Trinity Biotech

CAPTIA™ Syphilis (T. Pallidum)-G

REF	800-970	96 Tests
REF	800-960	960 Tests

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków
Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

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INTENDED USE

CAPTIA™ Syphilis (*T. pallidum*)-G is an enzyme immunoassay for the qualitative detection of IgG antibodies to *T. pallidum* in serum specimens, to be used in conjunction with non-treponemal testing to provide serological evidence of infection with *T. pallidum* (the agent of syphilis)

CAPTIA™ Syphilis *(T. pallidum)*-G is also intended for testing of serum or plasma specimens to screen blood and/or plasma donors to exclude a history of syphilis.
For *in vitro* Diagnostic Use Only
For Professional Use Only

Warning: A positive result is not useful for establishing a diagnosis of syphilis. In most situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of syphilis except for incubating or early primary disease.

INTRODUCTION

Syphilis is a disease, usually sexually transmitted, caused by infection with the spirochete *Treponema pallidum (T.pallidum)*. Infection is systemic from the outset and the disease is characterized by periods of latency, often in excess of twenty years. These features, together with the fact that *T. pallidum* cannot be isolated in culture mean that serological techniques play a major role in the diagnosis of syphilis and treatment follow-up.[1]

The procedures most commonly used to screen for antibodies to *T. pallidum* in clinical diagnostic laboratories are based upon their reaction with non-treponemal lipoidal antigens (the reagin tests). Reagin tests, such as the RPR or VDRL, can be used to test serial dilutions of the serum specimen. The end point values from sequentially obtained serum samples decline following successful treatment until after a period of several months the patient will usually become reagin test non-reactive.

Clinical diagnostic serum specimens which are reactive in reagin tests are typically confirmed using treponemal tests such as the Microhaemagglutination-*T. pallidum* (MHA-TP) or the Fluorescent Treponemal Antibody-Absorption (FTA-ABS) test. In contrast to the non-treponemal tests, treponemal test reactivity will persist following treatment in approximately 85% of the cases often for the life of the patient.[2] Any sera giving reactive or equivocal results on initial treponemal based assays must be supplemented with a quantitative non-treponemal test (such as RPR or VDRL) to distinguish from active disease and assist in ruling out false positives.

Donors of blood and/or plasma for transfusion are screened for *T. pallidum* antibodies using either reagin or treponemal tests. The detection of *T. pallidum* antibodies is used to help identify donors who present an increased risk of transmitting blood-borne infections.

CAPTIA™ Syphilis-G is a treponemal test for *T. pallidum* IgG class antibodies.[3,4] The enzyme immunoassay format allows use of a microplate reader which eliminates subjective interpretation of results and the test procedure can be automated for high-volume testing.

PRINCIPLE OF THE ASSAY

Microtitration wells coated with *T. pallidum* antigens are exposed to test specimens which may contain specific antibodies. After an incubation period, unbound components in the test sample are washed away. Specifically-bound IgG reacts with a conjugated horseradish peroxidase (HRP) monoclonal antibody (mAb) during a second incubation period. Following a second wash cycle, specifically-bound enzyme conjugate is detected by reaction with TMB (tetramethylbenzidine). The enzymatic reaction is stopped using 1 N Sulfuric acid. The assay is measured spectro-photometrically to indicate the presence or absence of IgG treponemal antibodies.

KIT PRESENTATION

MATERIALS SUPPLIED

CAPTIA™ Syphilis-G reagents supplied in this pack are for *in vitro* diagnostic use only.

1. Coated microwell strips. Plastic microtitration wells coated with whole-cell sonicated *T. pallidum* antigens, strain Nichols. (96T: one plate; 960T: ten plates)
2. High titre reactive control (HTR): containing human serum diluted in buffer containing <0.1% sodium azide as preservative. (96T: one bottle, 1.5 mL; 960T: two bottles, 1.5 mL each)
3. Low Titre reactive control (LTR): containing human serum diluted in buffer containing <0.1% sodium azide as preservative. (96T: two bottles, 1.8 mL each; 960T: four bottles, 1.8 mL each)
4. Non-reactive control (N): containing human serum diluted in buffer containing <0.1% sodium azide as preservative. (96T: one bottle, 1.5 mL; 960T: two bottles, 1.5 mL each)
5. Conjugate. HRP labeled mAb in buffer containing 0.01% bromonitrodioxane as preservative (96T: one bottle, 20 mL; 960T: five bottles, 20 mL each)
6. CAPTIA™ Wash Buffer (conc.x 20). Phosphate buffered saline pH 7.0-7.2, containing 0.05% Tween 20. (96T: one bottle, 100 mL; 960T: two bottles, 500 mL each)
7. CAPTIA™ Sample Diluent. Phosphate buffered saline, pH 7.0-7.2, containing protein stabilizer, 0.05% Tween 20 and < 0.1% ProClin 300 as a preservative (96T: one bottle, 115 mL; 960T: two bottles, 500 mL each)
8. CAPTIA™ Substrate Solution: Ready to use. Slight blue coloration. Tetramethylbenzidine (≤ 0.1%TMB) pH 3.7-3.9. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells. (96T: one bottle, 15 mL; 960T: ten bottles, 15 mL each)
9. Plate Sealers

ADDITIONAL REQUIREMENTS FOR MANUAL PROCESSING

- 1N (0.5M) Sulfuric acid. Add 2.77 mL concentrated H_2SO_4 (18M/36N) to 97.23 mL distilled or deionized water. Mix well.
- Disposable tip micropipettes to deliver 5 µL, 10 µL, 25 µL, 100 µL and 200 µL (multichannel pipette preferred for dispensing reagents into microtiter plates).
- Distilled or deionized water.
- 37°C incubator.
- Disposable tubes of approximately 1.0 mL capacity, for performing specimen dilutions. Types which can be racked in a configuration compatible with Microtitration plates are recommended.
- Clean, disposable glass/plastic test tubes approximate capacities 5 mL and 10 mL.
- Range of standard, clean volumetric laboratory glassware consisting of, at least, 15 mL and 100 mL beakers, 1 mL, 5 mL, and 10 mL glass pipettes.
- Absorbent paper towels.
- Automatic microtitration plate washer or laboratory wash bottle.
- Microtitration plate reader with 450 nm filter.
- Latex gloves, safety glasses and other appropriate protective garments.
- Biohazard infectious waste containers.
- Safety pipetting devices for 1 mL or larger pipettes.
- Timer.
- Plate Shaker.
- Vacuum line with trap.

