Fanttest®

ARTG ID: XXXXXX

At-Home Syphilis Self Test Cassette Kit Instruction for Use

PATIENT INFORMATION

This section outlines key health advice for syphilis testing and prevention. Read carefully before use.

1. Safe Sex & Regular Testing

·Safe sex practices are recommended, especially during pregnancy, to lower STI risk.

·Individuals with high-risk behaviors (e.g., unprotected sex) must complete regular screening for other STIs and blood-borne viruses (e.g., HIV, hepatitis B/C).

2. Pregnancy-Related Syphilis Risks

·Maternal syphilis poses health risks to the pregnant person and may cause congenital syphilis in the fetus, leading to severe birth defects.

·Pregnant individuals with a positive syphilis test or suspected exposure must seek immediate medical advice for diagnosis and treatment.

3. Window period

Definition of Window Period: The period after infection with Treponema pallidum (the syphilis-causing bacterium) during which the body has not yet produced sufficient detectable antibodies to be identified by this kit. Testing during this period may yield a negative result even if syphilis is present.

INTENDED USE

The At-Home Syphilis Self Test Cassette Kit is a qualitative rapid membrane immunochromatographic assay for the detection of Treponema Pallidum (syphilis) antibodies in human fingerstick blood.

The test is intended for the patient population whom individuals with symptoms or other epidemiological reasons to suspect a syphilis infection as an aid for presumptive screening.

SUMMARY

Treponema Pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and acytoplasmic membrane. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 10 days to 3 weeks after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

PRINCIPLE

The product adopts the principle of double antigen sandwich. When the sample contains Treponema pallidum antibody, the Treponema pallidum antibody in the sample reacts with the colloidal gold-labeled antigen (Treponema pallidum recombinant antigen 1)on the conjugate pad to form a labeled antigen-antibody complex, and the complex is chromatographed upward through capillary action, is captured by the detection line (T) antigen (Treponema pallidum recombinant antigen 2) coated on nitrocellulose membrane, and a red band appears. The complex continues to be chromatographed upward, and the rabbit IgG in the colloidal gold marker is captured by the control line (C) antibody (goat anti-rabbit IgG antibody) coated on the nitrocellulose membrane, and a red band appears. When the content of the analyte in the sample is lower than the analytical sensitivity, the detection line (T) does not develop color.

STORAGE CONDITIONS & VALIDITY

Storage conditions: The original packaging should be stored in a dry place at 2-30℃ protected from light, and do not freeze.

Validity period: 24 months.

The expiry date of the product can be viewed on the product labelling.

WARNINGS AND PRECAUTIONS

1. False negative results may arise if syphilis testing is performed within the window period.
2. The product is for single-use. If the aluminum foil bag is found to be damaged, please do not use it. All samples and post-use products should be treated as infectious agents and properly disposed of in accordance with local relevant regulations.
3. Since this product is for visual interpretation, in order to ensure accurate results, please do not interpret in dim light.
4. There is a desiccant in the aluminum foil bag, which should not be taken orally; the sample diluent should not be taken orally.
5. The sample diluent contains a small amount of preservatives, which may cause irritation to skin and eyes. If this solution comes into contact with skin or eyes, wash/rinse with plenty of water. If skin irritation or rash occurs, seek medical advice/attention.
6. Please judge the result within the specified reading time. Too early or too late may produce invalid results.
7. Please read the instructions carefully before operation. Too much or too little sample may produce invalid results.
8. If a negative syphilis result is obtained within three months of a high-risk event, testing should be repeated at three months to confirm the initial negative result.
9. Pregnant women undergoing syphilis testing should seek immediate medical advice if syphilis infection is suspected or exposure to syphilis has occurred; this test kit cannot replace routine prenatal care or professional syphilis testing during pregnancy.
10. A positive test result does not necessarily indicate that the individual is infectious; infectious status must be evaluated by a healthcare professional combining clinical symptoms and additional examinations.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. This product is only used for in vitro qualitative diagnosis.
2. Results of testing with the At-Home Syphilis Self Test Cassette Kit will likely be positive for individuals previously diagnosed with syphilis, even if they were successfully treated. The kit cannot determine whether there has been re-infection with syphilis, and testing must be performed by a healthcare provider to detect syphilis re-infection.
3. The test result (positive or negative) does not rule out the possibility of co-infection with other pathogens, nor does a negative result exclude the possibility of syphilis infection.
4. The At-Home Syphilis Self Test Cassette Kit is not intended to replace visits to a healthcare provider. The result obtained with this test should not be used to start, stop, or change any course of treatment unless advised by a healthcare provider.
5. The kit is for fingerstick blood only. Anti-Epstein Barr Virus (EBV) and Rheumatoid Factor positive (RF+) showed cross reactivity with 1 out of 10 samples.
6. This kit is a reagent for qualitative screening of Treponema pallidum antibodies, and the specific concentration of Treponema pallidum antibodies in samples cannot be determined.
7. Not for use in screening donated blood and tissue for syphilis.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The WHO 1st International Standard for human syphilitic plasma IgG (NIBSC 05/122) was tested with the At-Home Syphilis Self Test Cassette Kit. The LoD was determined to be 1mIU/mL.

