WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Determine HBsAg 2
WHO reference number: PQDx 0451-013-00

Determine HBsAg 2 with product codes **7D2942, 7D2943 and 7D2943 SET,** 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 2 September 2019.

Summary of WHO prequalification assessment for Determine HBsAg

	Date	Outcome
Prequalification listing	2 September 2019	listed
Dossier review	N/A	N/A
Site inspection(s) of the quality management system	29-31 March 2023	MR
Product performance evaluation	Quarter 2 of 2019	MR

MR: Meet Requirements
N/A: Not Applicable

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of the amendments	Date of report amendment
2.0	Change of the name of the manufacturer from Alere Medical Co., Ltd. to Abbott Diagnostics Medical Co., Ltd. Products themselves are completely the same. Correction on regulatory version from CE-Marked to Rest-of-World.	23 January 2020
3.0	Updated the labelling of the Chase Buffer (7D2243) included in each SET product.	14 July 2023
4.0	1. Changed the SET product included in the prequalified product to be downsized for the benefits of shipments and storage, and introduced plastic capillary tubes to replace glass capillary tubes.	3 October 2025

	2. Removed the CE mark from the included lancets from the external supplier; Health Canada registration of the lancets is retained. 3. IFU updates to address findings of the Gap Assessment against Technical Specification Series-13.	

Intended use:

According to the claim of intended use by the manufacturer, "*Determine HBsAg 2 is an in vitro, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid in the diagnosis of HBV infection through detection of HBsAg from infected individuals. The test is not intended for screening blood donors. The test is for professional use only".*

Assay description:

According to the manufacturer's claim, "*Determine HBsAg 2 is an immunochromatographic test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg). A specimen is added to the sample pad. The specimen mixes with biotinylated anti-HBsAg mouse monoclonal antibodies and black particles coated with anti-HBsAg mouse monoclonal antibodies. This mixture migrates along the solid phase to the immobilized avidin at the patient bar. If HBsAg is present in the specimen, the antigen binds to the biotinylated anti-HBsAg mouse monoclonal antibodies and the black particles coated with anti-HBsAg mouse monoclonal antibodies. This complex binds to the immobilized avidin forming a black bar on the test strip. If HBsAg is not present, black particles flow past the patient bar and no black bar is formed on the test strip. To ensure assay validity, a procedural control bar is incorporated in the assay device on the test strip. The red control bar will appear".*

Test kit contents:

Component	**20 tests (product code 7D2942)**	**100 tests (product code 7D2943)**	**100 tests (product code 7D2943SET**
Determine HBsAg 2 test cards	2 cards of 10 tests/card	10 cards of 10 tests/card	20 cards of 5 tests/card
Instructions for Use (IFU)	1	1	1
Chase buffer (7D2243)	Not provided	Not provided	1 bottle x 2.5ml and IFU
Capillary tubes, plastic	Not provided	Not provided	100
Blood lancets, sterile	Not provided	Not provided	100

Items required but not provided:

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)

Storage:
The test kit must be stored at a temperature between 2-30 °C.

Shelf-life upon manufacture:
18 months.

Warnings/limitations:

Refer to the instructions for use.

Prioritization for prequalification
Based on the established eligibility criteria, **Determine HBsAg 2** was given priority for the WHO prequalification assessment.

Product dossier assessment

In accordance with the WHO procedure for abridged prequalification assessment, Abbott Diagnostics Medical Co. Ltd (formerly called Alere Medical Co. Ltd) was not required to submit a product dossier for **Determine HBsAg 2** as per the *"Instructions for compilation of a product dossier"* (PQDx_018 version 3). Notwithstanding, certain aspects of the product dossier previously submitted for stringent regulatory review were reviewed by an assessor during the site inspection.

Manufacturing site inspection

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 assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

All published WHOPIRs are with the agreement of the manufacturer.
Based on the site inspection and corrective action plan review, the quality management system for Determine HBsAg 2 meets WHO prequalification requirements.

Product performance evaluation

Determine HBsAg 2 (Abbott Diagnostics Medical Co. Ltd, formerly Alere Medical Co.Ltd) was evaluated by WHO at the Virus Reference Department, Public Health England, London, UK, in the 2nd quarter of 2019 using plasma specimens. From this evaluation, we drew the following conclusions:
Determine HBsAg 2 is a rapid immunochromatographic assay for the detection of HBsAg in human serum, plasma or whole blood. A volume of 50 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities. Reading the results can be done visually.

In this limited evaluation on a panel of 514 clinically-derived serum/plasma specimens of European, African, Latin American and Asian origin, compared to the reference algorithm (Monolisa Ag HBs Plus [Bio-Rad Laboratories] and Hepanostika HBsAg Uniform II [bioMérieux]; followed by Hepanostika HBsAg Uniform II Confirmatory Assay [bioMérieux]), the following performance characteristics were estimated:

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity % (N=201)	100 (98.2-100)	100 (98.2-100)
Specificity % (N=313)	99.7 (98.2-100)	100 (98.8-100)
Invalid rate % (N=869)	0.12	
Inter-reader variability %	0	

In addition, analytical performance characteristics were assessed using commercially available and locally-made panels and the following results were obtained:

Additional performance characteristics	
Sensitivity during seroconversion on 5 seroconversion panels in comparison with a benchmark assay (Monolisa Ag HBs Plus)	Seroconversion sensitivity index of 0. Therefore Determine HBsAg 2 detected HBsAg on average 0 specimens earlier than the benchmark assay.
Analytical sensitivity on WHO Biological Preparation panel 03/262 and dilutions series of 3rd WHO International standard 12/226	Detected a concentration of 0.52 IU/ml (panel 03/262) and 0.125 IU/ml (dilutions of 12/226)
Analytical sensitivity on a low titer panel (PHA105, SeraCare)	10 of 14 specimens with low titer (< 1 IU/mL) were detected
Analytical sensitivity on the 1st WHO International Reference Panel for HBV Genotypes for HBsAg assays (PEI code number 6100/09)	All 15 HBsAg genotypes in the panel were detected.
Analytical sensitivity on HBV mutant panel	11 of 12 HBsAg mutants were detected to a concentration of 1 IU/mL
Lot to lot variation on a dilution panel in comparison with an agreed reference standard	Acceptable

Key operational characteristics	
Validated specimen types	Serum, plasma (EDTA), venous and capillary whole blood
Number of steps	1 with precision (serum/plasma) or 2 with/without precision (venous/capillary whole blood)
Time to result	15 minutes
Endpoint stability	15 minutes (read within a maximum of 30 minutes)
Internal QC	Yes, reagent addition control
In-use stability of reagents	The test should be used within 2 hours after removing the protective foil cover from the test strip.

Labelling

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

1. Labels

1.1 Determine HBsAg 2 Determine HBsAg (product code 7D2942) label.

DETERMINE™

HBsAg 2

4 571226 474358

EN

Determine™ HBsAg 2 is an *in vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. For professional use only.

7D2243 Chase Buffer is required for whole blood testing.

Kit contains:
Determine™ HBsAg 2 Test Cards: 2 cards (containing 10 tests/card)

2°C 30°C Σ 20 IVD

REF 7D2942

ES

Determine™ HBsAg 2 es un inmunoensayo cualitativo *in vitro* de lectura visual para la detección del antígeno de superficie del virus de la hepatitis B (HBsAg) en sangre total humana capilar y venosa, plasma o suero. Solo para uso profesional.

7D2243 requiere buffer de detección para todas las pruebas en sangre.

Contenido del kit:
Tarjeta de prueba Determine™ HBsAg 2:
2 tarjetas (con 10 pruebas/tarjeta)

FR

Determine™ HBsAg 2 est un dosage immunologique qualitatif *in vitro* à lecture visuelle pour la détection de l' antigène de surface de l' hépatite B (AgHBs) dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain. À usage professionnel uniquement.

La solution tampon de migration 7D2243 est nécessaire pour tester les échantillons de sang total.

Ce kit contient:
Planche de tests Determine™ HBsAg 2:
2 planches (avec 10 tests/planche)

PT

O Determine™ HBsAg 2 é um imunoensaio qualitativo, *in vitro* e de leitura visual para a detecção de Antígenos de Superfície da Hepatite B (HBsAg) em sangue total capilar e venoso, plasma ou soro humano. Exclusivamente para uso profissional.

7D2243 É necessário o tampão de detecção para realizar análises em sangue total.

O Conteúdo do kit:
Cartão de Testes Determine™ HBsAg 2:
2 cartões (com 10 testes/cartão)

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

241601/R3

Determine™ HBsAg2 **ROW** 20 Test Pouch Label **PN:** 241601/R3	**Pouch Size:** 544mm(w) x 160mm(h) **Label Artwork Size:** 204mm(w) x 132mm(h)	PMS 303 PMS 123 White

1.2 Determine HBsAg 2 (product code 7D2943) label.

DETERMINE™

HBsAg 2

4 571226 474365

EN

Determine™ HBsAg 2 is an *in vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. For professional use only.

7D2243 Chase Buffer is required for whole blood testing.

Kit contains:
Determine™ HBsAg 2 Test Cards: 10 cards (containing 10 tests/card)

2°C 30°C | Σ 100 | IVD | REF 7D2943

ES

Determine™ HBsAg 2 es un inmunoensayo cualitativo *in vitro* de lectura visual para la detección del antígeno de superficie del virus de la hepatitis B (HBsAg) en sangre total humana capilar y venosa, plasma o suero. Solo para uso profesional.

7D2243 requiere buffer de detección para todas las pruebas en sangre.

Contenido del kit:
Tarjeta de prueba Determine™ HBsAg 2:
10 tarjetas (con 10 pruebas/tarjeta)

FR

Determine™ HBsAg 2 est un dosage immunologique qualitatif *in vitro* à lecture visuelle pour la détection de l' antigène de surface de l' hépatite B (AgHBs) dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain.

À usage professionnel uniquement.

La solution tampon de migration 7D2243 est nécessaire pour tester les échantillons de sang total.

Ce kit contient:
Planche de tests Determine™ HBsAg 2:
10 planches (avec 10 tests/planche)

PT

O Determine™ HBsAg 2 é um imunoensaio qualitativo, *in vitro* e de leitura visual para a detecção de Antígenos de Superfície da Hepatite B (HBsAg) em sangue total capilar e venoso, plasma ou soro humano. Exclusivamente para uso profissional.

7D2243 É necessário o tampão de detecção para realizar análises em sangue total.