AUTOMATIC, OR SEMI-AUTOMATIC PROCESSING

CAPTIA™ Syphilis-G may be used with a variety of automatic or semi-automatic processors/liquid handling systems. It is essential that any such system is qualified, before it is used routinely, by demonstrating that the CAPTIA™ Syphilis-G results obtained using the automatic processor are equivalent to those obtained for the same specimens using the manual test method. Subsequently the automatic processor should be periodically requalified by the end user.

STORAGE AND STABILITY

All reagents should be stored at 2-8°C and should not be used beyond the expiration date on the label. Once opened, microtitration strips may be stored at 2-8°C until the expiration date on the label, provided that desiccated conditions are maintained. Unused strips should be returned to their original foil pouch along with the sachet of desiccant. Opened pouches should be securely resealed by folding over the open end and securing it with adhesive tape.

Microwell strips not needed for the assay may be returned to the plate pouch and sealed, and then used at a later time. Strips from different plates can only be mixed to assemble full or partial plates if they are from the same plate lot and have come from plates that have previously been tested with kit controls and yielded valid runs. When assembling a plate that contains strips from a newly opened, previously untested plate, one of these strips should be placed at the beginning of the plate and tested with the kit controls.

The concentrated CAPTIA™ Wash Buffer contains no preservatives and, therefore, working-strength Wash Buffer should not be stored for longer than 4 weeks at 2-8°C. It is recommended that Wash Buffer be freshly diluted before each assay. If the working strength buffer becomes visibly cloudy or develops precipitate during the 4 weeks, do not use it.

Indications of Deterioration

CAPTIA™ Syphilis-G may be considered to have deteriorated if:

1. The kit fails to meet the required criteria for a valid test (see **INTERPRETATION).**
2. Reagents becoming visibly cloudy or develop precipitate. Note: Concentrated wash buffer, when cold, normally develops crystalline precipitates which redissolve on heating at 37°C.
3. The CAPTIA™ Substrate Solution is blue. This is likely to be caused by chemical contamination of the CAPTIA™ Substrate Solution or the container**. Please note Substrate Solution** when supplied has a slight blue coloration.

WARNING AND PRECAUTIONS

SAFETY

For *In Vitro* Diagnostic Use Only. For Professional Use Only

The control sera in this kit contain < 0.1% sodium azide as preservative. Sodium azide can react with lead and copper plumbing to form potentially explosive metal azides. Upon disposal, flush with a large volume of water to prevent azide build-up.

Caution: All blood products should be treated as potentially infectious. Source material from which kit control sera were derived was found negative when tested in accordance with current FDA recommendations. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The *Treponema pallidum* antigen has been inactivated during the production processes. Nevertheless, treponemal antigen-coated microtitration wells should be handled using the normal precautions accorded to potentially infectious material.

Sulfuric acid is corrosive. Avoid contact with skin and eyes. If splashing onto skin or eyes occurs, rinse the affected area with copious quantities of water and seek medical attention.

PROCEDURAL

1. This kit should be used in strict accordance with the instructions in the Package Insert

2. CAPTIA™ enzyme immunoassay kits contain reagent systems which are optimized and balanced for each kit lot. Do not interchange reagents from kits with different lot numbers. Do not interchange vial caps or stoppers either within or between kits.
3. Do not use CAPTIA™ Syphilis-G kits after the expiration date printed on the outer carton label.
4. Do not cross-contaminate reagents. Always use fresh pipette tips when drawing from stock reagent bottles.
5. Always use clean, preferably disposable, glassware for all reagent preparation.
6. Allow foil to warm to room temperature before opening. This avoids condensation on the inner surface of the bag which may contribute to a deterioration of coated strips intended for future use.
7. Reagents should be dispensed with the tip of the micropipette touching the side of the well at a point about mid-section. Follow manufacturer's recommendations for automatic processors.
8. Always keep the upper surface of the microtitration strips free from excess fluid droplets. Reagents and buffer overspill should be blotted dry on completion of the manipulation.
9. Do not allow the wells to completely dry during an assay.
10. Disposal or decontamination of fluid in the waste reservoir from either the plate washer or trap for vacuum line in the manual system should be in accordance with guidelines set forth in the Department of Labor, Occupational Safety and Health Administration, occupational exposure to blood-borne pathogens; final rule (29 CFR 1910,1030) FEDERAL REGISTER, pp 64176-84177,12/6/91.
11. Automatic or semi-automatic EIA processors or liquid handling systems should be qualified specifically for use with CAPTIA™ Syphilis-G by demonstration of equivalence to the manual processing methods.
12. Consistent with good laboratory practice, it is recommended that all pipetting devices (manual or automatic) are regularly calibrated according to the manufacturer's instructions.
13. Care must be taken to ensure that specimens are dispensed correctly to each test well. If a specimen is inadvertently not added to a well, the result for that well will be non-reactive, regardless of the actual result of the specimen.

METHOD FOR USE

SPECIMEN COLLECTION AND STORAGE

CAPTIA™ Syphilis-G is intended for use with serum, EDTA or citrated plasma samples. If serum specimens are to be stored, they may be stored at 2-8°C for up to five days. However, if storage periods greater than five days are anticipated, the serum specimens should be stored frozen at -20°C or below. Specimens which have been frozen and thawed should be thoroughly mixed before testing. If plasma specimens are to be stored, they may be stored at 2-8°C for up to 48 hours. Plasma specimens should not be frozen due to fibrin clot formation.

Optimal performance of the Trinity Biotech ELISA kit depends upon the use of fresh serum/plasma samples (clear, non-hemolyzed, nonlipemic, non-icteric).

If serum specimens are to be shipped, they should be packaged and labeled in compliance with federal and international regulations covering the transportation of clinical specimens and etiologic agents. Serum specimens may be shipped ambient, refrigerated (2-8°C) on wet ice or frozen (-10°C or colder) on dry ice. Upon arrival, if serum specimens are to be stored, they may be stored at 2 to 8 °C for up to five days after collection or frozen (-20°C or colder).

The NCCLS provides recommendations for storing blood specimens (Approved Standard – Procedures for the Handling and Processing of Blood Specimens, H 18-A. 1990).

