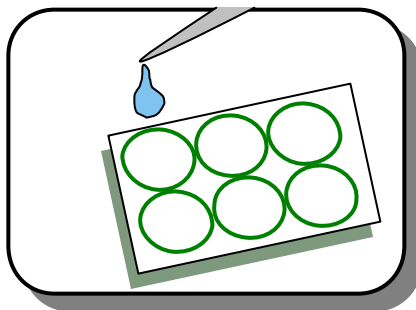
2. Dienes Diagnostica Syphilis Fast:

Equipment required but not supplied: micropipette and tips, volume 20 μ l, 40 μ l
automatic rotator (optional)

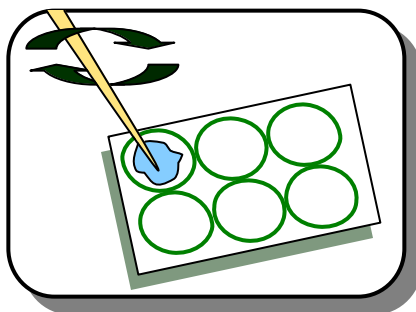
Standard Operating Procedure:



Place 40 μ l serum into a circle on the card.



Add 20 μ l coated latex (R1) into the same circle.

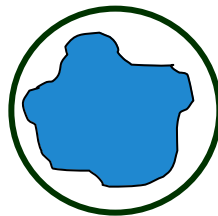


Mix with a stick and rotate for 8 minutes.

When using an automatic rotator, set at 100 rpm



negative



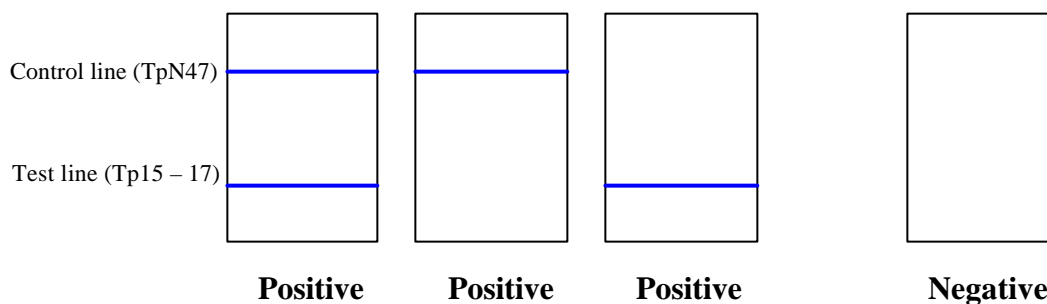
positive

3. Fujirebio Inc. Espline TP:

Equipment required but not supplied: micropipette and tips, volume 25 µl

Standard Operating Procedure:

1. Allow the test cassettes to warm up to room temperature in the aluminum pouch (30 minutes)
2. Remove the test cassette from the aluminum pouch
3. Using a micropipette, add 25 µl of serum to the sample window of the cassette
4. Quickly push on the protruding part of the cassette marked with 3 lines, to release the developing solution inside the cassette
5. Let the cassette stand in a horizontal position for 15 minutes
6. Interpret the results as follows:



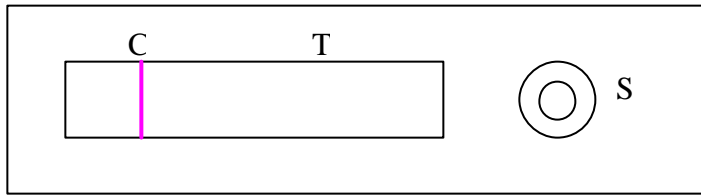
Note : Part of the blue test line may sometimes be missing. Please judge the test as positive in such a case.

4. Omega Diagnostics VISITECT Syphilis:

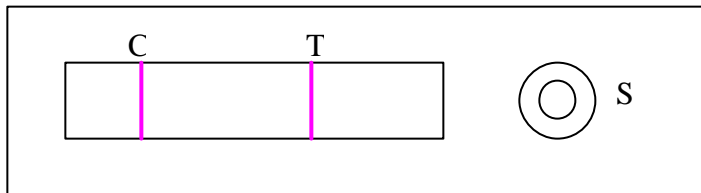
Equipment required but not supplied: none

Standard Operating Procedure:

1. Use dropper provided, dispense 1 drop of serum to sample well S
2. Add 2 drops of Diluent buffer from the buffer bottle to sample well S
3. Read results after 15 minutes



Negative: Appearance of only one pink to deep purple colored line at the control region "C".



