# WHO Prequalification of In Vitro Diagnostics
# PUBLIC REPORT

## Product: Determine Syphilis TP
## WHO reference number: PQDx 0485-013-00

Determine Syphilis TP with product codes 7D2452, 7D2453 and 7D2453SET, manufactured by Abbott Diagnostics Medical Co., Ltd., Rest of World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 22 December 2022.

## Summary of WHO prequalification assessment for Determine Syphilis TP

| | Date | Outcome |
|---|---|---|
| **Prequalification listing** | 22 December 2022 | listed |
| **Dossier assessment** | 29 November 2022 | MR |
| **Site inspection(s) of the quality management system** | 26-27 November 2018 | MR |
| **Product performance evaluation** | Quarter 1 2021 | MR |

MR: Meets Requirements

### Intended use

According to the claim of intended use from Abbott Diagnostics Medical Co., Ltd, *"Determine Syphilis TP is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to Treponema pallidum, which is the bacteria that causes syphilis infection, in human capillary and venous whole blood, plasma or serum. The test is intended as an aid to detect antibodies to Treponema pallidum from infected individuals. The test is for professional use only. The device is not automated."*

### Assay description

According to the claim of assay description from Abbott Diagnostics Medical Co., Ltd, *"Syphilis is caused by infection with the bacterium Treponema pallidum which can be transmitted congenitally or by sexual contact. The disease can evolve into a latent phase in which syphilis is clinically inapparent. Serologic tests (nontreponemal specific and treponemal specific) are currently the primary method for syphilis diagnosis and management. Nontreponemal tests (VDRL, RPR, etc.) are generally used for screening, and treponemal tests (TPHA/TPPA, FTA-ABS, etc.) are used as confirmatory tests."*

**Test kit contents**

| Component | 30 tests (product code 7D2452) | 100 tests (product code 7D2453) | 100 tests (product code 7D2453SET) |
|---|---|---|---|
| 10 Tests/ card | 3 | 10 | 10 |
| Chase Buffer (7D2243) bottle of 2.5 mL | \ | \ | 1 |
| EDTA Capillary Tubes (7D2222) pack of 100 | \ | \ | 1 |
| Blood Lancet (sterilized) (7D2233) box of 100 | \ | \ | 1 |
| Instructions of use | 1 | 1 | 1 |

**Items required but not provided**

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab and gauze pad
- Single-use sterile lancet (for fingerstick method)

**Storage**

The test kit must be stored at 2-30 °C.

**Shelf-life upon manufacture**

14 months.

**Warnings/limitations**

Please refer to the instructions for use attached to this public report.

**Prioritization for prequalification**

Based on the established eligibility criteria, Determine Syphilis TP was given priority for the WHO prequalification assessment.

## Dossier assessment

Abbott Diagnostics Medical Co., Ltd. submitted a product dossier for Determine Syphilis TP as per the "*Instructions for compilation of a product dossier*" (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 29 November 2022.

**Commitments for prequalification**

1. 7b1: Please provide details of the reference panels and the procedure for deeming equivalence from one lot of reference panels to the next.
2. 7c1: Please annotate Attachment 7c to specify what is meant by “score/signal score”.
3. 8a: Please provide the CoA for a current lot of the positive control.
4. 10a: Please justify the reading time of 15-30 minutes.
5. 10b: Please clarify the Determine Syphilis TP reading time for the results presented in the clinical study report.
6. 10c: Please provide the information that will be included in the IFU that corresponds to the conclusions made in the clinical study report.
7. 18a: Please clarify the steps in the operation of
the product that are undertaken by non-laboratory trained personnel.
8. 20a1: Please provide results for anti-TP positive specimens that contain endogenous interferents.
9. 20b1: Please clarify the acceptance criteria for the interfering substances studies.
10. 23c1: Please agree to modify the comment to be added to the IFU regarding the likelihood of a high-dose hook effect.
11. 24e1: Please provide evidence of drop-shock testing of the 7D2453SET configuration of the product.
12. 25a: Please provide details regarding the source and characterization of positive specimen used in the estimation of product shelf life and the relationship of its dilution series to other sensitivity specimens used for validation studies.
13. 27a1: Please provide the characterization of the specimens used in the tested performance panels at the epitope level.
14. 35a:
    - Please provide more information about the patients in the reported events and how it was determined that false negative results would be considered to cause no harm to a patient;
    - Please provide the SOP used to review the adverse events for reporting purposes at the time; and
    - Please provide the current SOP used for reporting adverse events if it has been updated.
15. Other IFU-related commitments:
    - Please include the target antibodies detected by the product, intended use population, and intended use setting in the IFU by 30 April 2023.
    - Please include a pen or pencil in the "Material Required But Not Provided" section of the IFU.
    - Please include specimen collection containers and instructions for obtaining serum and plasma in the IFU by 30 April 2023.

- Please include the instructions for users to store frozen specimens for 20 months and that a specimen is eligible for testing after only one freeze-thaw cycle.
- Please include the target detected or not detected in the interpretation of results section by 30 April 2023.
- Please update the clinical performance data in the IFU by 30 April 2023.

Based on the product dossier screening and assessment findings, the product dossier for Determine Syphilis TP meets WHO prequalification requirements.

## Manufacturing site inspection

An inspection of Abbott Diagnostics Medical Co., Ltd, located at 357 Matsuhidai, Chiba-ken Matsudo-shi, 270-2214, Japan, was conducted from 26-27 November 2018. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current inspection performed at a manufacturing site for *in vitro* diagnostic products and gives a summary of the inspection findings.

Information on the most current inspection can be found at:
https://extranet.who.int/pqweb/inspection-services/prequalification-reports/whopirs-vitro-diagnostics

All published WHOPIRs are with the agreement of the manufacturer.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 24 May 2019.

## Product performance evaluation

Determine Syphilis TP (Abbott Diagnostics Medical Co., Ltd) was evaluated by the National Serology Reference Laboratory (NRL) on behalf of WHO in the first quarter of 2021, according to protocol PQDx_326, version 2.0.

### Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 570 plasma/serum specimens was used. The specimens were characterized using the following reference assays: LIAISON Treponema Screen CLIA (DiaSorin S.p.A), followed by

SERODIA TP-PA (Fujirebio) for detection of anti-TP antibodies; and BD Macro-Vue RPR Card Tests (Becton Dickinson) for detection of non-TP antibodies.
The clinical performance characteristics of Determine Syphilis TP for the detection of anti-TP antibodies were as follows:

| **Clinical performance characteristics in comparison with an agreed reference standard** | |
|---|---|
| Sensitivity %<br>(N=270) | 100% (95% CI: 98.6-100) |
| Specificity %<br>(N= 300) | 98.7% (95%CI: 96.6-99.6) |
| Invalid rate %<br>(N= 570) | 0.4% |
| Inter-reader variability %<br>(N= 570) | 1.2% |

**Analytical performance evaluation**

| **Analytical performance characteristics** | |
|---|---|
| Sensitivity during seroconversion on 1 seroconversion panel in comparison with a benchmark assay (LIASION Treponema Screen CLIA) | Of a total of 9 specimens, 5 were detected by the assay under evaluation versus 4 specimens detected by the benchmark assay. |
| Analytical sensitivity on a performance panel (AccuSet Syphilis Performance Panel 0820-0300) | 20 of the 20 specimens were correctly classified. |
| Analytical sensitivity on dilutions of the WHO International Standard for human syphilitic IgG and IgM panel (NIBSC code 05/132) | The lowest concentration detected by the assay was 0.023 IU/mL on both lot numbers. |
| Lot to lot variation on a dilution panel | Lot to lot variation was within +/- 1 two-fold dilutions for 9 dilution series and 2 two-fold dilutions for 1 dilution series. |

**Operational characteristics and ease of use**

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or non-laboratory settings.
The assay was found easy to use by the operators performing the evaluation.

| **Key operational characteristics** | |
|---|---|
| Specimen type and volume | 50 µL of serum, EDTA plasma or EDTA whole blood (venous or capillary) |
| Number of steps* | For serum and plasma specimens: 1 step in total<br>For whole blood specimens: 2 steps in total (add specimen, add Chase buffer)<br>1 step with precision pipetting (for serum/plasma/venous whole blood) |
| Time to result | 15 minutes |
| Endpoint stability (interval) | 15 minutes (the test can be read between 15 and 30 minutes after the addition of the specimen) |
| Internal QC | Yes, Reagent addition control |

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for Determine Syphilis TP meets the WHO prequalification requirements.