RINSE CYCLE

Efficient rinsing to remove uncomplexed sample components is a fundamental requirement of enzyme immunoassay procedures. CAPTIA™ Syphilis-G utilizes two standard five-rinse cycles. Automatic plate washers may be used providing they meet the following criteria:

1. All wells are completely aspirated.
2. All wells are filled to the rims (350 µL) during the rinse cycle.
3. Wash buffer is dispensed at a good flow rate.
4. The microtitration plate washer must be well maintained to prevent contamination from previous use. Manufacturer's cleaning procedures must be followed diligently.
5. Validated by end user

For each rinse cycle, the machine should be set to five consecutive washes. On completion of the cycle, invert the microtitration plate and tap firmly on absorbent paper towels. Check for any residual wash buffer in the wells and blot dry the upper surface of the wells with a paper towel.

Alternatively, the following manual system may be employed:

1. Aspirate well contents using a vacuum line fitted with a trap.
2. Fill all wells to the brim with wash buffer dispensed from a squeeze-type laboratory wash bottle.
3. Aspirate all wells.
4. Repeat Steps 2 and 3, four times.
5. Invert the microtitration plate and tap firmly on absorbent paper towels.

PREPARATION FOR THE ASSAY

Specimen Dilution

Test specimens should be tested following a 1:21 dilution with CAPTIA™ Sample Diluent. This dilution can be performed off-plate in tubes, or directly in the microtitration well. Tube dilution is recommended for diagnostic lab use. In-well dilution is recommended for high volume (blood banks) screening.

Tube method

This is most accurately performed in disposable tubes of 1.0 - 1.5 mL capacity, which can be arranged in 8 x 12 - place racks that conform to microtitration plate geometry. This facilitates later transfer of diluted specimens from the tubes to the test microtitration plate using a multichannel micropipette.

Dispense 1.0 mL of CAPTIA™ Sample Diluent into each tube. Add 50 µL of test specimen and mix **6 to 8 times.** Use a fresh disposable micropipette tip for each serum specimen.

In-well method

Dispense 200 µL of CAPTIA™ Sample Diluent into all the wells designated for test specimens. Dispense 10 µL of each specimen into its designated well. Pump mixture in and out of the micropipette tip 3 times to ensure full delivery. When dispensing of test specimens into the microtitration plate is complete and the working strength controls have also been dispensed, mix the well contents thoroughly by shaking on a mechanical microtitration plate shaker for 5-10 seconds, or by mixing in-probe if automatic EIA processors are used. Thorough mixing is essential.

Kit Controls

Note: The kit controls provided are working strength and do not require dilution. The kit controls should be included on each microtitration plate. The Low Titre Reactive Control should always be tested in duplicate. Additionally, it is recommended that a well characterized low titre reactive specimen, or an independent reference sample, diluted in Sample Diluent, be included in each microplate set-up.

Wash Buffer

The 20 x concentrated CAPTIA™ Wash Buffer may have developed crystalline deposits during prolonged storage at 2-8°C. These should be redissolved by standing the bottle in a 37°C water bath until the crystals disappear. Prepare working-strength Wash Buffer by diluting 1 part concentrate with 19 parts of distilled or deionized water. If a kit is likely to be utilized over a period in excess of 4 weeks, then it is recommended that only enough stock concentrate be diluted sufficient for immediate needs (see STORAGE AND STABILITY). Each row of 8 wells may be adequately washed with 150 mL of working strength buffer.

ASSAY PROCEDURE

1. Allow all reagents to reach room temperature (18-25°C).
2. The kit controls should be included on each microtitration plate. The Low Titre Reactive Control should always be tested in duplicate.
3. Select sufficient microtitration well strips to accommodate test specimens and controls. Fit the strips into the holding frame. Label wells according to specimen: identify using the letter/number cross-reference system molded into the plastic.
4. If the tube dilution method has been used, dispense 100 µL of each diluted serum or plasma specimen into the correspondingly pre-labeled wells. Mix the diluted specimen 6 to 8 times using the 100 µL micropipette, prior to transfer. Use a fresh micropipette tip for each diluted specimen.
   Dispense 100 µl. of the kit control into the designated wells.
   Alternatively use the in-well dilution method described above. If this method is used, dispense 200 µL of the kit control into the designated wells.
   If the in-well dilution method has been used, agitate the plate on a mechanical microtitration plate shaker for 5-10 seconds or mix in-probe if automatic EIA processor is used.
5. Seal the strips and holding frame with a plate sealer and incubate at 37(± 1)°C for 60 (± 5) minutes.
6. Aspirate diluted specimen from the wells and wash the microtitration plate as described in the Rinse Cycle section.
7. Dispense 100 µL conjugate into each well, seal the strips with a plate sealer and incubate at 37(± 1)°C for 60 (± 5) minutes.
8. Aspirate the conjugate from the wells and wash the microtitration plate as described in the Rinse Cycle section.
9. Without delay, dispense 100 µL of substrate solution into each well. A multichannel pipette should be used for best results. Leave at room temperature (18-25°C) protected from direct sunlight, for 30 (±2) minutes.
10. Stop the reaction by adding 100 µL of stop solution (1 N sulfuric acid) to each well. Mix on a plate shaker for 5 to 10 seconds, or tap lightly. This is to ensure that the blue solution changes to a uniform yellow color in each well. Ensure that the undersides of the wells are dry and that there are no air bubbles in the well contents.
11. Within 30 minutes of adding the acid, read the absorbance values at 450 nm using a microtitration plate reader blanked on air unless the manufacturer specifically recommends otherwise.

INTERPRETATION

ASSAY VALIDATION

A CAPTIA™ Syphilis-G assay should be considered valid if:

- The absorbance of the Non-reactive Control (N) is less than or equal to 0.25.
- The absorbance value of the High Titre Reactive Control is greater than or equal to 0.8.
- The mean absorbance value of the Low Titre Reactive Control (LTR) is greater than or equal to 2.5 x the absorbance of the Non-reactive Control.

TROUBLESHOOTING ADVICE

If the kit controls fail to give the absorbance values indicated above, the following points should be considered:

1. Ensure that the details given in Procedural have been reviewed.
2. For a High Absorbance Non-reactive Control (>0.25):
   - Ensure that the washing procedure detailed in **Methods for Use: Rinse Cycle** was followed. If using an automatic washer, ensure all inlet and outlet probes are not blocked and that all wells are being filled and aspirated fully.
3. For a Low Absorbance High Titre Reactive Control (<0.8):
   - Check that the correct incubation conditions (time and temperature) were achieved.

- Ensure that all residual wash buffer has been removed from the wells after use.

4. For a LTR/N ratio <2.5, check all points detailed in (1) to (3) of this section.
   - After consideration of the points above, repeat the assay. If the kit controls again fail to validate, contact your supplier for further advice.