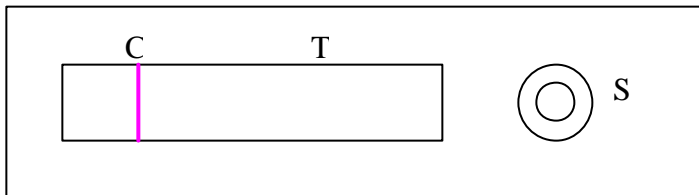
Positive: In addition to the control band, a distinct pink to deep purple colored line also appears on the test region "T".

5. Qualpro Diagnostics: Syphicheck-WB:

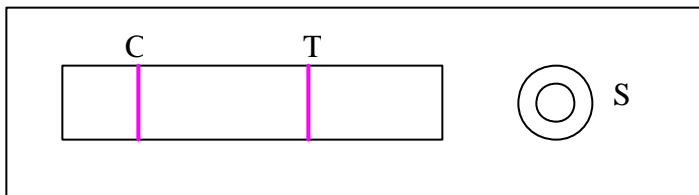
Equipment required but not supplied: none

Standard Operating Procedure:

1. Remove the test from the pouch and place on a flat surface
2. Using the dropper provided, add one drop of serum to the sample well S
3. Add 2 drops of diluent buffer from the diluent bottle to sample well S
4. Read the results in 15 minutes as follows:



Negative: Appearance of only one pink to deep purple colored line at the control region “C”.



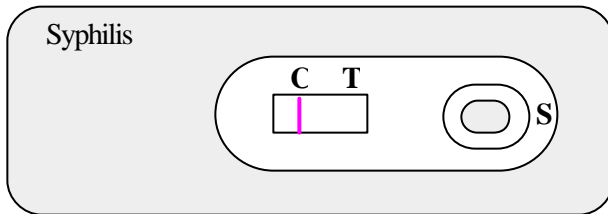
Positive: In addition to the control band, a distinct pink to deep purple colored line also appears on the test region “T”.

6. Standard SD Bioline Syphilis 3.0

Equipment required but not supplied: micropipette and tips, volume 10 μ l

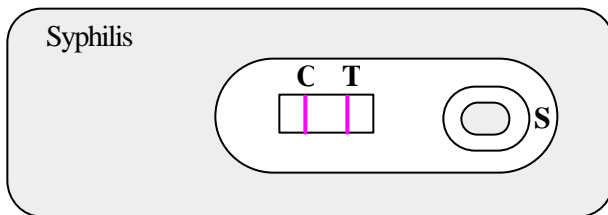
SOP:

1. Remove the test from the foil pouch and place on a flat dry surface
2. Slowly add 10 μ l of serum to the sample well
3. Add 3 drops of assay diluent to the sample well
4. Read the test at 5-20 minutes as follows:



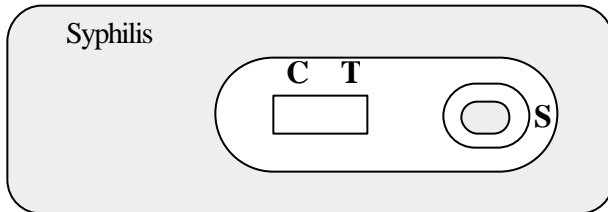
Negative result

The presence of only one band within the result window indicates a negative result



Positive result

The presence of two colour bands ("T" and "C") within the result window, no matter which band appears first, indicates a positive result for TP antibodies.



Invalid result

If the purple colour band is not visible within the result window after performing the test, the result is considered invalid.

6.2.2.. SOP for determining inter-observer variability

1. Each test should be performed and read by technician 1 according to the instructions described and record the results in a laboratory record book.
2. The test should then be mounted onto a numbered folder and handed to technician 2
3. Technician 2 will interpret the test result independently.
4. Technician 2 will record the results in a separate laboratory record book.
5. Technician 2 will read the test result again 1 hour after the first reading and record the results. At the conclusion of the evaluation, this result will be entered into the spreadsheet in the column, "designated time + 1 hr" in the laboratory data collection form.

6.2.3. Handling of indeterminate results

If the results are indeterminate, it should be recorded as such. The test may be repeated if there are sufficient test kits available after the evaluation.

6.2.4. Assessing operational characteristics:

Each rapid test will be assessed for the following operational characteristics by technician 1 after completing the testing of the first 25 specimens from the evaluation panel:

Clarity of kit instructions (maximum possible score of 3)

Technical complexity or ease of use (maximum possible score of 3)

Ease of interpretation of results (maximum possible score of 3)

In addition, a score of 1 will be given to the rapid tests that do not require any additional equipment or supplies.

The total possible score is 10. A score of 10 indicates that the test has operational characteristics that makes it very suitable for use in primary health care settings in resource-limited settings.