O Conteúdo do kit:
Cartão de Testes Determine™ HBsAg 2:
10 cartões (com 10 testes/cartão)

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

241602/R3

Determine™ HBsAg2 **ROW** 100 Test Pouch Label **PN:** 241602/R3	**Pouch Size:** 544mm(w) x 160mm(h) **Label Artwork Size:** 204mm(w) x 132mm(h)	PMS 303 PMS 123 White

1.3. Determine HBsAg 2 (product code 7D2943SET) label.

61.0

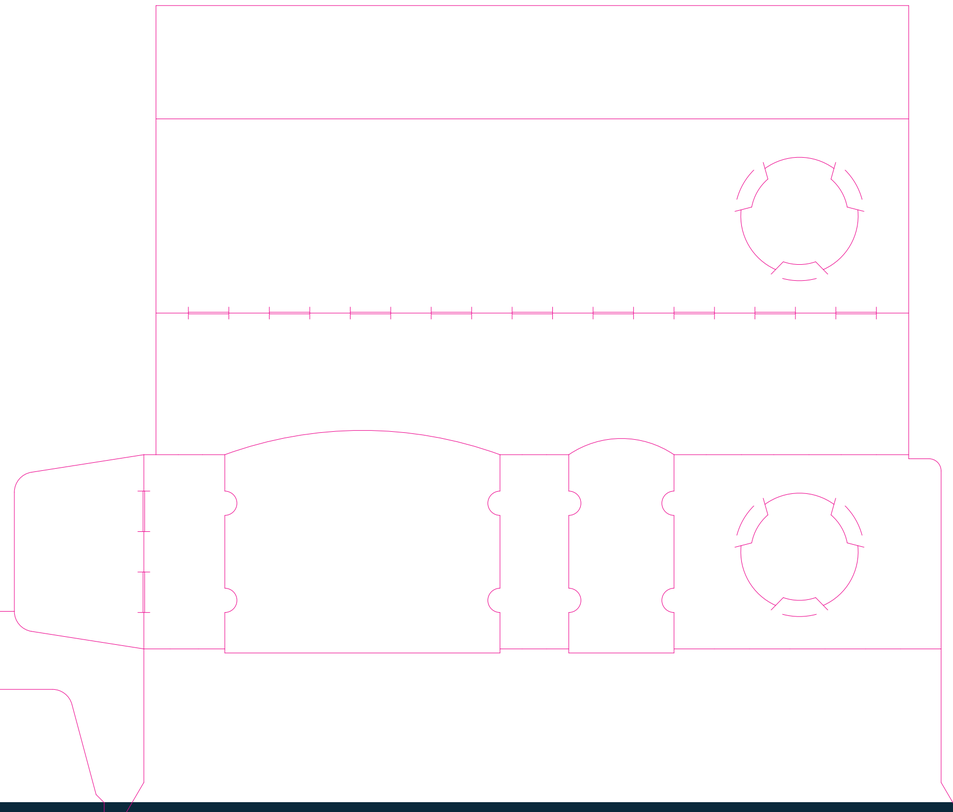
213.0

Determine HBsAg 2 SET
ROW 100 Test Set Box

PN: 241787/R2

PMS 303

PMS 123



2°C-30°C 100 IVD

HBsAg 2 SET
DETERMINE™

Abbott

1/4

162.0

Abbott

DETERMINE™
HBsAg 2 SET

EN
Determine™ HBsAg 2 is an in *vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum.
For professional use only.

ES
Determine™ HBsAg 2 es un inmunoensayo cualitativo *in vitro* de lectura visual para la detección del antígeno de superficie del virus de la hepatitis B (HBsAg) en sangre total humana capilar y venosa, plasma o suero.
Solo para uso profesional.

FR
Determine™ HBsAg 2 est un dosage immunologique qualitatif *in vitro* à lecture visuelle pour la détection de l' antigène de surface de l' hépatite B (AgHBs) dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain.
À usage professionnel uniquement.

PT
O Determine™ HBsAg 2 é um imunoensaio qualitativo, *in vitro* e de leitura visual para a detecção de Antígenos de Superfície da Hepatite B (HBsAg) em sangue total capilar e venoso, plasma ou soro humano.
Exclusivamente para uso profissional.