ANALYSIS

Calculate the mean absorbance value of the duplicate Low Titre Reactive Controls. This is the cut-off value for CAPTIA™ Syphilis-G and was derived from clinical trials as the value giving optimum discrimination between specimens which are reactive or non-reactive for antibodies to *T. pallidum* as characterized by a range of standard serological techniques.

Specimen absorbance values within 10% of the mean of the Low Titre Reactive Controls should be considered equivocal results.

A specimen may be considered reactive for IgG antibodies to *T. pallidum* if it gives an absorbance value greater than the mean of the Low Titre Reactive Controls and outside the equivocal range.

A specimen may be considered non-reactive for IgG antibodies to *T. pallidum* if it gives an absorbance value less than the mean of the Low Titre Reactive Controls and outside the equivocal range.

It is often useful to ascribe a numerical value to a specimen which represents its CAPTIA™ Syphilis-G reactivity so that comparisons can be made between different assays. Such a value is derived by expressing the absorbance of the test specimen as a ratio of the mean absorbance of the kit Low Titre Reactive Controls.

For example:

Test serum absorbance	=	0.75
Mean LTR* absorbance	=	0.30
Antibody Index $\frac{0.75}{0.30}$	=	2.50

*LTR - Low Titre Reactive Control

An Antibody Index between 0.9 and 1.1 should be considered equivocal.

An Antibody Index greater than or equal to 1.1 is a reactive result and an Index less than or equal to 0.9 is a non-reactive result.

A CAPTIA™ Syphilis-G reactive result (following a reactive nontreponemal test result in the diagnostic application) indicates a current or past infection with *T. pallidum.*

A non-reactive result indicates absence of infection at any time more than 2-3 weeks previous to drawing the specimen. (See ***Limitations of Use***).

CAPTIA™ SYPHILIS-G USED AS A CLINICAL LAB TEST.

Initially reactive or equivocal results should be repeat tested in duplicate. If the repeat test is again equivocal a fresh serum specimen should be tested. The CAPTIA™ Syphilis-G is a treponemal assay, therefore patients with previously treated syphilis will be positive on the assay. The test can not distinguish between present and past infection. Any sera giving reactive or equivocal results on initial testing must be supplemented with a quantitative nontreponemal test (such as RPR and VDRL) to distinguish active disease and assist in ruling out false positives.

The following table is used for result interpretation:

Non-Treponemal Result (NT)	Treponemal Result Captia™ Syphilis - G	Report/interpretation for all except neonates or infants.[2]
nonreactive	negative (nonreactive)	No serological evidence of infection with *T. Pallidum* (incubating or early primary syphilis cannot be excluded).
reactive	negative (nonreactive)	Current infection unlikely, probability of biological false positive secondary to other medical conditions (febrile diseases, immunizations, IV DU, autoimmune diseases, etc.). Recommend repeat testing (nontreponemal and treponemal by other test method).
nonreactive	positive (reactive)	Probably past infection or potential cross-reactivity with other spirochetes/related antigens; additional testing appropriate to clinical findings/history;[1] possibility of false negative nontreponemal (NT) due to prozone and late syphilis or neurosyphilis.
reactive	positive (reactive)	Presumptive evidence of current infection (or inadequately treated infection, persistent infection, reinfection, or biological false positive if prior history); additional testing consistent with clinical assessment.[1]
nonreactive	not done	Current infection unlikely; effectively treated infection if previous diagnosis and treatment; cannot exclude incubating or early primary syphilis; cannot exclude latent or neurosyphilis.
not done	negative (nonreactive)	Current or past infection unlikely; cannot exclude incubating or early syphilis.

[1] Quantitative nontreponemal testing; clinical history; repeated (sequential) serological testing for changes in titer.

HIV-infected individuals may have delayed seroreactivity or negative serology.

CAPTIA™ SYPHILIS-G USED AS A PRIMARY BLOOD OR PLASMA DONOR SCREEN FOR BLOOD BANKS AND PLASMAPHARESIS CENTERS.

Initially reactive or equivocal results should be repeat tested in duplicate. Where plasma specimens have been tested initially, serum specimens are preferred for retesting. If the repeat test is again reactive or equivocal the specimen should be referred for confirmation to a Syphilis Reference Laboratory. Specimens which give repeat equivocal results by CAPTIA™ should be considered reactive until confirmatory testing (RPR, VDRL) has been done. In practice, equivocal results are found in less than 0.5% of specimens tested (see Trial 9 in **Performance Characteristics).**

CAPTIA™ SYPHILIS-G USED AS A DIAGNOSTIC CONFIRMATORY TEST

Specimens giving equivocal results should be retested in duplicate. If the result is again equivocal, a fresh serum specimen should be tested. When retesting sera giving equivocal results on initial testing, the sample should be tested using a nontreponemal test and another treponemal test. A second serum sample should also be obtained (one drawn at a later date) if results of the nontreponemal and treponemal tests do not resolve the diagnosis.

EXPECTED VALUES

The percentage of specimens reactive by CAPTIA™ Syphilis-G is dependent upon the population from which the specimens were derived. It can be expected that specimens derived from 'high risk' patients (e.g. those attending genitourinary clinics) will show a higher reactivity rate than those derived from a low risk population (e.g. blood donors). Also the number of specimens reactive will be dependent upon the type of laboratory carrying out the testing - a Reference Laboratory testing samples that may already have been screened for syphilis by a serological assay will have a higher incidence of reactive specimens than a routine Clinical Laboratory testing specimens for the first time.

From the results presented in the section **Performance Characteristics** it could be expected that a Clinical Laboratory testing referred samples and routine specimens including those from genitourinary clinics may have a reactivity rate of approx. 4.5% (61/1321 -Trial 1).

From the data presented in Trial 9, it could be expected that a Blood Testing Center would obtain approx. 0.8% (73/9323) reactive specimens using CAPTIA™ Syphilis G.