6.2.5. Performing test reproducibility (reference laboratories only)

The objectives of this type of testing are to answer the following questions:

1. Lot to lot reproducibility: will the test give the same results with tests of different manufacturing lots using the same specimens?
2. Operator reproducibility: will the test give the same results on the same specimen if it is performed by two different operators?
3. Run to run variability: will tests performed on the same specimen on different days give the same results? (this is a rapid test variation of the in-run and between-run precision for ELISA or other assays)

These 3 aspects of test reproducibility should be determined using 100 replications as follows:

1. Lot-to-lot reproducibility: 25 serum specimens to be run on 2 lots of each rapid test
2. Operator reproducibility: 2 technicians each performing the test using the same 10 specimens
3. Run to run reproducibility: 6 serum specimens to be tested on 5 successive days for each rapid test

6.3. Quality Assurance

All the laboratory sites have already shown their proficiency at performing standard reference tests for syphilis by scoring 90% or better on their qualifying panel of 20 sera. The RPR and TPPA results for the sera in each of the evaluation panel will be validated by one of the SDI reference centres.

The laboratory notebook for each technician should be signed off by the supervisor at the end of each day. The data entry into the spreadsheet should be double-checked against the notebooks from both Technician 1 and 2.

7. Evaluation data

7.1. Data entry

The evaluation results will be recorded in the laboratory note books of technicians 1 and 2. The results will be entered into the Laboratory Data Collection Form provided as an Excel spreadsheet SDI. If a test is repeated for any reason, all results should be entered into the spreadsheet and the reason for repeating noted.

The scoring scheme for the operational characteristics of each rapid test should be filled out by technician 1 and entered in the Excel file provided by SDI. Examples of the Laboratory Data Collection Form and the scoring scheme for the evaluation of operational characteristics are attached in Appendix 2.

All laboratory notebooks and electronic records of study data should be kept until the conclusion of the study.

7.2. Data analysis

The reference or "gold" standard is the TPPA or TPHA results previously obtained for each serum specimen at each site, validated by the reference centres.

Quantitative determinations for each test at each site:

1. The sensitivity, specificity for each rapid test compared to the validated reference test results obtained at each site will be calculated as follows:

		Reference test results		
		+	-	
Rapid test results	+	A	b	a+b
	-	C	d	c+d
		a+c	b+d	

Rapid test sensitivity = $a/(a+c)$

Rapid test specificity = $d/(b+d)$

The sensitivity and specificity will be calculated as percentages from the data submitted and adjusted to a total score out of 80.

There will be no discrepant analyses.

Inter-observer variability is calculated as the number of tests for which different results are obtained by 2 independent different readers, divided by the number of specimens tested. This data will be used as supplemental data in the final selection of tests for field trials and will not be part of the score.

2. Test reproducibility: since the test results are qualitative, the % false positives and % false negative results can be used as a measure of precision instead of deviation from a numeric value.

$$\% \text{ false positive} = \# \text{ false positive results} \times 100 / \text{total \# known negative results}$$

$$\% \text{ false negative} = \# \text{ false negative results} \times 100 / \text{total known positive results}$$

The score will be adjusted to a total score of 10.

Qualitative determinations at each site:

The suitability of the rapid test for use in primary health care settings in developing countries will be assessed qualitatively based on the operational characteristics as described in Appendix 2. The score will be based on a total of 10.

8. CRITERIA FOR TEST SELECTION FOR FIELD TRIALS

8.1. Scoring scheme

Each test kit will receive numeric scores based on the data from each site. The final score will be the mean of scores from all the sites. The total score will be 100, weighted as follows:

1. A maximum score of 80 for test performance based on test sensitivity and specificity
2. A maximum score of 10 for test reproducibility
3. A maximum score of 10 for operational characteristics

The tests will be ranked based on these scores. If there are wide discrepancy between sites on a particular test kit, additional testing at the reference laboratories will be considered.

9. PUBLICATION OF RESULTS

9.1. Preparation of evaluation report

Results from this evaluation will be published in a WHO report for member states and made available on the WHO/TDR and SDI web sites:

www.who/tdr

www.who.int/STD-diagnostics

Manufacturers of rapid test kits will be sent a courtesy draft of the report before publication. They will be able to raise points of discussion with SDI, the reference centres and the evaluation sites but will not be in a position to modify conclusions in accordance with the terms of the Confidentiality Agreement they signed with WHO.

9.2. Ownership of evaluation data

Each site signed a Technical Services Agreement with WHO. The evaluation data is jointly owned by WHO and the site.

Appendix 1

Contact details for SDI funded sites

And reference laboratories

Contact details for SDI funded sites

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Appendix 2

Laboratory Data Collection Form

**Evaluation of Operational Characteristics
of Rapid Syphilis Tests**