Analytical Specificity (Cross reactivity)

The cross reactivity of the At-Home Syphilis Self Test Cassette Kit was tested with different cross reactants in ten samples.

There results of the study show 0% reactivity for all cross reactants except for one each at 10% reactivity for acute Epstein-Barr virus (IgM). Results are summarized below:

Cross-Reactivity	Number of positive	Percent cross-reactivity
hepatitis B infection	0/10	0%
hepatitis C infection	0/10	0%
acute hepatitis A infection	0/10	0%
acute cytomegalovirus (IgM)	0/10	0%
acute Epstein-Barr virus (IgM)	1/10	10%
malaria	0/10	0%
visceral leishmaniasis	0/10	0%
tuberculosis	0/10	0%
brucellosis	0/10	0%
leptospirosis	0/10	0%
leprosy	0/10	0%
Herpes simplex virus type 2	0/10	0%
Chlamydia trachomatis	0/10	0%
human papillomavirus	0/10	0%
trichomoniasis	0/10	0%
Lyme disease	0/10	0%
Leptospira	0/10	0%
Tannerella forsythia	0/10	0%
influenza vaccines recipient	0/10	0%
vaccine-induced HIV seropositivity	0/10	0%

Analytical Specificity (Endogenous interferences)

To evaluate the effect of elevated levels of various endogenous substances on the At-Home Syphilis Self Test Cassette Kit, samples were spiked with the following levels of endogenous interferences and assayed at two syphilis antibody levels: negative and weak positive. No interference was observed at the following tested concentrations:

Endogenous Interference	Concentration
Hemoglobin	1.1 mg/dL
Hyperglobulinaemia	2000 mg/dL
Cholesterol	200 mg/dL
triglycerides	500 mg/dL
bilirubin	40 mg/dL

To evaluate the effect of various autoimmune conditions, pregnancy, heterophilic antibodies and vaccination on At-Home Syphilis Self Test Cassette Kit performance, negative sample and spiked with syphilis antibodies to a weak positive were tested. The results are presented in the following table and no interference was observed for each condition except for one each at 10% reactivity for rheumatoid factor.

Endogenous Interference	Negative			Weak Positive		
	N	Fanttest Positive	Fanttest Negative	N	Fanttest Positive	Fanttest Negative
Heterophilic antibodies	10	0	10	10	10	0
Human anti-mouse antibodies	10	0	10	10	10	0
systemic lupus erythematosus	10	0	10	10	10	0
anti-nuclear antibodies	10	0	10	10	10	0
rheumatoid factor	10	1	9	10	10	0
Flu Vaccine Specimen	10	0	10	10	10	0
Pregnancy (1st Trimester)	10	0	10	10	10	0
Pregnancy (2nd Trimester)	10	0	10	10	10	0
Pregnancy (3rd Trimester)	10	0	10	10	10	0
Multiparous Pregnancy	10	0	10	10	10	0
Sickle-cell disease	10	0	10	10	10	0
Thyroiditis	10	0	10	10	10	0

Analytical Specificity (Exogenous interferences)

A drug interference study was performed with fifteen common therapeutic drugs representing common over the-counter, anti-inflammatory drugs and anti-bacterial and anti-viral drugs. Each drug was spiked into the samples at two syphilis antibody levels: negative and weak positive. No interference was observed at the following tested concentrations:

Exogenous Interference	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ampicillin	7.5 mg/dL
Cefoxitine	660 mg/dL
Chloroquine	7.5 ug/dL
Doxycycline	1.8 mg/dL
Entecavir	2.4 ug/dL
Isoniazid	6m g/dL
Mefloquine	1m g/dL
Metronidazole	12 mg/dL

Exogenous Interference	Concentration
Rifampicin	4.8 mg/dL
Quinine	5.4 mg/dL
Ribavirin	1.1 mg/dL
Ritonavir	4.4 mg/dL
Valganciclovir Hydrochloride	2 mg/dL
Ascorbic Acid	2g /dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Oxalic Acid	600 mg/dL

COMMON QUESTION & ANSWERS

1. What puts me at risk for syphilis?

Risk of syphilis results from unprotected sexual contact with one or multiple partners who is/are currently infected with syphilis. It is possible for a person to be infected with syphilis without having symptoms (i.e.; "asymptomatic") and still transmit the infection to another.