2°C 30°C 100 IVD

REF 7D2943SET

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

4 571226 474570

241787/R2

Abbott

DETERMINE™
HBsAg 2 SET

Abbott

Abbott

DETERMINE™
HBsAg 2 SET

DETERMINE™
HBsAg 2 SET

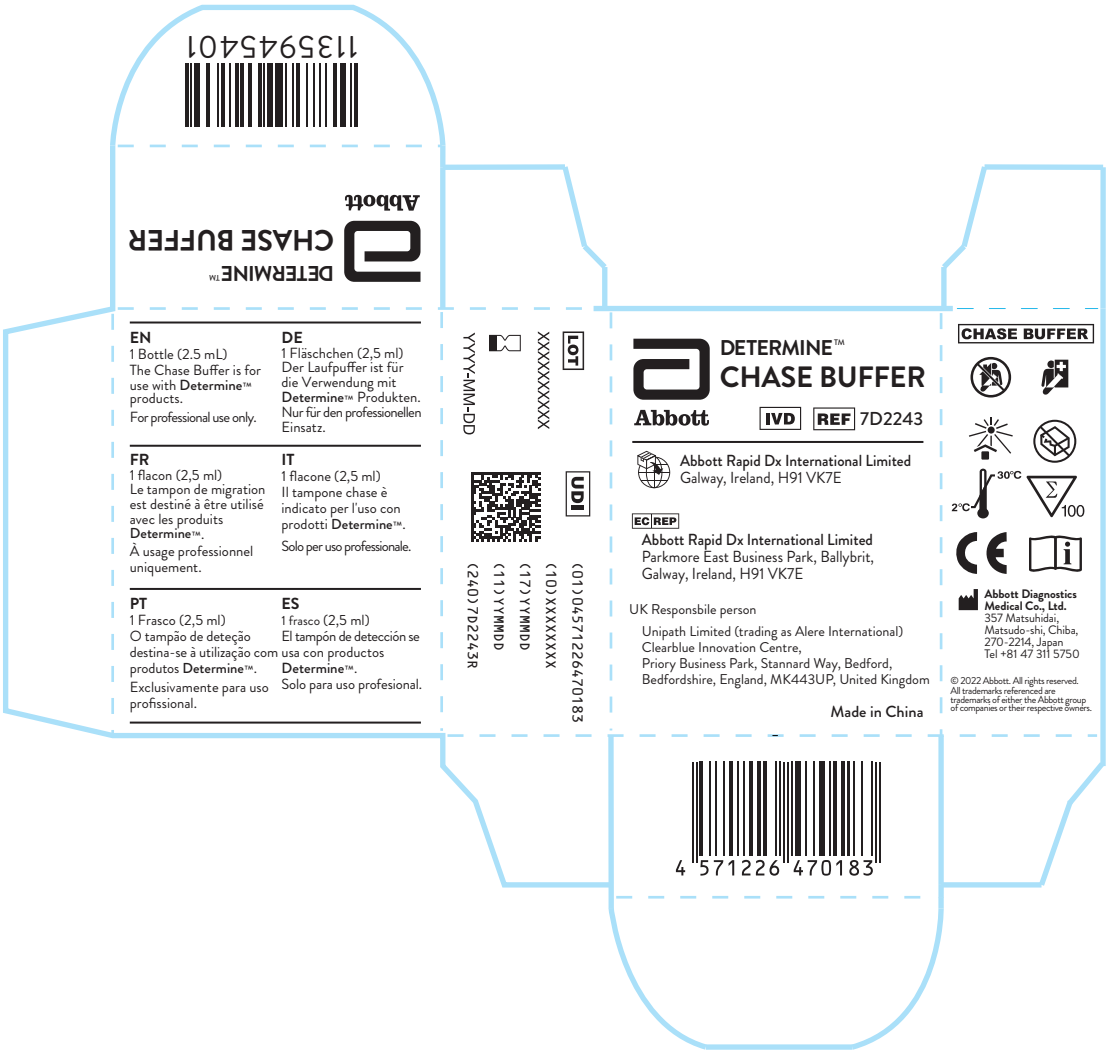
Abbott

1.4 Blood lancet, sterile label

Box Drawing

100mm
96mm
19mm
Instructions for Use
1. Twist Cap
2. Pull Cap
3. Recapping
Do not use lancet if protective cap has been previously removed.
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.
Model: I
28 gauge
LOT : 220802T
: 2027-08-01
: 2022-08-02
(01) 06957138607882
(10) 220802T
(17) 270801
(11) 220802
(240) IR28100100
STERILE R Irradiation Sterilization
Single Use Only
Rev# 2024-04-22
Made in China
Litetouch™
Sterile Lancet
medicore™
Austell, GA, USA
1-855-867-2190
100T QTY: 100pcs
Item No: M2721
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: +86 022-58775333 +86 4008-587-753
Fax: +86 022-58775353
E-mail: huahongsales@163.com

1.5 Chase buffer labels (7D2243)



Chase Buffer Box Size: (W)22mm x (L)44mm x (H)56mm	Black	PN: 1135945401

1156253101

REF 7D2243

1156253101
April 2022

DETERMINE™ CHASE BUFFER

Abbott

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

EC REP Abbott Rapid Dx International Limited
Parkmore East Business Park, Ballybrit,
Galway, Ireland, H91 VK7E

UK Responsible person Unipath Limited (trading as Alere International)
Clearblue Innovation Centre,
Priory Business Park, Stannard Way, Bedford,
Bedfordshire, England, MK443UP, United Kingdom

EN

Intended Purpose
Chase Buffer is intended for use with Determine™ in vitro diagnostic rapid test devices. Chase Buffer enables the migration of the specimen and conjugate through the test device when testing whole blood specimens. It is specially formulated and optimised to ensure the Determine™ test performs correctly and controls assay flow. It is for professional use and near-patient testing, and not for self-testing.

For full procedure refer to the diagnostic assay IFUs:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

When adding Chase Buffer to the sample pad, hold the bottle vertically. One drop to be used per test (one bottle of Chase Buffer can be used for 100 tests). Avoid drop with bubble, do not add buffer to specimen.

USER TRAINING, QUALIFICATION AND EXPERIENCE REQUIREMENTS
This Chase Buffer is designed for use by professionals in both laboratory and near-patient settings including laboratory technologists. Suitable personnel shall have a consummate level of training and experience in specimen preparation, the running and interpretation of specimens, management of all supplies and waste disposal as per local regulations and generation of reports.