# Labelling

1. **Labels**
2. **Instructions for use**

## 1. Labels

### 1.1 Pouch label for product code 7D2452

DETERMINE™

# SYPHILIS TP

4 571226 474945

2°C – 30°C

Σ 30

IVD

REF 7D2452

## EN

**Determine™** Syphilis TP is a visual read, qualitative immunoassay for the detection of antibodies to *Treponema pallidum*.
Chase buffer is required for whole blood testing.
For professional use only.

**Kit contains:**
3 *Treponema pallidum* antigen coated test cards.

## ES

**Determine™** Syphilis TP es un inmunoanálisis cualitativo de lectura visual para la detección de anticuerpos frente al *Treponema pallidum*.
Se requiere buffer de detección para todas las pruebas por sangre.
Solo para uso profesional.

**Contenido del equipo:**
3 tarjetas de ensayo recubiertas de antígenos del *Treponema pallidum*.

## FR

**Determine™** Syphilis TP est un dosage immunologique qualitatif, à lecture visuelle, pour la détection des anticorps dirigés contre le *Treponema pallidum*.
La solution tampon de migration est nécessaire pour tester les échantillons de sang total.
À usage professionnel uniquement.

**Le kit contient:**
3 tests recouverts d'antigène *Treponema pallidum*.

## PT

**Determine™** Sífilis TP é um imunoensaio qualitativo de leitura visual para a detecção de anticorpos contra *Treponema pallidum*.
É necessário o tampão de detecção para realizar análises em sangue total.
Exclusivamente para uso profissional.

**O kit contém:**
3 cartões de ensaio revestidos de antigénios *Treponema pallidum*.

**Abbott Diagnostics Medical Co., Ltd.**
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214, Japan
Tel +81 47 311 5750



241886/R1

**Determine**
**Syphilis TP for ROW**
30 Test Pouch Label

**PN:** 241886/R1

**Pouch Size:**
544mm(w) x 160mm(h)

**Label Artwork Size:**
204mm(w) x 132mm(h)

White

PMS 303

PMS 227

**1.2 Pouch label for product code 7D2453**

DETERMINE™

# SYPHILIS TP

4 571226 474952

2°C 30°C  Σ 100  IVD

REF 7D2453

## EN

**Determine™** Syphilis TP is a visual read, qualitative immunoassay for the detection of antibodies to *Treponema pallidum*.
Chase buffer is required for whole blood testing.
For professional use only.

**Kit contains:**
10 *Treponema pallidum* antigen coated test cards.

## ES

**Determine™** Syphilis TP es un inmunoanálisis cualitativo de lectura visual para la detección de anticuerpos frente al *Treponema pallidum*.
Se requiere buffer de detección para todas las pruebas por sangre.
Solo para uso profesional.

**Contenido del equipo:**
10 tarjetas de ensayo recubiertas de antígenos del *Treponema pallidum*.

## FR

**Determine™** Syphilis TP est un dosage immunologique qualitatif, à lecture visuelle, pour la détection des anticorps dirigés contre le *Treponema pallidum*.
La solution tampon de migration est nécessaire pour tester les échantillons de sang total.
À usage professionnel uniquement.

**Le kit contient:**
10 tests recouverts d'antigène *Treponema pallidum*.

## PT

**Determine™** Sífilis TP é um imunoensaio qualitativo de leitura visual para a detecção de anticorpos contra *Treponema pallidum*.
É necessário o tampão de detecção para realizar análises em sangue total.
Exclusivamente para uso profissional.

**O kit contém:**
10 cartões de ensaio revestidos de antigénios *Treponema pallidum*.

**Abbott Diagnostics Medical Co., Ltd.**
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214, Japan
Tel +81 47 311 5750



241887/R1

**Determine**
**Syphilis TP for ROW**
100 Test Pouch Label

**PN:** 241887/R1

**Pouch Size:**
544mm(w) x 160mm(h)

**Label Artwork Size:**
204mm(w) x 132mm(h)

White
PMS 303
PMS 227

**1.3 Box Artwork for product code 7D2453SET**

61.0

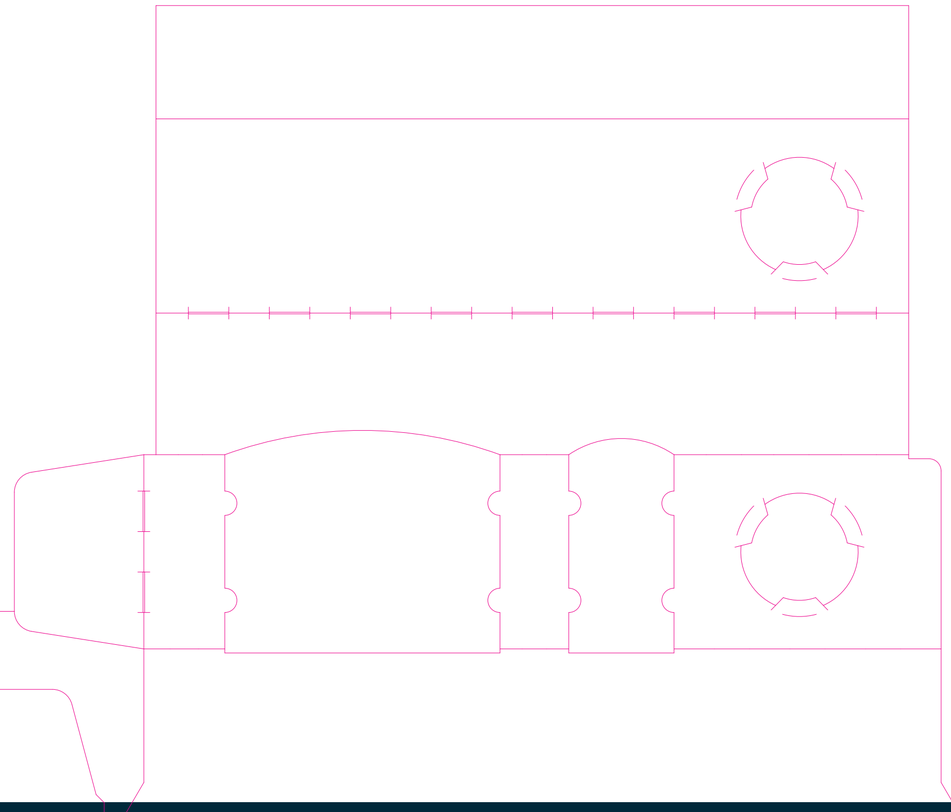
213.0

**Determine Syphilis TP SET**
100 Test Set Box

**PN:** 241888/R1

PMS 303

PMS 227



2°C–30°C 100 IVD

DETERMINE™
SYPHILIS TP SET

Abbott

1/4

162.0

DETERMINE™
# SYPHILIS TP SET

**EN**
**Determine™** Syphilis TP is a visual read, qualitative immunoassay for the detection of antibodies to *Treponema pallidum*.
For professional use only.

**ES**
**Determine™** Syphilis TP es un inmunoanálisis cualitativo de lectura visual para la detección de anticuerpos frente al *Treponema pallidum*.
Solo para uso profesional.

**FR**
**Determine™** Syphilis TP est un dosage immunologique qualitatif, à lecture visuelle, pour la détection des anticorps dirigés contre le *Treponema pallidum*.
À usage professionnel uniquement.

**PT**
**Determine™** Sífilis TP é um imunoensaio qualitativo de leitura visual para a detecção de anticorpos contra *Treponema pallidum*.
Exclusivamente para uso profissional.