LIMITATIONS OF USE

1. Results from CAPTIA™ Syphilis-G should be considered in the context of all available clinical and laboratory data.
2. A CAPTIA™ Syphilis-G non-reactive result does not preclude the possibility of:
   - a very recent infection (within the last 2-3 weeks) with *T. pallidum*.
   - an old, successfully cured infection with *T. pallidum* (for example >10 years previous).
3. CAPTIA™ Syphilis-G may be reactive with sera from patients with Yaws (*T. pallidum* subspecies pertenue) or Pinta (*T. carateum*).
4. Detection of treponemal antibodies may indicate recent, past, or successfully treated syphilis infections, therefore, the test cannot be used to differentiate between active and cured cases.
5. When performing clinical lab assays, any sera giving reactive or equivocal results must be supplemented with a quantitative nontreponemal test (such as RPR and VDRL) to distinguish active disease and assist in ruling out false positives. The CAPTIA™ Syphilis-G is a treponemal assay, therefore patients with previously treated syphilis will be positive on the assay.
6. The use of CAPTIA™ Syphilis-G as an initial screening test for blood donors may result in higher numbers of reactive donors who may not be currently infected compared to screening donors with standard, nontreponemal assays. It is recommended that CAPTIA™ Syphilis-G repeat reactive specimens be tested by methods capable of indicating the current disease status of the donor e.g. RPR and VDRL tests.
7. AIDS patients with impaired immunity and who are coinfected with syphilis may react falsely nonreactive in treponemal and nontreponemal tests.
8. Reactive treponemal IgG antibody test results usually remain reactive for a lifetime, therefore antibody indices cannot not be used to determine response to therapy.

PERFORMANCE CHARACTERISTICS

CLINICAL LAB TEST APPLICATION

Comparison with other serological tests.

CAPTIA™ Syphilis-G has been evaluated at a number of independent clinical laboratories. Serum specimens routinely referred for syphilis serology were analyzed by CAPTIA™ Syphilis-G in parallel with haemagglutination (MHA-TP) and VDRL tests. Specimens giving reactive results by any test were further tested by the FTA-ABS procedure. The tables below summarize results from initial testing at two trial centers. In all cases a reactive is defined as a serum specimen which gives a reactive result by either the MHA-TP or VDRL test and which is confirmed by the FTA-ABS test.

Trial 1

Total 1321 Specimens

	CAPTIA™ SYPHILIS-G		MHA-TP		VDRL	
T. pallidum antibody status	R	N	R	N	R	N
Reactive	60	1[d]	60	1[a]	25	36[e]
Non-reactive	9[b]	1251	6[c]	1254	12	1248
Relative Sensitivity	98.4%		98.4%		NA	
Relative Specificity	99.3%		99.5%		N/A	

N = Non-reactive R = Reactive

Note: Equivocals scored as reactive.

[a] Confirmed untreated primary infection, reactive by CAPTIA™ Syphilis-G.
[b] Includes 7 specimens in equivocal range.
[c] On repeat testing confirmed as non-specific agglutination, therefore are inconclusive.
[d] Weakly reactive case of treated latent syphilis.
[e] The proportion of this specimen group representing cases of successfully treated syphilis, which would not normally be VDRL reactive, is not known.

Trial 2

Total 177-179 Specimens

T. pallidum antibody status	CAPTIA™ SYPHILIS-G		MHA-TP		VDRL	
	R	N	R	N	R	N

Reactive	76	0	76	0	25	49[b]
Non-reactive	0	103	3[a]	100	0	103
Relative Sensitivity	100%		100%		N/A	
Relative Specificity	100%		97.1%		N/A	
N = Non-reactive	R = Reactive					

Note: Equivocals scored as reactive.

[a] Includes 2 serum specimens which, on repeat testing, were confirmed as causing non-specific agglutination, therefore are inconclusive.

[b] The proportion of this specimen group representing cases of successfully treated syphilis, which would not normally be VDRL reactive, is not known.

Trial 3

Reaction with serum specimens classified according to stage of disease.

The following table summarizes CAPTIA™ Syphilis-G results using serum specimens taken from patients at various stages of the disease and following treatment. Diagnosis was based on clinical history together with serological data from VDRL and FTA-ABS tests.[3]

	Number Reactive by Test			
Syphilis Category	Number of Specimens	CAPTIA™ Syphilis-G	VDRL	FTA-ABS
Untreated				
Primary	17	14	16	17
Secondary	13	13	13	13
Early Latent	14	14	12	14
Late Latent	33	33	17	33
Neurosyphilis	3	3	3	3
Congenital	1	1	1	1
Reinfection	15	15	15	15
Treated				
Uncharacterized	72	72	46	Data Not Available
Total:	168			
Sensitivity:		165/168 = 98.2%	77/96 = 80.2%*	96/96 = 100%*

* Calculated from untreated cases only

Trial 4

The Centers For Disease Control and Prevention analyzed serum samples from a high risk population using CAPTIA™ Syphilis-G, the RPR and FTA-ABS tests. Serum samples were from patients with primary, secondary or latent infections and patients with no history of syphilis known to give false reactive reactions in nontreponemal tests.

	RPR		FTA-ABS		CAPTIA™ Syphilis G	
STAGE	R	N	R	N	R	N
PRIMARY						
untreated	4	1	5	0	5	0
treated	5	0	5	0	5	0
SECONDARY						
untreated	3	0	3	0	3	0
treated	3	0	3	0	3	0
LATENT						
untreated	4	0	4	0	4	0
treated	9	2	11	0	11	0
NONSYPHILIS[a]	12	6	0	18	1	17
N=non-reactive	R=reactive					

[a] These serum samples were obtained from individuals without syphilis, but who had diseases known to cause false reactive results in the nontreponemal tests.

Sensitivity:	RPR	FTA-ABS	CAPTIA™ Syphilis-G
untreated	11/12=92%	12/12=100%	12/12=100%
treated	17/19=90%	19/19=100%	19/19=100%
overall	28/31=90%	31/31=100%	31/31=100%
Specificity	Inappropriate	18/18=100%	17/18=94%
Agreement of CAPTIA" Syphilis-G with FTA-ABS: 48/49= 97.96%			
Agreement of RPR with FTA-ABS 40/49= 81.63%			

Trial 5

Comparison with the RPR test

585 serum specimens routinely submitted to a clinical serology laboratory, were tested by RPR and CAPTIA™ Syphilis-G. Serum specimens yielding reactive or equivocal results by either method were further tested by the FTA-ABS procedure.

Of the 585 specimens tested, only 69 were initially reactive, and then tested in the FTA-ABS procedure. The remaining 516 serum specimens were non-reactive in both the RPR test and CAPTIA™ Syphilis-G.