Caution: Do not eat, drink, smoke or apply make-up while using this product.
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Contents
CHASE BUFFER 1 Bottle (2.5 mL) Chase Buffer contains: phosphate buffer solution (20mM pH7.4) containing preservatives Nipasept™ and A56620 (sarafloxacin).

Storage Instruction
Recap the Chase Buffer to avoid evaporation or spillage and store at 2-30 °C until expiration date.

ES

Finalidad prevista
Chase Buffer está destinado a utilizarse con los dispositivos de pruebas rápidas de diagnóstico in vitro Determine™. Chase Buffer permite la migración de la muestra y el conjugado a través del dispositivo de prueba cuando se analizan muestras de sangre completa. Está especialmente formulado y optimizado para garantizar que la prueba Determine™ funcione correctamente y controle el flujo del ensayo. Es para uso profesional y para pruebas cercanas a los pacientes, no es apto para autopruebas.

Para conocer el procedimiento completo, consulte las instrucciones de uso del ensayo de diagnóstico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Cuando añada Chase Buffer a la almohadilla de muestras, mantenga el frasco en posición vertical. Se debe utilizar una gota por prueba (un frasco de Chase Buffer puede utilizarse para 100 pruebas). Evite que la gota tenga una burbuja, no añada tampón a la muestra.

REQUISITOS DE FORMACIÓN, CUALIFICACIÓN Y EXPERIENCIA DEL USUARIO
Chase Buffer está diseñado para ser utilizado por profesionales tanto en el laboratorio como en entornos cercanos al paciente, incluidos técnicos de laboratorio. El personal adecuado deberá tener un nivel consumado de formación y experiencia en la preparación de muestras, la ejecución e interpretación de las mismas, la gestión de todos los suministros y la eliminación de residuos de acuerdo con la normativa local y la generación de informes.

Precaución: No coma, ni beba, ni fume, ni se maquille mientras usa este producto.
Para los pacientes/usuarios/terceros en la Unión Europea y en países con idéntico régimen normativo (Reglamento 2017/746/UE sobre productos sanitarios de diagnóstico in vitro); si ocurriera un incidente grave durante el uso de este dispositivo o como resultado de su uso, informe al fabricante o a su representante autorizado, así como a su autoridad nacional.

Contenido
CHASE BUFFER 1 frasco (2.5 mL) de Chase Buffer contiene: solución tampón de fosfato (20mM pH 7.4) que contiene los conservantes Nipasept™ y A56620 (sarafloxacina).

Instrucción de almacenamiento
Vuelva a tapar el frasco de Chase Buffer para evitar que se evapore o derrame y conserve a 2-30 °C hasta la fecha de caducidad.

DE

Verwendungszweck
Chase Buffer ist für die Verwendung mit Determine™ In-vitro-Diagnostik-Schnelltests vorgesehen. Chase Buffer ermöglicht bei der Untersuchung von Vollblutproben die Migration von Probe und Konjugat durch die Testvorrichtung. Es ist speziell formuliert und optimiert, um die korrekte Durchführung des Determine™ Tests zu gewährleisten und den Testfluss zu kontrollieren. Es ist für den professionellen Gebrauch und patientennahe Tests und nicht für Selbsttests geeignet.

Das vollständige Verfahren ist in den IFUs der diagnostischen Tests beschrieben:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Halten Sie die Flasche senkrecht, wenn Sie Chase Buffer in das Probenpad geben. Pro Test ist ein Tropfen zu verwenden (eine Flasche Chase Buffer kann für 100 Tests verwendet werden). Tropfen mit Blasenbildung vermeiden, keinen Puffer zur Probe hinzufügen.

ANFORDERUNGEN AN AUSBILDUNG, QUALIFIKATION UND ERFAHRUNG DER BENUTZER
Dieser Chase Buffer ist für die Verwendung durch Fachkräfte im Labor und im patientennahen Bereich, einschließlich Labortechniker, bestimmt. Das geeignete Personal muss über ein hohes Maß an Ausbildung und Erfahrung in der Probenvorbereitung, der Untersuchung und Auswertung der Proben, der Verwaltung aller Vorräte und der Abfallentsorgung gemäß den örtlichen Vorschriften sowie der Erstellung von Berichten verfügen.

Achtung: Essen, trinken, rauchen oder schminken Sie sich nicht, während Sie dieses Produkt verwenden.
Für Patienten/Anwender/Dritte in der Europäischen Union und in Ländern mit identischem Regelwerk (Verordnung 2017/746/EU über In-vitro-Diagnostika): Wenn während der Verwendung dieses Produkts oder als Folge seiner Verwendung ein schwerwiegender Zwischenfall aufgetreten ist, melden Sie dies bitte dem Hersteller und/oder seinem Bevollmächtigten sowie Ihrer nationalen Behörde.

Inhalt
CHASE BUFFER 1 Flasche (2.5 mL) Chase Buffer enthält: Phosphatpufferlösung (20mM pH7.4) mit den Konservierungsmitteln Nipasept™ und A56620 (Sarafloxacin).

Anweisungen zur Lagerung
Verschließen Sie den Chase Buffer, um Verdunstung oder Verschütten zu vermeiden, und lagern Sie ihn bis zum Verfallsdatum bei 2–30 °C.