2°C–30°C 100 IVD

REF 7D2453SET

Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi,
Chiba, 270-2214, Japan
+81 47 311 5750



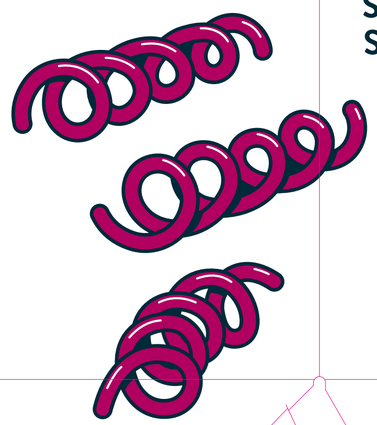
4 571226 474969

241888/R1

DETERMINE™
SYPHILIS TP SET

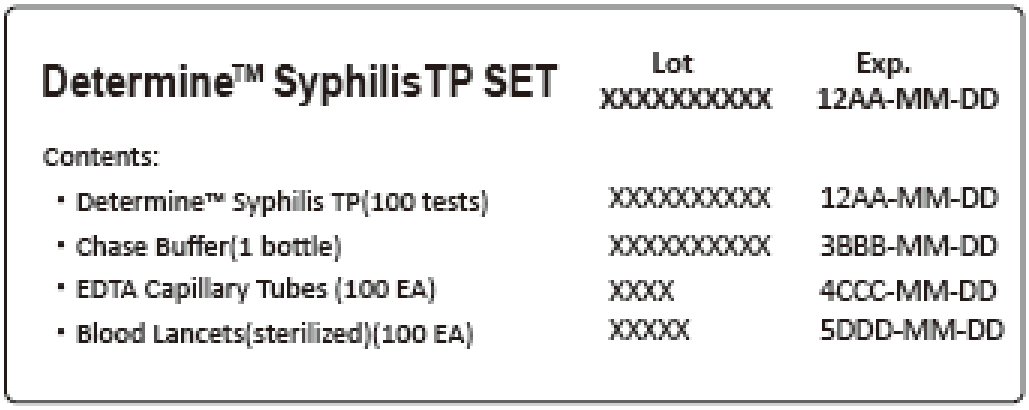
DETERMINE™
# SYPHILIS TP SET

**Lot/Exp. Label**

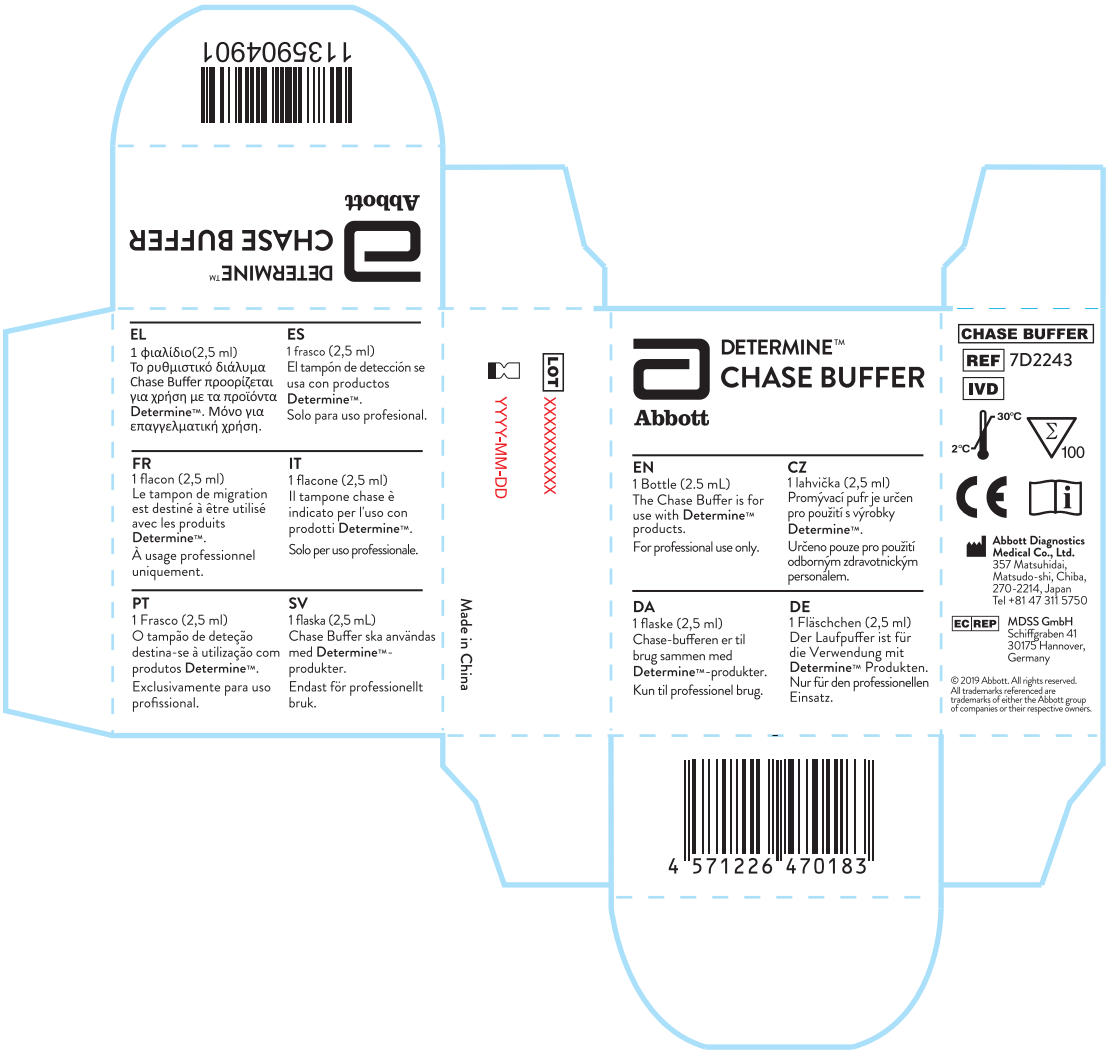


DETERMINE™
SYPHILIS TP SET

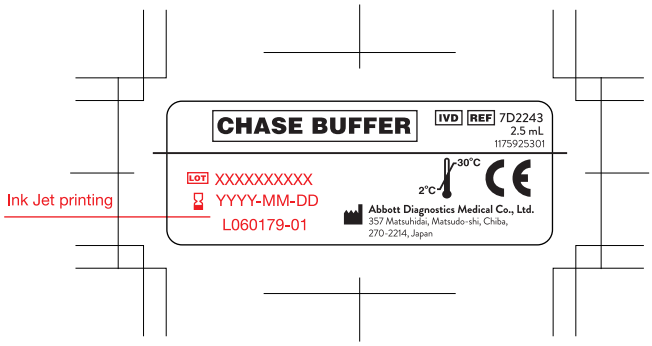
**1.4 Label for the box**




**1.5 Chase buffer labels**




| | |
|---|---|
| **Chase Buffer** Black<br>Box<br>Size: (W)22mm x (L)44mm x (H)56mm | **PN: 1135904901** |




**Chase Buffer:**
Bottle Label

**PN: 1175925301**

**Size:** 51.0 x 19.0 mm

Round Corner: 2R

Black

**1.6 Chase Buffer IFU**

1156173202

REF 7D2243

DETERMINE™

# CHASE BUFFER

Abbott

Key to symbols used/Používané symboly/Symbolforklaring/Erläuterung der verwendeten Symbole/
Πίνακας συμβόλων/Clave de los símbolos utilizados/Légende des symboles utilisés/
Legenda dei simboli utilizzati/Legenda dos símbolos utilizados/Symbolförklaring

2°C – 30°C Store at 2-30°C/Skladujte při teplotě 2-30°C/
Opbevares ved 2-30°C/Lagerung bei 2 bis 30°C/
Φυλάσσεται στους 2-30°C/Almacenar a 2-30°C/
Conserver entre 2 et 30°C/Conservare a 2-30°C/
Conservar a 2°C-30°C/Förvaras vid 2-30°C

CHASE BUFFER Chase Buffer/Promývací pufr/
Chase-buffer/Laufpuffer/
Ρυθμιστικό διάλυμα σταθεροποίησης/
Tampón de detección/
Tampon de migration/
Tampone chase/Tampão de deteção/
Fixeringsbuffert

IVD For *In Vitro* Diagnostic Use/Pro diagnostické účely *in vitro*/
Til in vitro-diagnostisk brug/
Der Test ist nur für die In-vitro-Diagnos vorgesehen/
Για *in vitro* διαγνωστική χρήση/Para uso en diagnósticos *in vitro*/
Pour usage diagnostic *in vitro*/Per uso diagnostico *In vitro*/
Para uso em Diagnóstico *In Vitro*/För diagnostisk användning *in vitro*

## EN

### Name and Intended Use
The Chase Buffer is for use with **Determine**™ products.
Refer to the package insert of the diagnostic assay for full procedure.
When adding Chase Buffer to the sample pad, hold the bottle vertically.
One bottle of Chase Buffer can be used for 100 tests.
For professional use only.

### Contents
**CHASE BUFFER** 1 Bottle (2.5 mL) Chase Buffer prepared in phosphate buffer.
Preservatives: Antimicrobial Agents.