RPR Card	CAPTIA™ Syphilis G	FTA-ABS	Number with Pattern
N	N	N	7
N	R	R	15
R	R	R	37
N	R	N	3
N	E	R	2
N	E	N	1
N	N	R	1
R	N	N	3
N=non-reactive		R=reactive	E=Equivocal

Agreement between CAPTIA™ Syphilis-G and the FTA -ABS test results

	CAPTIA™ Syphilis-G Reactive	CAPTIA™ Syphilis-G Non-reactive
FTA-ABS Reactive	54	1
FTA-ABS Non-reactive	4	10
Equivocal results scored as reactive. Agreement = 64/69 or 92.7%		

Trial 6

Clinical Sensitivity

A panel of frozen retrospective characterized sera obtained from the CDC (Centers for Disease Control) were assayed on the CAPTIA™ Syphilis-G by Trinity Biotech. The panel consists of 100 sera with clinical diagnosis of Syphilis with different stages of disease. Treated and untreated patients are included in each disease stage. The following table illustrates the performance of the assay with the serum panel. The data is presented for information on the assay with a characterized serum panel and does not infer an endorsement of the assay by the CDC.

Results of the CDC Serum Panel on the Captia Syphilis G

Disease	+	E	-	Total	% Positive
Stage					
Primary Treated	15	0	1	16	93.8%
Primary Untreated	8	0	0	8	100%
Secondary Treated	27	0	0	27	100%
Secondary Untreated	21	0	1	22	95.5%
Late Treated	20	0	1	21	95.2%
Late Untreated	6	0	0	6	100%
Total	97	0	3	100	97%

Trial 7

Clinical Sensitivity

A panel of frozen retrospective characterized sera were assayed on the Captia Syphilis-G by a public health laboratory in the United Kingdom. The panel consists of 200 sera with clinical diagnosis of Syphilis with different stages of disease. Treated and untreated patients are included in each disease stage. The following table illustrates the performance of the assay with the serum panel.

Results of the characterized Serum Panel on the Captia Syphilis G

Disease	+	E	-	Total	% Positive
Stage					
Primary Treated	5	0	0	5	100%
Primary Untreated	19	1	0	20	95%
Secondary Treated	27	1	1	29	93.1%
Secondary Untreated	23	0	0	23	100%
Late Treated	29	0	1	30	96.7%
Late Untreated	92	1	0	93	98.9%
Total	195	3	2	200	97.5%

Provided below is a Summary Table of Trials 3, 4, 6 and 7 of data obtained from collections which were characterized by syphilis disease states:

Summary Table from Trials 3, 4, 6, 7

		RPR/VDRL		CAPTIA™ Syphilis-G Results			CAPTIA™ Syphilis-G *Reactive* and RPR or VDRL Reactive	RPR or VDRL Reactive and FTA Reactive
Patient Category	# Patients	+	-	+	+/-	-		
Untreated Syphilis								
Primary	50	46	4	46	1	3	44	38[1]
Secondary	60	60	0	59	0	1	59	56[2]
Latent	117	115	2	116	1	0	114	108[3]
Treated Syphilis								
Primary	26	26	0	25	0	1	26	24[4]
Secondary	59	59	0	57	1	1	57	59
Latent	62	60	2	60	0	2	58	60

[1] FTA not performed on 8 samples
[2] FTA not performed on 4 samples
[3] FTA not performed on 7 samples
[4] FTA not performed on 2 samples

Trial 8
RPR Positive and FTA Negative Sera

Two sites (Public Heath Labs located in New York and Maryland) tested 25 frozen retrospective sera on the CAPTIA™ Syphilis G that were RPR positive on initial screen and FTA negative on confirmation. The following table summarizes the results.

	CAPTIA™ Syphilis Positive	CAPTIA™ Syphilis Equivocal	CAPTIA™ Syphilis Negative	% Negative
Site 1	0	0	25	100%
Site 2	0	2*	23	92%

*The two equivocals were negative with repeat testing.

Trial 9
Blood and Plasma Donor ScreeningApplication
Comparison with the RPR test

CAPTIA™ Syphilis-G was evaluated at 2 major US blood centers and a plasma center, in comparison with the RPR test. A total of 9,323 donors were tested as plasma specimens by CAPTIA™ Syphilis-G and as serum specimens by the RPR test. 152 of the specimens were known reactive from previous serological testing which did not include the FTA-ABS test. 4,274 of these donors were additionally tested as serum specimens using CAPTIA™ Syphilis-G. Initially-reactive specimens were repeat tested in duplicate. Repeat-reactive specimens were confirmed using an FTA-ABS test. The following tables compare the CAPTIA™ Syphilis-G and RPR before and after reconciliation of discordant results by the FTA test.

CAPTIA™ Tests Plasma Specimens: CAPTIA™ Syphilis-G, RPR and FTA-ABS Results

CAPTIA™	RPR	NUMBER		FTA-ABS	
Syphilis-G		Initial	Repeat	Reactive	Non-reactive
R	R	131	130	127	3
R	N	69	72	57	15
E	R	3	3	3	0
E	N	22	13	8	5
N	R	23	23	1	22
N	N	9075	7	-	-
TOTALS		9323	248	196	45
N=non-reactive		R=reactive		E=Equivocal	

Of 241 samples that were repeat reactive in either or both CAPTIA™ Syphilis-G and RPR tests, 196 were FTA reactive, and 45 were FTA non-reactive.

CAPTIA™ Syphilis-G (Tests Plasma Specimens)	RPR		Reactives and Discordants Reconciled by FTA-ABS	
	Reactive	Non-reactive	Reactive	Non-reactive
Reactive	133	85a	195	23
Non-reactive	23[b]	9082*	1	9140*
% Agreement	98.84 %		-	
Relative Sensitivity	133/156 = 85.26%		195/196 = 99.50 %	
Relative Specificity	9082/9167 = 99.01%		9104/9127 = 99.75 %	

* includes 9082 specimens which were CAPTIA™ and RPR concordant non-reactive and therefore not tested by FTA-ABS. [a]65/85 were FTA reactive
[b] 22/23 were FTA non-reactive. Equivocals were scored as reactive. In this study, there were 25 specimens (0.27%) initially equivocal by CAPTIA™ and 16 specimens (0.17%) repeat equivocal.

CAPTIA™ Tests Serum Specimens. CAPTIA™ Syphilis-G, RPR and FTA-ABS Results

CAPTIA™	RPR	NUMBER		FTA-ABS	
Syphilis-G		Initial	Repeat	Reactive	Non-reactive
R	R	114	115	113	2
R	N	46	45	41	4
E	R	5	4	3	1
E	N	13	10	10	0
N	R	17	17	0	17
N	N	4079	4	-	-
TOTALS		4274	195	167	24
N=non-reactive		R=reactive		E=Equivocal	

Of 191 samples that were repeat reactive in either or both tests (CAPTIA™ and RPR), 167 were FTA-ABS reactive and 24 were FTA-ABS non-reactive.