FR

Usage prévu
Chase Buffer est destiné à être utilisé avec les dispositifs de test rapide pour diagnostic in vitro Determine™. Chase Buffer permet la migration de l'échantillon et du conjugué à travers le dispositif de test lors de l'analyse d'échantillons de sang total. Il est spécialement formulé et optimisé pour garantir que le test Determine™ fonctionne correctement et contrôle le flux de dosage. Il est destiné à un usage professionnel et aux tests au chevet du patient, et non à l'autotest.

Pour la procédure complète, se référer aux modes d'emploi des tests de diagnostic :
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Lorsque vous ajoutez Chase Buffer au tampon d'échantillonnage, tenez le flacon verticalement. Une goutte à utiliser par test (un flacon de Chase Buffer peut être utilisé pour 100 tests). Évitez les gouttes avec des bulles, n'ajoutez pas de tampon à l'échantillon.

EXIGENCES EN MATIÈRE DE FORMATION, DE QUALIFICATION ET D'EXPÉRIENCE DES UTILISATEURS
Ce Chase Buffer est conçu pour être utilisé par les professionnels à la fois dans les laboratoires et les environnements au chevet des patients, y compris les techniciens de laboratoire. Le personnel approprié doit avoir un niveau de formation et d'expérience complet dans la préparation, l'exécution et l'interprétation des échantillons, la gestion de toutes les fournitures et l'élimination des déchets conformément aux réglementations locales et la génération de rapports.

Mise en garde: Ne pas manger, boire, fumer ou se maquiller pendant l'utilisation de ce produit.
Pour un patient/utilisateur/tiers dans l'Union européenne et dans les pays ayant un régime réglementaire identique (Règlement 2017/746/UE sur les dispositifs médicaux de diagnostic in vitro) ; si, pendant l'utilisation de ce dispositif ou à la suite de son utilisation, un incident grave s'est produit, veuillez le signaler au fabricant et/ou à son représentant autorisé et à votre autorité nationale.

Contenu
CHASE BUFFER 1 flacon (2.5 ml) Chase Buffer contient : solution tampon phosphate (20mM pH7.4) contenant les conservateurs Nipasept™ et A56620 (sarafloxacine).

Instruction de stockage
Re-bouchonner le Chase Buffer pour éviter toute évaporation ou tout déversement et le conserver à une température comprise entre 2 et 30 °C jusqu'à la date de péremption.

IT

Scopo previsto
Chase Buffer è destinato all'uso con i dispositivi per test diagnostici rapidi in vitro Determine ™. Chase Buffer consente la migrazione del campione e del coniugato attraverso il dispositivo di test durante l'analisi di campioni di sangue intero. È appositamente formulato e ottimizzato per garantire che il test Determine™ funzioni correttamente e controlli il flusso del test. È indicato per l'uso professionale e per test decentralizzati, non per autotest.

Per la procedura completa, fare riferimento alle istruzioni per l'uso del test diagnostico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Quando si aggiunge il Chase Buffer al tampone per campioni, tenere il flacone in verticale. Utilizzare una goccia per test (un flacone di Chase Buffer può essere utilizzato per 100 test). Evitare le gocce contenenti bolle, non aggiungere tampone al campione.

REQUISITI DI FORMAZIONE, QUALIFICA ED ESPERIENZA DEGLI UTENTI
Questo Chase Buffer è progettato per l'uso da parte di professionisti sia in laboratorio che in ambienti decentralizzati, inclusi i tecnici di laboratorio. Il personale idoneo deve avere un eccellente livello di formazione ed esperienza nella preparazione dei campioni, nell'esecuzione e nell'interpretazione dei campioni, nella gestione di tutte le forniture, nello smaltimento dei rifiuti secondo le normative locali e nella generazione dei rapporti.

Attenzione: non mangiare, bere, fumare o truccarsi durante l'utilizzo di questo prodotto.
Per un paziente/utente/terza parte nell'Unione Europea e in paesi con identico regime normativo (Regolamento 2017/746/UE sui Dispositivi medici per la diagnostica in vitro): se, durante l'uso di questo dispositivo o a seguito del suo utilizzo, si è verificato un incidente grave, segnalarlo al produttore e/o al suo rappresentante autorizzato e alla propria autorità nazionale.

Contenuto
CHASE BUFFER 1 flacone (2.5 ml) di Chase Buffer contiene: soluzione tampone a base di fosfato (20mM pH7.4) contenente i conservanti Nipasept™ e A56620 (sarafloxacina).

Istruzioni per la conservazione
Richiudere il Chase Buffer per evitare l'evaporazione o la fuoriuscita e conservare a 2-30 °C fino alla data di scadenza.

PT

Utilização prevista
O Chase Buffer (solução tampão) destina-se a ser utilizado em testes rápidos de diagnóstico in vitro Determine™.
O Chase Buffer permite a migração da amostra e conjugado através do dispositivo de teste ao testar amostras de sangue total. Foi especialmente desenvolvido e otimizado para assegurar que o teste Determine™ funciona corretamente e controla o fluxo de ensaio. Destina-se a utilização profissional, testes junto ao paciente e não é adequado para autoteste.