### Storage Instruction
Recap and store the chase buffer at 2-30°C to avoid evaporation or spillage.

### Advice Line
For further information, please contact your distributor, or call Abbott Technical Specialists:

Africa: Tel: +27 10 500 9700
Email: arcis.techsupport@abbott.com
Russia & CIS: Tel: +44 161 483 9032
Email: arcis.techsupport@abbott.com
Asia Pacific: Tel: +61 7 3363 7100
Email: AP.TechSupport@abbott.com
Europe & Middle East: Tel: +44 161 483 9032
Email: EME.TechSupport@abbott.com
Latin America: Tel: +57 1 482 4033
Email: LA.TechSupport@Abbott.com

## CZ

### Název a použití
Promývací pufr je určen pro použití s výrobky **Determine**™.
Úplný postup naleznete v příbalovém listu diagnostické soupravy.
Při přidávání pufru do testovací kazety držte lahvičku ve vertikální poloze.
Jedna lahvička pufru vystačí na 100 testů.
Určeno pouze pro použití odborným zdravotnickým personálem.

### Složení
**CHASE BUFFER** 1 lahvička (2,5 ml) - Promývací pufr připravený ve fosfátovém pufru.
Konzervační činidla: antimikrobiální látky.

### Pokyny pro skladování
Promývací pufr znovu uzavřete, aby nedošlo k jeho odpařování nebo vylití, a skladujte při teplotě 2–30°C.

### Informační Linka
Pro další informace prosím kontaktujte svého distributora, nebo volejte Abbott Techničtí specialisté:

Africe: Tel: +27 10 500 9700
Email: arcis.techsupport@abbott.com
Rusku a Společenství nezávislých států: Tel: +44 161 483 9032
Email: arcis.techsupport@abbott.com
Asie a Tichomoří: Tel: +61 7 3363 7100
Email: AP.TechSupport@abbott.com
Evropa a Střední Východ: Tel: +44 161 483 9032
Email: EME.TechSupport@abbott.com
Latinská Amerika: Tel: +57 1 482 4033
Email: LA.TechSupport@Abbott.com

## DA

### Betegnelse og anvendelse
Chase-bufferen er til brug sammen med **Determine**™-produkter.
Se indlægssedlen til den diagnostiske analyse for den fulde procedure.
Hold flasken lodret, når Chase Buffer påføres prøvefeltet.
En flaske Chase Buffer kan bruges til 100 tests.
Kun til professionel brug.

### Indhold
**CHASE BUFFER** 1 flaske (2,5 ml) chase-buffer i fosfatbuffer.
Konserveringsmiddel: antimikrobielle midler.

### Opbevaringsinstruktion
Sæt hætte på og opbevar chase-bufferen ved 2-30°C for at undgå fordampning eller spild.

### Rådgivning
Yderligere oplysninger fås ved at kontakte forhandleren eller ringe til Abbott Technical Specialists:

Afrika: Tlf.: +27 10 500 9700
E-mail: arcis.techsupport@abbott.com
Rusland og CIS: Tlf.: +44 161 483 9032
E-mail: arcis.techsupport@abbott.com
Asien/Stillehavet: Tlf.: +61 7 3363 7100
E-mail: AP.TechSupport@abbott.com
Europa og Mellemøsten: Tlf.: +44 161 483 9032
E-mail: EME.TechSupport@abbott.com
Latinamerika: Tlf.: +57 1 482 4033
E-mail:LA.TechSupport@Abbott.com

## DE

### Produktbezeichnung und Verwendungszweck
Der Laufpuffer ist für die Verwendung mit **Determine**™ Produkten.
Informationen zur vollständigen Testdurchführung entnehmen Sie bitte der Packungsbeilage des diagnostischen Tests.
Halten Sie die Flasche Laufpuffer senkrecht, wenn Sie den Puffer auf das Proben-Pad geben.
Eine Flasche Laufpuffer kann für 100 Tests verwendet werden.
Nur für den professionellen Einsatz.

### Inhalt
**CHASE BUFFER** 1 Fläschchen (2,5 ml) Laufpuffer, hergestellt in Phosphatpuffer.
Konservierungsmittel: Bakteriostatika.

### Lagerungsvorschriften
Verschließen Sie den Laufpuffer wieder und lagern Sie ihn bei 2-30°C, um Verdunstung oder Verschütten zu vermeiden.

### Infotelefon
Weitere Informationen erhalten Sie von Ihrem Vertreiber oder vom technischen Kundendienst von Abbott:

Afrika: Tel: +27 10 500 9700
E-Mail: arcis.techsupport@abbott.com
Russland & GUS: Tel: +44 161 483 9032
E-Mail: arcis.techsupport@abbott.com
Asien/Pazifikraum: Tel: +61 7 3363 7100
E-Mail: AP.TechSupport@abbott.com
Europa & Mittlerer/ Naher Osten: Tel: +44 161 483 9032
E-Mail: EME.TechSupport@abbott.com
Lateinamerika: Tel: +57 1 482 4033
E-Mail: LA.TechSupport@Abbott.com

## EL

### Ονομασία και σκοπός χρήσης
Το ρυθμιστικό διάλυμα Chase Buffer προορίζεται για χρήση με τα προϊόντα **Determine**™. Ανατρέξτε στο αντίστοιχο φύλλο οδηγιών χρήσης κάθε διαγνωστικής εξέτασης για την πλήρη διαδικασία.
Κατά την προσθήκη ρυθμιστικού διαλύματος Chase Buffer στο χώρο υποδοχής του δείγματος, κρατάτε τη φιάλη κατακόρυφη.
Μία φιάλη ρυθμιστικού διαλύματος Chase Buffer επαρκεί για 100 τεστ.
Μόνο για επαγγελματική χρήση.

### Περιεχόμενα
**CHASE BUFFER** 1 φιαλίδιο (2,5 mL) ρυθμιστικού διαλύματος σταθεροποίησης που παρασκευάζεται σε ρυθμιστικό διάλυμα φωσφωρικού άλατος.
Συντηρητικά: αντιμικροβιακοί παράγοντες.

### Οδηγίες αποθήκευσης
Επιπωματίστε εκ νέου και φυλάξτε το ρυθμιστικό διάλυμα chase σε θερμοκρασία 2-30°C για την αποφυγή της εξάτμισης ή της διαρροής.

### Γραμμή βοήθειας
Για περισσότερες πληροφορίες επικοινωνήστε με τον τοπικό διανομέα του προϊόντος, ή καλέστε το Εξειδικευμένο Τεχνικό Ιατρικό Προσωπικό της Abbott:

Αφρική: Τηλ: +27 10 500 9700
Email: arcis.techsupport@abbott.com
Ρωσία και & ΚΑΚ: Τηλ: +44 161 483 9032
Email: arcis.techsupport@abbott.com
Ασία Ειρηνικός: Τηλ: +61 7 3363 7100
Email: AP.TechSupport@abbott.com
Ευρώπη & Μέση Ανατολή: Τηλ: +44 161 483 9032
Email: EME.TechSupport@abbott.com
Λατινική Αμερική: Τηλ: +57 1 482 4033
Email: LA.TechSupport@Abbott.com

## ES

### Nombre y finalidad de uso
El tampón de detección se usa con productos **Determine**™. Consulte el folleto del ensayo de diagnóstico para obtener información de todo el procedimiento.
Sostenga el bote en posición vertical cuando añada el tampón de detección Chase Buffer a la almohadilla de muestra.
Un bote de tampón de detección Chase Buffer se puede utilizar para 100 pruebas.
Solo para uso profesional.

### Contenido:
**CHASE BUFFER** 1 frasco (2,5 ml) de tampón de detección preparado en tampón fosfato.
Conservantes: agentes antimicrobianos.

### Instrucciones de almacenamiento
Vuelva a tapar y almacene el buffer de detección a 2-30°C para evitar evaporaciones o derrames.

### Asistencia
Para obtener mas informacion, pongase en contacto con su distribuidor, o llame a los especialistas tecnicos de Abbott:

Africa: Tel: +27 10 500 9700
Correo electronico: arcis.techsupport@abbott.com
Rusia y CIS: Tel: +44 161 483 9032
Correo electronico: arcis.techsupport@abbott.com
Asia del Pacifico: Tel: +61 7 3363 7100
Correo electronico: AP.TechSupport@abbott.com
Europa y Oriente Medio: Tel: +44 161 483 9032
Correo electronico: EME.TechSupport@abbott.com
Latinoamerica: Tel: +57 1 482 4033
Correo electronico: LA.TechSupport@Abbott.com

## FR

### Dénomination et domaine d'application
Le tampon de migration est destiné à être utilisé avec les produits **Determine**™.
Reportez-vous à la notice du test de diagnostic pour connaître tous les détails de la procédure.
Au moment de déposer le tampon de migration sur la zone de dépôt, maintenir le flacon à la verticale.
Un flacon de tampon de migration est suffisant pour la réalisation de 100 tests.
À usage professionnel uniquement.