CAPTIA™ (Tests Plasma Specimens)	RPR		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	119	55[a]	167	7
Non-reactive	17[b]	4083*	-	4100*
% Agreement	98.32 %		-	
Relative Sensitivity	119/136 = 87.5%		167/167 = 100 %	
Relative Specificity	4083/4138 = 98.67%		4100/4107 = 99.83 %	

* includes 4083 specimens which were CAPTIA™ and RPR concordant non-reactive and therefore not tested by FTA-ABS
[a] 51/55 reactive by FTA
[b] All non-reactive by FTA
Equivocals were scored as reactive. In this study, there were 18 specimens (0.42%) initially equivocal by CAPTIA™ and 14 specimens (0.33%) repeat equivocal.

Comparison with an automated MHA-TP (haemagglutination) test

CAPTIA™ Syphilis-G was evaluated at two major US blood centers, in comparison with a commercially available automated MHA-TP system (PK-TP test). A total of 6,196 donors were tested as plasma specimens by CAPTIA™ Syphilis-G. 2,156 of these donors were additionally tested as serum specimens by CAPTIA™ Syphilis-G. The MHA-TP initial tests were performed with plasma specimens, and MHA-TP repeat tests were performed with serum specimens. Specimens which were repeat reactive in either test were confirmed using an FTA-ABS test.

The following tables summarize the results of all tests and compare CAPTIA™ and MHA-TP before and after reconciliation of discordant results by the FTA-ABS tests.

CAPTIA™ Tests Plasma Samples: CAPTIA™ Syphilis-G, MHA-TP and FTA-ABS Results

CAPTIA™	RPR	NUMBER		FTA-ABS	
Syphilis-G		Initial	Repeat	Reactive	Non-reactive
R	R	85	91	91	0
R	E	6	0	0	0
R	N	16	19	9	10
E	R	2	1	1	0
E	E	1	1	1	0
E	N	15	7	2	5
N	R	49	4	1	3
N	E	24	1	0	1
N	N	5998	74	-	-
TOTALS		6196	198	105	19
N=non-reactive		R=reactive		E=Equivocal	

Of 124 samples that were repeat reactive in either or both tests (CAPTIA™ and MHA-TP), 105, were FTA-ABS reactive and 19 were FTA-ABS non-reactive

CAPTIA™ (Tests Plasma Specimens)	MHA-TP		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	93	26[a]	104	15
Non-reactive	5[b]	6072*	1	6076*
% Agreement	99.32 %		-	
Relative Sensitivity	93/98 = 94.90%		104/105 = 99.05%	
Relative Specificity	6072/6098 = 99.57%		6076/6091 = 99.75%	

* includes 6072 specimens which were CAPTIA™ and MHA-TP concordant non-reactive and therefore not tested by FTA-ABS
[a] 11/26 FTA Reactive
[b] 4/5 FTA Non-Reactive
Equivocals were scored as reactive. In this study there were 18 specimens (0.29%) initially equivocal by CAPTIA™, and 9 specimens (0.15%) repeat equivocal.

CAPTIA™ Tests Serum Samples: CAPTIA™ Syphilis-G, MHA-TP and FTA-ABS Results

CAPTIA™	MHA-TP	NUMBER		FTA-ABS	
Syphilis-G		Initial	Repeat	Reactive	Non-reactive
R	R	81	83	83	0
R	E	1	0	0	0
R	N	2	2	2	0
E	R	3	6	6	0
E	E	5	1	1	0
E	N	2	2	2	0
N	R	17	3	1	2
N	E	14	1	0	1
N	N	2031	27	-	-
TOTALS		2156	125	95	3
N=non-reactive		R=reactive		E=Equivocal	

Of 98 samples that were repeat reactive in either or both tests (CAPTIA™ and MHA-TP), 95 were FTA-ABS reactive, and 3 were FTA-ABS non-reactive.

CAPTIA™ (Tests Plasma Specimens)	MHA-TP		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	90	4[a]	94	0
Non-reactive	4[b]	2058*	1	2061*
% Agreement	99.63%		-	
Relative Sensitivity	90/94 = 95.74%		94/95 = 98.95%	
Relative Specificity	2058/2062 = 99.81%		2061/2061 = 100%	

* includes 2058 specimens which were CAPTIA™ and MHA-TP concordant non-reactive and therefore not tested by FTA-ABS.
[a] All reactive by FTA
[b] 3/4 non-reactive by FTA
Equivocals were scored as reactive. In this study, there were 10 specimens (0.46%) initially equivocal by CAPTIA™, and 9 specimens (0.42%) repeat equivocal.

CAPTIA™ Syphilis-G: comparison of performance with plasma and serum specimens

A total of 4,274 serum/plasma pairs were tested at 2 major US blood centers and a plasma center using CAPTIA™ Syphilis-G. Results are summarized in the following table. 4,258 pairs (99.62%) gave concordant results on initial testing (equivocal scored as positive). Eleven (11) specimen pairs gave discordant results on repeat testing. Of these 11 repeat discordant pairs, the FTA-ABS test confirmed the plasma result for 6 pairs, and the serum results for the remaining 5 pairs

CAPTIA™ Syphilis-G		Number		FTA-ABS	
Serum	Plasma	Initial	Repeat	Reactive	Non-reactive
Reactive	Reactive	154	156	150	6
Reactive	Equivocal	4	3	3	
Reactive	Non-reactive	I	I	I	
Equivocal	Reactive	11	8	8	
Equivocal	Equivocal	4	6	5	
Equivocal	Non-reactive	4	1		1
Non-reactive	Reactive	5	7	4	3
Non-reactive	Equivocal	6	2	1	1
Non-reactive	Non-reactive	4085	6		
Total Tested		4274	189	183	
Total Reactive		189	183	172	

SPECIFICITY AND CROSS-REACTIVITY

The following table summarizes CAPTIA™ Syphilis-G results from serum specimens taken from subjects with no known history or serological evidence of syphilis. This Group included serum specimens representing other disease states and/or characteristics known to cause false reactives in other serological tests for syphilis.