Para obter o procedimento completo, por favor, consulte as Instruções de utilização do ensaio de diagnóstico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Ao adicionar o Chase Buffer ao bloco de amostras, mantenha o frasco na posição vertical. Use uma gota por teste (um frasco de tampão pode ser usado para 100 testes). Evite gotas com bolhas e não adicione tampão à amostra.

REQUISITOS DE FORMAÇÃO, QUALIFICAÇÃO E EXPERIÊNCIA DO UTILIZADOR
O Chase Buffer foi concebido para ser utilizado por profissionais, tanto em laboratório como em ambientes junto do paciente, incluindo técnicos de laboratório. Os profissionais deveram ter um nível consumado de formação e experiência na preparação de amostras, no funcionamento e interpretação de amostras, na gestão de todos os consumíveis e eliminação de resíduos, de acordo com os regulamentos locais e na elaboração de relatórios.

Cuidado: não comer, beber, fumar ou aplicar maquilhagem durante a utilização deste produto.
Para um paciente/utilizador/terceiro na União Europeia e em países com regime regulamentar idêntico (Regulamento 2017/746/UE relativo a dispositivos médicos de diagnóstico in vitro); se, durante a utilização deste dispositivo ou em resultado da sua utilização, tiver ocorrido um incidente grave, informe imediatamente o fabricante e/ou o seu representante autorizado e a respetiva autoridade nacional.

Conteúdo
CHASE BUFFER 1 frasco (2.5 mL) de Chase Buffer contém: solução tampão fosfato (20mM pH7.4) contendo conservantes Nipasept™ e A56620 (sarafloxacina).

Instrução de armazenamento
Voltar a tapar o Chase Buffer para evitar evaporação ou derramamento e armazenar entre 2-30 °C até à data de validade.

Glossary of Symbols / Glossar der Symbole / Glosario de símbolos / Glossaire des symboles / Glossario dei simboli / Glossário de símbolos

Σ 100	Contains sufficient for 100 tests / Enthält genügend Material für 100 Tests / Contenido suciente para 100 pruebas / Contient suffsamment de produit pour 100 tests / Contenuto sufficiente per 100 test / Contém o suficiente para 100 testes
EC REP	Authorized representative in the European Community / Bevollmächtigter in der Europäischen Gemeinschaft / Representante autorizado en la Comunidad Europea / Représentant autorisé dans l' Union européenne / Rappresentante autorizzato nella Comunità Europea / Representante autorizado na Comunidade Europeia
	Importer / Importeur / Importador / Importateur / Importatore / Importador
UDI	Unique Device Identification / Eindeutige Geräteidentifikation / Identificación única del dispositivo / Identification unique du dispositif / Identificazione univoca del dispositivo / Identificação única de dispositivo
IVD	In vitro diagnostic medical device / In-vitro-Diagnostikum / Producto sanitario de diagnóstico in vitro / Dispositif médical de diagnostic in vitro / Dispositivo medico per la diagnostica in vitro / Dispositivo médico de diagnóstico in vitro
CHASE BUFFER	Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer
	Manufacturer / Hersteller / Fabricante / Fabricant / Produttore / Fabricante
REF	Catalogue number / Katalognummer / Número de catálogo / Référence / Numero di catalogo / Número de catálogo
	Consult instructions for use / Siehe Gebrauchsanweisung / Consultar las instrucciones de uso / Consulter le mode d' emploi / Consultare le istruzioni per l' uso / Consultar as instruções de utilização
	Device for Near-Patient Testing / Gerät für patientennahe Tests / Dispositivo para pruebas cercanas al paciente / Dispositif pour tests au chevet du patient / Dispositivo per test decentralizzato / Dispositivo para testes junto do paciente
2°C 30°C	Store between 2-30°C / Lagerung bei 2–30 °C / Almacenar entre 2 y 30 °C / Ranger à une température comprise entre 2 et 30 °C / Conservare a 2-30 °C / Armazenar entre 2-30 °C
LOT	Lot Number / Chargennummer / Número de lote / Numéro de lot / Numero di lotto / Número do lote
CE	CE marking according to IVD Medical Devices Regulation (EU) 2017/746 / CE-Kennzeichnung gemäß der IVD-Medizinprodukte-Verordnung (EU) 2017/746 / Marcado CE según el Reglamento sobre los productos sanitarios para diagnóstico in vitro (UE) 2017/746 / Marquage CE conformément au règlement sur les dispositifs médicaux de diagnostic in vitro (UE) 2017/746 / Marchio CE secondo il Regolamento sui dispositivi medici IVD (UE) 2017/746 / Marcação CE de acordo com o Regulamento relativo aos dispositivos médicos para IVD (UE) 2017/746
	Do not use if package is damaged / Nicht verwenden, wenn die Verpackung beschädigt ist / No utilizar si el envase está dañado / Ne pas utiliser si l' emballage est endommagé / Non utilizzare se la confezione è danneggiata / Não utilizar se a embalagem estiver danificada
	Keep away from sunlight / Vor Sonnenlicht schützen / Mantener alejado de la luz solar / Garder à l' abri de la lumière du soleil / Tenere lontano dalla luce solare / Manter afastado da luz solar
	Not for Self- Testing / Nicht für Selbsttest / No apto para autopruebas / N'est pas destiné à l' autotest / Non per autotest / Não adequado para autotestes