### Contenu
**CHASE BUFFER** 1 flacon (2,5 ml) de tampon de migration préparé dans du tampon phosphate.
Conservateurs : Agents antimicrobiens.

### Consignes de conservation
Refermez et conservez la solution tampon de migration entre 2 et 30°C pour prévenir toute évaporation ou tout déversement.

### Conseil
Pour de plus amples informations, contactez votre distributeur ou appeler les techniciens specialistes de Abbott:

Afrique: Tel: +27 10 500 9700
Adresse elec.e: arcis.techsupport@abbott.com
Russie et Ex-pays de l'URSS: Tel: +44 161 483 9032
Adresse elec.e: arcis.techsupport@abbott.com
Asie et Pacifique: Tel: +61 7 3363 7100
Adresse elec.e: AP.TechSupport@abbott.com
Europe et Moyen-Orient: Tel: +44 161 483 9032
Adresse elec.e:EME.TechSupport@abbott.com
Amerique latine: Tel: +57 1 482 4033
Adresse elec.e: LA.TechSupport@Abbott.com

## IT

### Denominazione e finalità d'uso
Il tampone chase è indicato per l'uso con prodotti **Determine**™.
Per la procedura completa, consultare il foglietto illustrativo del test diagnostico.
Quando si aggiunge il Chase Buffer al supporto assorbente del campione, tenere il flacone in posizione verticale.
Un flacone di tampone è sufficiente per 100 test.
Solo per uso professionale.

### Contenuto
**CHASE BUFFER** 1 flacone (2,5 ml) di tampone chase (tampone di spinta) preparato in tampone fosfato.
Conservanti: Sostanze antimicrobiche.

### Istruzioni di conservazione
Richiudere e conservare il tampone chase (tampone di migrazione) a 2-30°C per evitare l'evaporazione o la fuoriuscita.

### Assistenza
Per ulteriori informazioni, contattare il proprio distributore o il servizio di assistenza tecnica di Abbott ai seguenti recapiti:

Africa: Tel.: +27 10 500 9700
E-mail: arcis.techsupport@abbott.com
Russia e CIS: Tel.: +44 161 483 9032
E-mail: arcis.techsupport@abbott.com
Asia Pacifico: Tel.: +61 7 3363 7100
E-mail: AP.TechSupport@abbott.com
Europa e Medio Oriente: Tel.: +44 161 483 9032
E-mail: EME.TechSupport@abbott.com
America Latina: Tel.: +57 1 482 4033
E-mail: LA.TechSupport@Abbott.com

## PT

### Nome e aplicação diagnóstica
O tampão de deteção destina-se à utilização com produtos Determine™.
Consulte o folheto informativo do ensaio de diagnóstico para o procedimento completo.
Ao adicionar a solução tampão de deteção à área de amostra, segure verticalmente no frasco.
Um frasco de solução tampão de deteção pode ser utilizado para 100 testes.
Exclusivamente para uso profissional.

### Conteúdo
**CHASE BUFFER** 1 Frasco (2,5 ml) de tampão de detecção preparado em tampão fosfato.
Conservantes: agentes antimicrobianos.

### Instruções de armazenamento
Volte a colocar a tampa e a armazenar o tampão de deteção entre 2 a 30°C para evitar evaporação ou derrame.

### Linha de Apoio
Para informacao adicional, por favor contacte o seu distribuidor, ou ligue para os Tecnicos Especialistas da Abbott.

Africa: Tel: +27 10 500 9700
Email: arcis.techsupport@abbott.com
Russia & CES: Tel: +44 161 483 9032
Email: arcis.techsupport@abbott.com
Asia Pacifico: Tel: +61 7 3363 7100
Email: AP.TechSupport@abbott.com
Europa & Medio Oriente: Tel: +44 161 483 9032
Email: EME.TechSupport@abbott.com
America Latina: Tel: +57 1 482 4033
Email: LA.TechSupport@Abbott.com

## SV

### Namn och användningsområde
Chase Buffer ska användas med **Determine**™-produkter.
Se bipacksedeln i det diagostiska testet för fullständig procedur.
Håll flaskan lodrätt när du tillsätter Chase Buffert till provdynan.
En flaska Chase Buffert räcker till 100 tester.
Endast för professionellt bruk.

### Innehåll
**CHASE BUFFER** 1 flaska (2,5 mL) fixeringsbuffert som preparerats i fosfatbuffert.
Konserveringsmedel: antimikrobiella agens.

### Instruktioner förvaring
Sätt på locket och förvara chase-buffer i 2–30°C för att undvika avdunstning och spill.

### Rådgivning
För ytterligare information, vanligen kontakta din leverantor eller Abbott Technical Specialists:

Afrika: Tel: +27 10 500 9700
E-post: arcis.techsupport@abbott.com
Ryssland & OSS: Tel: +44 161 483 9032
E-post: arcis.techsupport@abbott.com
Asien Stillahavsområdet: Tel: +61 7 3363 7100
E-post: AP.TechSupport@abbott.com
Europa & Mellanostern: Tel: +44 161 483 9032
E-post: EME.TechSupport@abbott.com
Latinamerika: Tel: +57 1 482 4033
E-post: LA.TechSupport@Abbott.com

CE

**Abbott Diagnostics Medical Co., Ltd.**
357 Matsuhidai, Matsudo-shi, Chiba,
270-2214, Japan
Tel +81 47 311 5750

EC REP MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany



**Chase Buffer** Black
Package Insert
Size: 176 x 250 mm

**PN: 1156173202**

**1.7 EDTA Capillary Tube label**

EDTA Capillary Tubes

Black

7D2222
Label

Size: 3.5” x 3”

PN: 242047/R11

Date of Last Revision:
2021/02/05

Abbott

# EDTA CAPILLARY TUBES

REF 7D2222

100 Each

IVD

242047/R11

**EN** EDTA Capillary Tubes are to be used in the fingerstick collection of whole blood specimens for use in **Determine**™ products. Refer to the package insert of the diagnostic assay for full procedure. Bring to room temperature before opening the cap. For professional use only.

**Caution: Risk of glass breakage and injury. Handle with care. Store in a dry location.**

**ES** Los tubos de capilares con EDTA se utilizan en la obtención mediante punción dactilar de muestras de sangre total para productos **Determine**™. Consulte el folleto del ensayo de diagnóstico para obtener información de todo el procedimiento. Deben estar a temperatura ambiente antes de abrir la tapa. Solo para uso profesional.

**Precaución: Riesgo de rotura de cristales y lesiones. Manipular con cuidado. Almacenar en un lugar seco.**

**FR** Les tubes capillaires EDTA sont utilisés pour recueillir des échantillons de sang total par piqûre du doigt pour les produits **Determine**™. Reportez-vous à la notice du test de diagnostic pour connaître tous les détails de la procédure. Amenez à température ambiante avant d'ouvrir le bouchon. À usage professionnel uniquement.

**Attention: risque de blessure par éclats de verre. À manipuler avec soin. À conserver dans un endroit sec.**

**PT** Os tubos capilares EDTA devem ser utilizados na colheita por picada no dedo de amostras de sangue total para utilização nos produtos **Determine**™. Consulte o folheto informativo do ensaio de diagnóstico para o procedimento completo. Coloque à temperatura ambiente antes de abrir a tampa. Exclusivamente para uso profissional.

**Atenção: risco de quebra do vidro e de ferimentos. Manusear com cuidado. Armazenar em local seco.**

2°C 30°C

4 571226 470176

**Advice Line Telephone number**

| | |
|---|---|
| Europe & Middle East: | + (44) 161 483 9032 |
| Asia Pacific: | + (61) 7 3363 7100 |
| Africa: | + (27) 10 500 9700 |
| Russia & CIS: | + (44) 161 483 9032 |
| Latin America: | + (57) 1 482 4033 |



Produced by:
Drummond Scientific Co.
Broomall, PA USA 19008

**Abbott Diagnostics Medical Co., Ltd.**
357 Matsuhidai, Matsudo-shi,
Chiba, 270-2214, Japan

Exp.