2. How can I protect myself from being infected with syphilis?

If you are sexually active, doing the following can lower your chances of getting syphilis: (1) being ina long-term, mutually monogamous relationship witha partner who has been tested and has negative STD test results, or (2) using latex condoms the right way every time you have sex.

3. When should I test for syphilis?

If you're sexually active and have symptoms or have had unprotected sex, you should get tested.

4. How soon after a risk event can I test myself ?

Most people develop antibodies between 10 days and 3 weeks after symptoms appear.

5. How accurate is the test?

A clinical evaluation and usability evaluation were conducted comparing the results obtained using the At-Home Syphilis Self Test Cassette Kit to fourth generation enzyme immunoassay (EIA).

In the clinical evaluation:

Disease Stages	Sensitivity
Primary	95.63%(153/160)
Secondary	100%(156/156)
Tertiary	100%(51/51)
Early Latent	100%(50/50)
Late Latent	100%(54/54)

The sensitivity of this test has been calculated to be 98.51% (464/471).

The specificity of this test has been calculated to be 99.40% (497/500).

In the usability evaluation:

The sensitivity of this test has been calculated to be 98.72% (77/78).

The specificity of this test has been calculated to be 100% (80/80).

6.When should I retest?

If you still think you have syphilis after a negative result, you can test again 10 days after symptoms show or 90 days after you were sexually active with someone that you believe had syphilis.u were sexually active with someone that you believe had syphilis.

MEDICAL DEVICE INCIDENT REPORT

You can contact the TGA to report performance or usability issues via the Users Medical Device Incident Report, email iris@health.gov.au or call 1800809361.

INDEX OF SYMBOLS

	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Keep away from sunlight
2℃-30℃	Store between 2-30°C		Keep dry
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
LOT	Batch code		Manufacturer
	Contains sufficient for <n> tests	REF	Catalogue number

SUPPORTSERVICES

ACT Canberra Sexual Health Centre.
Phone:(02)5124 2184
Website: www.health.act.gov.au/cshc

NSW Phone:1800 451624
Website: www.shil.nsw.gov.au

NT Clinic 34
Phone: 08 8999 2678- Darwin
Website: https://nt.gov.au/welbeing/hospital-health-services/clinic-34

QLD Queensland Health
Phone: 13HEALTH (13 43 25 84)
Website: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/sex-health

SA Shine SA
Phone: 1300794 584
Website: www.shinesa.org.au

VIC Sexual Health Victoria
Phone:1800 013 952
Website: www.shvic.org.au

TAS Sexual Health Service Tasmania
Phone:(03) 6166 2672 Hobart
Website: https://www.health.tas.gov.au/health-topics/sexual-and-reproductive-health/sexual-health-services

WA Could I have it?
Phone:1800 022222
Website:www.couldihaveit.com.au

For general health advice,
Health Direct is available 24 hours a day.
Phone:1800022222

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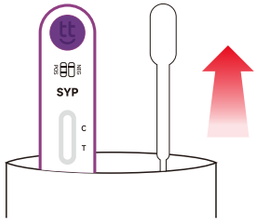
Version No.: 1.0

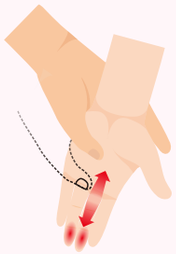
PREPARATION

Wash hands in warm water and dry.
Rub your hands together.



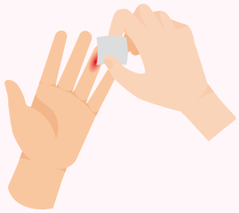
Tear open the aluminum foil bag

01



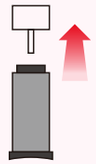
Massage and rub your hand & finger to increase circulation.

02



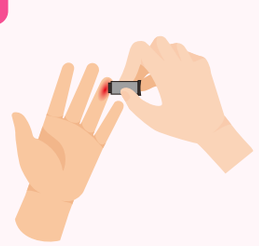
Clean your finger with Alcohol Pad.

03



Remove the lancet cover.