CATEGORY OF SPECIMEN	n	CAPTIA™ Syphilis-G Reactive*
Normal ante-natal	1002	0
HBsAg Reactive	68	1
ALT	125	2
Sera from HBV Vaccines	11	0
HIV 1/2 Antibody Reactive	32	0
HCV Antibody Reactive	134	2
HTLV 1 Antibody Reactive	34	0
Heterophile Antibody Glandular Fever) Reactive	17	0
Rheumatoid Factor R	33	1
Systemic Lupus E	22	1
Autoimmune/Connective Tissue Disease	16	0
Reagin Test False Reactive	66	0
Lyme's Disease	34	1
Genital Herpes	10	0
Acute Leptospirosis	10	0
Sera from Intravenous Drug	39	0
Hypergammaglobulinaemia	120	0
Miscellaneous**	18	0
Total Specimens	1690	
Total Representing Known Disease	688	
Total CAPTIA™ Reactive/FTA Non-Reactive	8	

* FTA Non-reactive

** Miscellaneous included 2 specimens from patients with arthritis and scleroderma, and one specimen each from patients with alzheimer; arthralgia; aspergillosis; coeliac disease; colitis C4 depressed; gout; immune complex infection; macroglobulinemia; myeloma (unspecified); myeloma IgA; myeloma IgG; myeloma light chain; nephrotic syndrome and acute renal failure.

REPRODUCIBILITY

The reproducibility of CAPTIA™ Syphilis-G was evaluated concurrently at 3 separate US blood/plasma centres. Each centre tested 6 standard serum samples, replicated x 3 in each assay, on each of 5 days. The serum samples comprised: 2 x high titre reactive serum specimens; 2 x low titre (near the cut-off) reactive serum specimens and 2 x non-reactive serum specimens. Results are summarized in the following table:

	SAMPLE NUMBER					
PARAMETER	1	2	3	4	5	6
Intra-assay						
Mean antibody index: 15 runs: 3 sites	3.02	2.70	1.88	1.43	0.26	0.37
Range of within run %CV: 3 sites	2.95-4.38	3.20-5.40	3.23-6.47	3.01-8.01	3.76-4.44	1.79-5.81
Inter-assay						
Range of inter-assay %CV from 5 runs: 3 sites	5.87-11.21	5.52-10.23	4.66-9.53	8.34-13.47	6.56-11.21	7.40-12.81

The reproducibility of CAPTIA™ Syphilis-G was evaluated at two separate Public Health Labs. Each centre tested 6 standard serum samples, replicated x 3 in each assay, on each of 5 consecutive days. The same 6 samples were then replicated x 3 in each assay, separated by one week intervals for five weeks. The last two assays were each performed with different lots of kits. The serum samples comprised: 2 x high titre reactive serum specimens; 2 x low titre (near the cut-off) reactive serum specimens and 2 x non-reactive serum specimens. Results are summarized in the following table:

	SAMPLE NUMBER					
PARAMETER	1	2	3	4	5	6
Intra-assay						
Mean antibody index: 20 runs: 2 sites	3.60	4.89	1.48	1.41	0.15	0.13
Range of within run %CV: 2 sites	1.09-17.48	0.71-12.88	0.82-19.57	1.05-17.57	0.00-74.19	2.17-410.2
Inter-assay						
Range of inter-assay %CV from 20 runs: 2 sites	15.94-18.81	12.94-21.97	10.96-14.96	17.19-20.72	15.87-68.02	22.68-69.03

Sample #3 was equivocal 4/60 times
Sample #4 was equivocal 10/60 times
All other sera remained in the same status 60/60 times.

CAPTIA SYPHILIS-G SUMMARY OF ASSAY PROCEDURE

Note: Read the full product instruction leaflet before starting the assay. This summary is for quick reference only.

1. Dilute 1 part CAPTIA™ Wash Buffer concentrate with 19 parts distilled water. 150 mL is sufficient to wash 1 x 8 well row.
2. Dilute the test sera by adding **50 µL to 1000 µL (1.0 mL)** CAPTIA™ Dilution Buffer III in disposable tubes. Do NOT dilute kit controls.

Incubation One:

3. Dispense into labeled wells l00 µL of the
   (i) diluted test sera
   (ii) Kit Low Titre Reactive Control IN DUPLICATE
   (iii) Kit High Titre Reactive Control
   (iv) Kit Non Reactive Control
4. Seal the strips with a plate sealer. Incubate at **37(±1)°C for 60(±5)** minutes.
5. Aspirate the sera from the wells. Wash the plate five times. Ensure there is no residual fluid in the wells

Incubation Two:

6. Pipette 100 µL working strength conjugate into each well.
7. Seal the strips with a plate sealer. Incubate at **37(±1)°C for 60 (±5)** minutes.
8. Aspirate the conjugate from the wells. Wash the plate five times. Ensure there is no residual wash buffer in the wells.

Incubation Three:

9. Dispense **100 µL** of **substrate** solution into the wells.
10. Incubate at **room temperature** for **30 (±2)** minutes.
11. Add **100 µL 1N sulfuric acid** to each well. Tap the plate or mix on a plate shaker for 5 to 10 seconds until the blue solution changes to a uniform yellow.
12. Within 30 minutes, blank a plate reader on air and read the absorbance of Kit Controls and test sera at **450 nm**.

The safety data sheet is available upon request.
WARNING: Sample Diluent contains < 0.1% but > 0.05% ProClin 300, a biocidal preservative that may cause sensitization by skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

WARNING

H317: May cause an allergic skin reaction.

P280: Wear protective gloves / protective clothing / eye protection / face protection.

P302 + **P352**: IF ON SKIN: Wash with plenty of soap and water.

P333 + **P313**: If skin irritation or rash occurs: Get medical advice/ attention.

P501: Dispose of contents and container in accordance to local, regional, national and international regulations.

Prepared in accordance with requirements for EEC label. EINECS 247-852-1

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ORDERING INFORMATION

KIT		Captia™ Syphilis-G Test Kit
Catalog No.	Item	Quantity
800-970	Captia™ Syphilis-G Test Kit	96 Tests
800-960	Captia™ Syphilis-G Test Kit	960 Tests


Manufactured

Authorized Representative


Consult accompanying documents

High titre reactive control (HTR)

Low Titre reactive control (LTR)

Non-reactive control (N)

Product Number

Calibrator

Lot

Coefficient Factor


Use by

Range

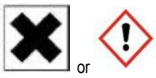

Caution, consult accompanying documents

Standard

Store at 2-8ºC

For *In Vitro* Diagnostic use

Store at 2-30ºC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