Lot

**1.8 Lancet label**

6.4x4.4x7.5cm

▼ Pull down to dispense ▼

Litetouch™
Blood Lancets

Product Code:
7D2233

medicore™
Nashville, TN
1-800-327-8894

LOT :

:

CE 0197 STERILE R

Single Use Only

Tianjin Huahong Technology Co., Ltd.
A01, Plant B, No 278, Hangkong Road,
Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin, 300308, China
Tel:+86 21 5854 2656

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726

*Made in China*

6 957138 600173

REV.05 2018/10 JP

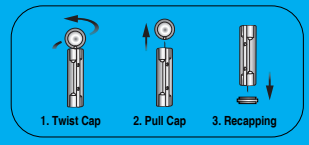
Litetouch™
Blood Lancets

**100** Sterile Lancets

- Fine gauge, tri-bevel tip for virtually painless sampling
- Consistent depth penetration
- Universal design fits almost all lancing devices

**28** gauge

## Instructions for Use:




**NOTE: If using a lancing device, follow instructions for use of that device.**

1. Twist lancet-cap to separate. **NOTE:** Do not use if cap appears damaged or loose before twisting.
2. Pull off the cap to expose needle tip. Save cap for later use (step 04).
3. Perform lancing procedure using medically accepted aseptic techniques.
4. After procedure, help minimize accidental needle-stick by pressing needle-tip into flat side of the saved cap.
5. Discard used lancets in a suitable container and/or in accordance with local requirements.

## 2. Instructions for use[1]

[1] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

# DETERMINE™ SYPHILIS TP

REF 7D2452/7D2453/
7D2453SET

October 2022
24xxxx/R1

**Key to symbols used/**
**Clave de los símbolos utilizados/**
**Légende des symboles utilisés/**
**Designação dos símbolos utilizados**


Store at 2-30ºC/
Guardar a temperaturas entre 2 y 30ºC/
Conserver entre 2-30ºC/
Armazenar a 2-30ºC

REF Catalogue Number/
Número de catálogo/
Référence catalogue/
N° de Catálogo

Do not reuse/
No reutilizar/
Ne pas réutiliser/
Não reutilizar

IVD *In Vitro* Diagnostic Medical Device/
Dispositivo de diagnóstico médico *in vitro*/
Dispositif médical de diagnostic *In Vitro*/
Dispositivo Médico para Diagnóstico *In Vitro*

Do not use if package is damaged/
No utilizar si el envase está roto/
Ne pas utiliser si l'emballage est endommagé/
Não utilizar caso a embalagem esteja danificada

Keep away from sunlight/
No exponer a la luz solar/
Conserver à l'abri de la lumière du soleil/
Manter afastado da luz solar

Σ 30 Contains Sufficient for 30 tests/
Contiene material suficiente para realizar 30 pruebas/
Permet de réaliser 30 tests/
Contém o suficiente para 30 testes

Σ 100 Contains Sufficient for 100 tests/
Contiene material suficiente para realizar 100 pruebas/
Permet de réaliser 100 tests/
Contém o suficiente para 100 testes

Consult instructions for use/
Consulte las instrucciones de uso/
Veuillez consulter le mode d'emploi/
Consulte as instruções de utilização

## Advice Line

For further information, please contact your distributor, or call to one of the following Abbott Product Support Care Centers:

| Region | Phone | E-Mail Address |
|---|---|---|
| Europe | + (44) 161 483 9032 | EME.TechSupport@abbott.com |
| Middle East | +(965) 2202 2828 | EME.TechSupport@abbott.com |
| Asia Pacific | + (61) 7 3363 7711 | AP.TechSupport@abbott.com |
| Africa | + (27) 10 500 9700 | arcis.techsupport@abbott.com |
| Russia & CIS | +(7) 499 403 9512 | arcis.techsupport@abbott.com |
| Latin America | +(57) 601 482 4033 | LA.TechSupport@abbott.com |

## Línea de consulta

Para mayor información, por favor contacte a su distribuidor, o llame a uno de los siguientes Centros de Soporte al Producto de Abbott:

| Región | Teléfono | Dirección de correo electrónico |
|---|---|---|
| Europa | + (44) 161 483 9032 | EME.TechSupport@abbott.com |
| Medio Oriente | +(965) 2202 2828 | EME.TechSupport@abbott.com |
| Asia Pacífica | + (61) 7 3363 7711 | AP.TechSupport@abbott.com |
| Africa | + (27) 10 500 9700 | arcis.techsupport@abbott.com |
| Rusia, & CEI | +(7) 499 403 9512 | arcis.techsupport@abbott.com |
| América Latina | +(57) 601 482 4033 | LA.TechSupport@abbott.com |

## Ligne consacrée aux conseils

Pour de plus amples renseignements, s'il vous plaît contactez votre distributeur ou appelez l'un des centres de produits de support Abbott:

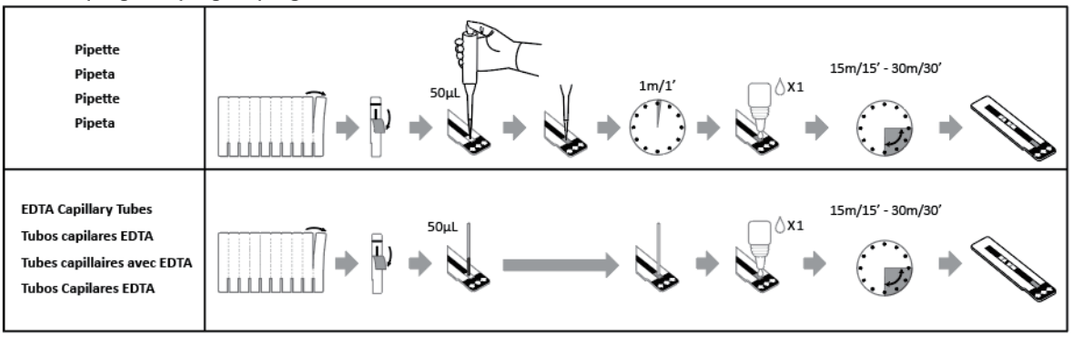
| Region | Phone | E-Mail Address |
|---|---|---|
| Europe | + (44) 161 483 9032 | EME.TechSupport@abbott.com |
| Moyen-Orient | +(965) 2202 2828 | EME.TechSupport@abbott.com |
| Asie Pacifique | + (61) 7 3363 7711 | AP.TechSupport@abbott.com |
| Afrique | + (27) 10 500 9700 | arcis.techsupport@abbott.com |
| Russie & CEI | +(7) 499 403 9512 | arcis.techsupport@abbott.com |
| Amerique Latine | +(57) 601 482 4033 | LA.TechSupport@abbott.com |

## Linha de Aconselhamento

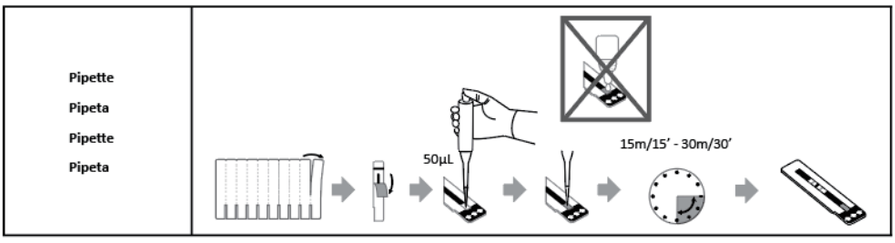
Para mais informações, por favor contacte o seu distribuidor, ou ligue para um dos seguintes Centros de Suporte ao Produto Abbott:

| Região | Telefone | Direção do e-mail |
|---|---|---|
| Europa | + (44) 161 483 9032 | EME.TechSupport@abbott.com |
| Oriente Médio | +(965) 2202 2828 | EME.TechSupport@abbott.com |
| Ásia-Pacífico | + (61) 7 3363 7711 | AP.TechSupport@abbott.com |
| África | + (27) 10 500 9700 | arcis.techsupport@abbott.com |
| Rússia e CEI | +(7) 499 403 9512 | arcis.techsupport@abbott.com |
| América Latina | +(57) 601 482 4033 | LA.TechSupport@abbott.com |

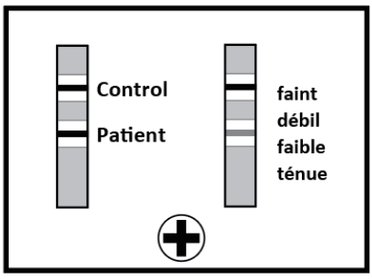
**Whole Blood / Sangre Total / Sang Total / Sangue Total**



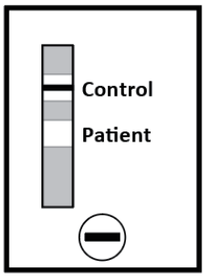

**Serum, Plasma / Suero, Plasma / Sérum, Plasma / Soro, Plasma**



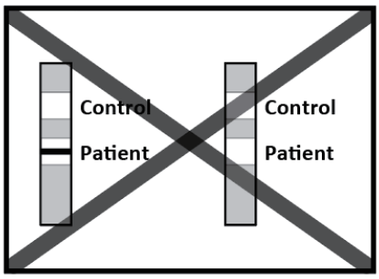

**Positive / Positivo**
**Positif / Positivo**




**Negative / Negativo**
**Négatif / Negativo**




**Invalid / No válido**
**Non valide / Inválido**




**Abbott Diagnostics Medical Co., Ltd.**
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214 Japan
Tel +81 47 311 5750

EN

October 2022
24xxxx/R1

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

## NAME AND INTENDED USE

**Determine**™ Syphilis TP is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies to *Treponema pallidum*, which is the bacteria that causes syphilis infection, in human capillary and venous whole blood, plasma or serum. The test is intended as an aid to detect antibodies to *Treponema pallidum* from infected individuals. The test is for professional use only. The device is not automated.