04

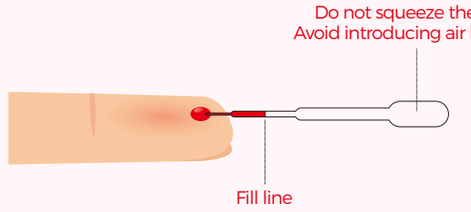


Press the lancet against the finger until it click.

05

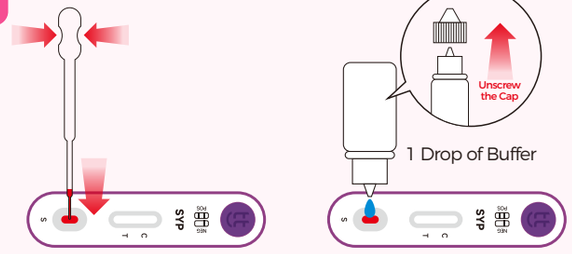
Wipe away the first blood.
Rub the hand from base to finger and form a round shape of blood over the puncture site.

06



Without squeezing the capillary dropper bulb, bring it into contact with the blood. The blood will automatically migrate into the capillary dropper up to the indicated line. If the blood does not reach the line, gently massage your finger again to produce more blood.

07

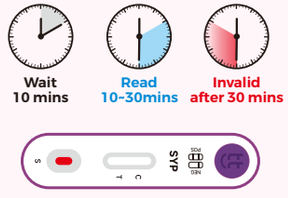


Wait for the blood to be totally dispensed in the well.
Add 1 drop of buffer into the sample well (S) of the cassette.

08

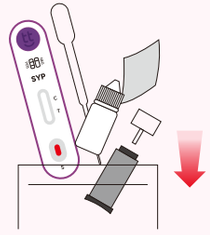
Put on a bandage.

09



Wait for the colored line(s) to appear.
Read the results whthin 10 minutes.
Do not interpret the result after 30 minutes.

10



After test is completed, place all the components of the test kit in plastic Biosafety Bag and dispose according to local regulation.

Scan the QR code or visit our website for instructional video, product information and IFU:
https://www.biotop6.com/fanttest-at-home-syphilis-self-test-cassette-kit/

Customer Support help line: 02 7908 9566
Customer Service hours: 9 AM ~ 8 PM, 7 Days. ~ UTC+10

POSITIVE

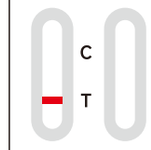
Positive: Colored brand appear in both the detection line (T) and the control line (C). The results show that the sample contains syphilis antibodies.

Individuals who receive a positive result must consult a medical practitioner for confirmatory testing via a laboratory test, and to receive appropriate clinical advice regarding treatment. If you are unable to see a doctor, contact your local health department. Avoid sexual contact with others until after you have spoken with a doctor.
You should notify anyone you have had sexual contact with in the last 90 days (3 months) if you receive a positive test result or before your symptoms began. If you have not had sex in the last 90 days, notify your most recent partner.

NEGATIVE

Negative: There is no colored band in the detection line (T), and a red band appears in the control line (C). The results show that syphilis antibodies are not detected in the sample.

See your healthcare provider if you still have symptoms. It is possible you tested too early or have a different sexually transmitted infection.



INVALID

Invalid: If no control(C)line appears, regardless of whether there is a colored band in the detection line (T), the test is judged to be invalid.

If you get an invalid result, please call our toll-free number at 02 7908 9566.

MATERIALS PROVIDED

Component \ REF	ISY-402-A010	ISY-402-A020
	1 Test	2 Tests
1. Test Cassette	x1	x2
2. Buffer	x1	x1
3. Sterile Lancet	x2	x4
4. Alcohol Pad	x2	x4
5. Capillary Dropper	x1	x2
6. Bandage	x1	x2
7. Biosafety Bag	x1	x2
8. Instruction for Use	x1	x1

Each test requires the following material:
1. Test cassette: Individually packaged in a foil pouch with a desiccant and capillary dropper.
2. Buffer: A bottle that contains buffer solution, a phosphate buffer solution used for aiding the sample across the cassette.
3. Sterile lancet: For pricking the patient's finger to allow for fingerstick sample collection.
4. Alcohol pad: For disinfection of the patient's finger prior to pricking.
5. Capillary dropper: For collection and dispensing of a fingerstick sample into the Sample well of the cassette.
6. Bandage: For hemostasis, wound protection and infection prophylaxis.
7. Biosafety bag: For collection of components pre- or post-test kit use.
Note 1: The components in the kits of different batch numbers are not interchangeable.
Note 2: Timer and Tissue need to be prepared by the users.