## SUMMARY AND EXPLANATION OF THE TEST

Syphilis is caused by infection with the bacterium *Treponema pallidum*[1] which can be transmitted congenitally or by sexual contact. The disease can evolve into a latent phase in which syphilis is clinically inapparent. Serologic tests (nontreponemal specific and treponemal specific) are currently the primary method for syphilis diagnosis and management. Nontreponemal tests (VDRL, RPR, etc.) are generally used for screening, and treponemal tests (TPHA/TPPA, FTA-ABS, etc.) are used as confirmatory tests.

## BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine Syphilis TP is an immunochromatographic test for the qualitative detection of antibodies to *Treponema pallidum* antigens.
A Specimen is added to the sample pad. The specimen migrates through the conjugate pad and mixes with the *Treponema pallidum* antigen-selenium colloid conjugate. This mixture continues to migrate through the solid phase to the immobilized *Treponema pallidum* antigens at the patient window site.
If antibodies to *Treponema pallidum* are present in the specimen, the antibodies bind to the *Treponema pallidum* antigen-selenium colloid and the *Treponema pallidum* antigen at the patient window, forming a red bar at the patient window site.
If antibodies to *Treponema pallidum* are not present, the *Treponema pallidum* antigen-selenium colloid flows past the patient window, and no red bar is formed at the patient window site.
To ensure assay validity, a procedural control bar is incorporated in the assay device at the control window.

## CONTENTS

- **Determine** Syphilis TP, 30 Tests (7D2452): 3 cards (10 tests/card) *Treponema pallidum* antigen coated.
- **Determine** Syphilis TP, 100 Tests (7D2453): 10 cards (10 tests/card) *Treponema pallidum* antigen coated.
- **Determine** Syphilis TP SET (7D2453SET) 100 Tests for testing whole blood samples
  - **Determine** Syphilis TP (7D2453) 10 cards (10 tests/card) *Treponema pallidum* antigen coated.
  - Chase Buffer (7D2243) 1 bottle of 2.5ml
  - EDTA Capillary Tubes (7D2222) 1 pack for 100 tests
  - Blood Lancet (sterilized) (7D2233) 1 box for 100 tests

## ACCESSORIES (required but not provided)

**For testing Whole Blood samples**

- 1 Bottle (2.5 mL) Chase Buffer (7D2243) containing phosphate buffered saline, preservative and antimicrobial agent.

**For testing Whole Blood samples (fingerstick assay)**

- EDTA Capillary Tubes (7D2222)

**Materials Required But Not Provided**

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab and gauze pad
- Single use sterile lancet (for fingerstick method)

## WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.
For professional use only.
Safety data sheet available for professional user on request.

## CAUTION

This product contains *Treponema palladium* sourced potentially infectious components. Refer to the **CONTENTS** section of this package insert. No known test method can offer complete assurance that products derived from microorganisms will not transmit infection.
Therefore, it is recommended that the test device considered potentially infectious and handled with appropriate biosafety practices.[2,3]
When handling specimens and reagents, use appropriate biosafety practices. These precautions include, but are not limited to the following:

- Wear gloves.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect all spills of specimens or reagents using suitable disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectant.[5]
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations.[5]

## STORAGE

Store Determine Syphilis TP Test Cards and Chase Buffer at 2-30°C until expiration date. After open the Chase Buffer, recap and store at 2-30°C to avoid evaporation or spillage.

- When handled and stored as directed, kit components are stable until the expiration date. Do not use kit components beyond expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close.
- Do not use devices that have become wet or the packaging has become damaged.

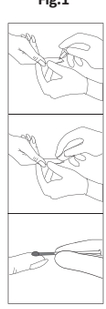
## SPECIMEN COLLECTION

**Serum, Plasma, and Whole Blood Collection by Venipuncture**
Use EDTA collection tubes for whole blood and plasma specimens.

- Collect human whole blood by aseptic venipuncture
- To obtain serum, separate from the clot. To obtain plasma, separate from the packed cells. Separate specimens as soon as possible to avoid any hemolysis.

**Whole Blood Collection by Fingerstick[4] (See Fig.1)**
Use EDTA Capillary Tubes (7D2222).
**CAUTION:** Glass capillaries may be damaged during transportation or when in use. Handle with care in order to avoid injury when removing from the package as well as during use and during disposal.

**Fig.1**



Before collecting a fingerstick specimen, place an EDTA capillary tube on a clean dry surface.

1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused) for adults and children older than one year. Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
2. Clean fingertip with alcohol; allow to air dry.
3. Position the hand palm-side up. Use a new lancet for each person. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose the lancet in an appropriate biohazard sharps container.
4. Wipe away the first drop of blood with a sterile gauze pad.
5. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times.

6. Touch the tip of the EDTA Capillary Tube to the drop of blood. Avoid air bubbles. Fill the tube with blood up to between the two marked lines (50 µL).

## SPECIMEN STORAGE

- Store serum and plasma specimens at 2-8°C and run the test within 7 days of collection. If testing is delayed more than 7 days, freeze the specimen at -20°C or colder.
- Avoid repeated freeze/thaw cycles.
- If serum or plasma specimens show particulate matter or turbidity, centrifuge at 10,000g for 5 minutes at room temperature before sampling. Carefully take the 50 µL test sample from the supernatant. If a lipid layer is formed on the surface of the liquid, ensure that the sample is taken from the clear liquid below that layer.
- For whole blood collected by venipuncture, store at 2-8°C. Do not freeze whole blood specimens. Run the test within 7 days of collection.
- For whole blood collected by fingerstick, test immediately.

## TEST PROCEDURE

Test at 15- 40 °C
**NOTE:**

- To preserve the lot number which appears on the left side of the test card, remove individual test strips starting from the right side of the test card. The lot number and expiry date are not printed on the individual test strips.
- After removing the protective foil cover from each test strip, start the assay within 2 hours
- For serum or plasma, ensure thorough mixing of sample prior to use. For whole blood sample, mix well by gentle inversion of the tube immediately before testing.
- Running the test in high temperature/low humidity may affect the appearance of the patient bar. If the test strip is partially dried and difficult to read at 15 to 30minutes, the test should be repeated using a new test strip and result read at 15 minutes.
  When the test strip is partially dried, it appears as mixed white spot and grayish area.
- If serum or plasma sample does not flow or shows abnormal flow, such as stopping in the middle of the window, centrifuge the specimen and repeat the test with a new test strip.

1. Remove the desired number of test strips from the 10 tests card by bending and tearing at the perforation.
2. Label or write the patient identification on the top white area of the device.
3. Remove the protective foil cover from each test.
   - After removing the protective foil cover from each test strip, start the assay within 2 hours.
4. **For serum or plasma samples:**
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 15 minutes (up to 30 minutes) and read result.
5. **For whole blood (venipuncture) samples:**
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait one minute, then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically
   c. Wait a minimum of 15 minutes (up to 30 minutes) and read result.
6. **For whole blood (fingerstick) samples:**
   a. Place the capillary tube containing the blood sample to the middle of the sample pad (marked by the arrow symbol) at an upright (vertical) position.
   b. Wait until blood is transferred from the capillary tube to the sample pad. Then immediately apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   **Caution:** do not lift the capillary tube from the sample pad before all the blood has been transferred - a bubble may form which will prevent the complete transfer of sample and invalidate the test. It may take more than one minute for full transfer of the sample.
   c. Dispose the used capillary tube as biohazardous material according to local regulations.
   d. Wait a minimum of 15 minutes (up to 30 minutes) and read result.

## QUALITY CONTROL

To ensure assay validity, a procedural control is incorporated in the device and is labeled "Control". If the control bar does not turn red by assay completion, the test result is invalid. Repeat the test using a new test strip.

## INTERPRETATION OF RESULTS

**NOTES:**

- Interpret any visible red bar (even very faint) in the window as a valid result.
- The test result is reactive even if the patient bar appears lighter or darker than the control bar.
- A test which gives very high background should be considered invalid.
- If an invalid test result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support.

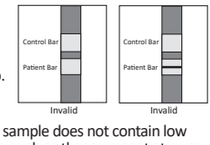
**POSITIVE (Two Bars)**
Red bars appear in both the control window (labeled "Control") and the patient window (labeled "Patient") of the strip. Any visible red bar in the patient window should be interpreted as positive.

Positive

**NEGATIVE (One Bar)**
One red bar appears in the control window of the strip (labeled "Control"), and no red bar appears in the patient window of the strip (labeled "Patient").

Negative

**INVALID (No Control Bar)**
If there is no red bar in the control window of the strip, and even if a red bar appears in the patient window of the strip, the result is invalid. Repeat the test using a new test strip.



Invalid Invalid

## LIMITATIONS OF THE PROCEDURE

- No test provides absolute assurance that a sample does not contain low levels of antibodies to *Treponema pallidum*, such as those present at a very early stage of infection, or antibodies with low reactivity to the *Treponema pallidum* antigens. Therefore, a negative result at any time does not preclude the possibility of exposure to infection with syphilis.
- A non-reactive result at any time does not preclude the possibility of exposure to or infection with syphilis.
- Biotin treatment higher than 200mg per day may lead to decreased Control Bar intensity. Biotin concentrations up to 750 ng/mL in serum or plasma does not impact the Control Bar. There is no impact to the patient bar.

**PERFORMANCE CHARACTERISTICS**
**SPECIFICITY AND SENSITIVITY**

Serum specimens from 1133 cases of non-syphilis and 266 cases of syphilis from three clinical sites in Japan were tested by Determine Syphilis TP (Table I).

**Table I**
**Specificity and Sensitivity of Determine™ Syphilis TP for Detection of Syphilis**

| | Population | Number of Specimens Tested | **Determine™** Syphilis TP |
|---|---|---|---|
| Specificity (95%CI) | Non-syphilis | 1133 | 99.74%(1130/1133) (99.23% - 99.95%) |
| Sensitivity (95%CI) | Syphilis | 266 | 99.62%(265/266) (97.92% - 99.99%) |

Whole blood specimens with paired serum and plasma from 79 cases of non-syphilis and 96 cases of syphilis from three clinical sites in Japan were tested with Determine Syphilis TP (Table II).

**Table II**
**Specificity and Sensitivity of Determine™ Syphilis TP in Whole Blood and Paired Serum and Plasma Specimens**

| Population | | Number of Secimens Tested | **Determine** Syphilis TP | | |
|---|---|---|---|---|---|
| | | | Whole Blood | Plasma | Serum |
| Specificity (95%CI) | Non-syphilis | 79 | 98.73% (78/79) (93.15% - 99.97%) | 98.73% (78/79) (93.15% - 99.97%) | 98.73% (78/79) (93.15% - 99.97%) |
| Sensitivity (95%CI) | Syphilis | 96 | 92.71% (89/96) (85.55% - 97.02%) | 97.92% (94/96) (92.68% - 99.75%) | 98.96% (95/96) (94.33% - 99.97%) |

**Cross reactivity and endogenous Interference**
Determine Syphilis TP was evaluated for potential cross-reactivity and endogenous interference with 381 samples of patients which include infections other than syphilis, immunization and endogenous interfering substances.

**Table III Cross Ractivity**

| Category | Sample group | Number of tested | Determine Syphilis TP | |
|---|---|---|---|---|
| | | | Positive | Negative |
| Viral infections | HIV | 10 | 0 | 10 |
| | Hepatitis A virus | 5 | 0 | 5 |
| | Hepatitis B virus (HBsAg) | 16 | 0 | 16 |
| | Hepatitis C virus | 16 | 0 | 16 |
| | Cytomegalovirus (CMV) IgG | 17 | 0 | 17 |
| | Cytomegalovirus (CMV) IgM | 14 | 0 | 14 |
| | EBV (Epstein-Barr virus) IgG | 14 | 0 | 14 |
| | EBV (Epsterin-Barr virus) IgM | 13 | 1** | 12 |
| | Herpes simplex virus (HSV)1/2 | 12 | 0 | 12 |
| Immunization | Flu Vaccine Specimens | 10 | 0 | 10 |
| Interfering substances | Antiretroviral treated specimens | 3 | 0 | 3 |
| | Human anti mouse antibody (HAMA) | 10 | 0 | 10 |
| | Anti-nuclear antibody (ANA) | 10 | 0 | 10 |
| | Rheumatoid Factor (RF) | 10 | 0 | 10 |
| | Systemic lupus erythematosus (SLE) | 5 | 0 | 5 |
| | Triglyceride | 5 | 0 | 5 |
| | High IgM | 5 | 0 | 5 |
| | Cholesterol | 5 | 0 | 5 |
| | High total protein | 4* | 0 | 4* |
| | Multiparous pregnancy (MP) | 197 | 2*** | 195 |
| Total of cross reactivity and Interfering substances | | 381 | 3 | 378 |

*: 1 out of 5 high total protein samples was assay invalid due no red color of control bar.
**: 1 out of 13 EBV IgM samples was false positive.
***: 2 out of 197 showed false positive.
Total specificity in the potential cross reactivity and endogenous interference samples is 99.21% (95% CI 97.72-99.84%) representing no significant difference from clinical study.

**Interference of exogenous substances**
The interference of Bilirubin, Hemoglobin, Triglycerides, and EDTA was tested by spiking the interference materials into serum samples. 20 mg/dL Bilirubin, 500 mg/dL Hemoglobin, 1g/dL Triglyceride, and 200 mg/dL EDTA showed no interference.

The interference of relevant medicines were evaluated.
There is no interference for spiked positive and negative for the medicine in Table IV.

**Table IV Interference**

| Type | Medicine | Concentration |
|---|---|---|
| Anti-parasitic medications | Eflornithine<br>Metronidazole | 16.8 mg/ml<br>0.123 mg/ml |
| Anti-bacterial medications | Amoxicillin<br>Ciprofloxacin<br>Azithromycin<br>Levofloxacin | 54.0 µg/ml<br>12.0 µg/ml<br>11.1 µg/ml<br>36.0 µg/ml |
| Anti-malarial medications | Mefloquine<br>Quinine<br>Pyrimethamine<br>Primaquine | 9.84 µg/ml<br>53.7 µg/ml<br>2.58 µg/ml<br>7.23 µg/ml |
| Anti-retroviral medication | Ritronavir | 44.4 µg/ml |
| Anti-tuberculosis medication | Isoniazid (INH) | 60.0 µg/ml |
| Antiviral | Ribavirin<br>Entercavir<br>Valgancidovir hydrochloride | 11.0 µg/ml<br>24.6 ng/ml<br>21.4 µg/ml |
| Common over the counter analgesic medications | Aspirin<br>Paracetamol | 0.782 mg/ml<br>0.156 mg/ml |

**Analytical sensitivity**
WHO International Standard (NIBSC code: 05/122) for Syphilis was tested with Determine Syphilis TP. Determine Syphilis TP detected 18.75mIU/ml.

**Seroconversion Panel Testing**
Commercially available seroconversion panels were evaluated.
Determine Syphilis TP could be detected before CE marked CLIA test and the same as RPR.

**Table V Seroconversion Panel**

| Seroconversion Panel | Days from 1st bleeding date | Non-treponema RPR test | CE marked CLIA test | Determine Syphilis TP |
|---|---|---|---|---|
| PSS901-01 | 0 | - | - | - |
| PSS901-02 | 5 | - | - | - |
| PSS901-03 | 10 | - | - | - |
| PSS901-04 | 13 | - | - | - |
| PSS901-05 | 31 | + | - | + |
| PSS901-06 | 45 | + | + | + |
| PSS901-07 | 48 | + | + | + |
| PSS901-08 | 52 | + | + | + |
| PSS901-09 | 59 | + | + | + |

**Hook Effect**
Determine Syphilis TP could detect 11 high titer positive samples as positive. 10 of the high titer positive samples had a TPPA titer of 40960 and the remaining 1 sample had a TPPA titer of 81920.

**Reproducibility**
Reproducibility of Determine Syphilis TP has been determined using in-house reference panels. There were no differences observed;

- within-run (replicates tested by one operator)
- day to day (five days)
- between run (three different test operators)
- between sites (three sites)
- lot-to-lot (3 different lots).

The manufacturing process produces different lot numbers for the kit and test cards; these lot numbers are traceable.

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