Advice Line/Infotelefon/Asistencia/Conseil/Assistenza/Rådgivning

For further information, please contact your distributor, or call Abbott Technical Specialists: Europe:
Tel: +44 161 483 9032 Email:EME.TechSupport@abbott.com

Weitere Informationen erhalten Sie von Ihrem Vertreiber oder vom technischen Kundendienst von Abbott: Europa:
Tel: +44 161 483 9032 Email:EME.TechSupoort@abbott.com

Para obtener mas informacion, pongase en contacto con su distribuidor, o llame a los especialistas tecnicos de AbbottEuropa:
Tel: +44 161 483 9032
Correo electronico: EME.TechSupport@abbott.com

Pour de plus amples informations, contactez votre distributeur ou appeler les techniciens specialistes de Abbott: Europa: Europe:
Tel: +44 161 483 9032
Adresse elec.e: EME.TechSupport@abbott.com

Per ulteriori informazioni, contattare il proprio distributore o il servizio di assistenza tecnica di Abbott ai seguenti recapiti:
Europa: Tel: +44 161 483 9032
E-mail: EME.TechSupport@abbott.com

Para informacao adicional, por favor contacte o seu distribuidor, ou ligue para os Tecnicos Especialistas da Abbott: Europa:
Tel: +44 161 483 9032 Email: EME.TechSupport@abbott.com

Middle East:Tel: + (965) 2202 2828
Email: EME.TechSupport@abbott.com
Asia Pacific: Tel + (61) 7 3363 7711
Email: AP.TechSupport@abbott.com
Africa: Tel + (27) 10 500 9700
Email: arcis.techsupport@abbott.com
Russia & CIS: Tel:+ (7) 499 403 9512
Email: arcis.techsupport@abbott.com
Latin America: Tel:+ (57) 1 482 4033
Email: LA.TechSupport@abbott.com
Australia: Tel:+ (1) 800 622 642
Email: rapiddx.ANZ.TechSupport@abbott.com

Chase Buffer

Package Insert

Size: 176 x 250 mm

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.

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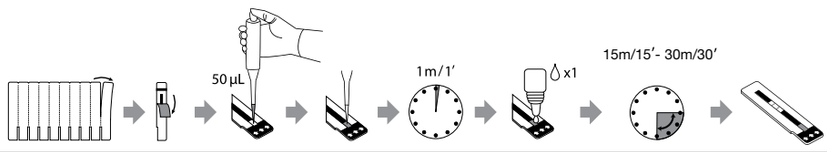
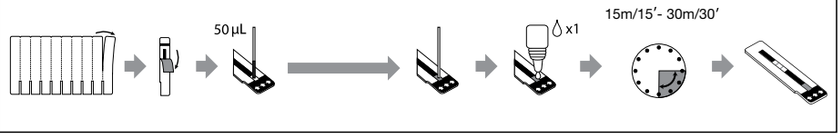
REF 7D2942/7D2943/7D2943SET

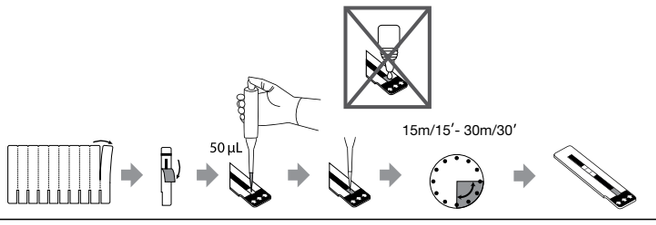
Read Highlighted Changes

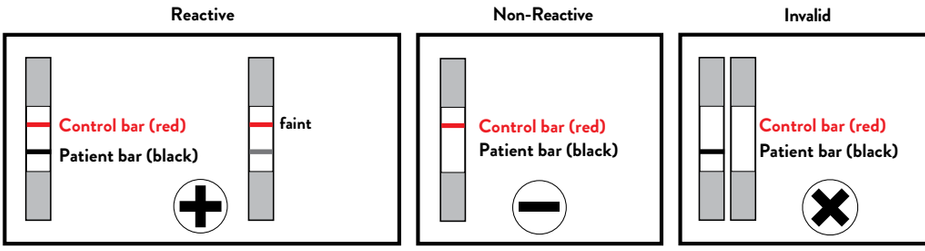
DETERMINE™ HBsAg 2

Whole Blood / Sangre Total / Sang Total / Sangue Total

Pipette **Pipeta** **Pipette** **Pipeta**	
EDTA Capillary Tubes **Tubos capilares EDTA** **Tubes capillaires avec EDTA** **Tubos Capilares EDTA**	

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

Pipette **Pipeta** **Pipette** **Pipeta**	



EN

February 2025
D10193421_AB

This instruction for use must be read carefully prior to use. All procedures must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this IFU.

NAME AND INTENDED USE

Determine™ HBsAg 2 is an *in vitro,* visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid in the diagnosis of HBV infection through detection of HBsAg from infected individuals. The test is not intended for screening blood donors. The test is for professional use only.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis B virus (HBV), is a DNA virus transmitted percutaneously, sexually and perinatally. Worldwide it causes deaths from cirrhosis, liver failure and hepatocellular carcinoma[1]. HBsAg seropositivity is the first serological marker to appear in acute HBV infection[2].

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine HBsAg 2 is an immunochromatographic test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg).
A specimen is added to the sample pad. The specimen mixes with biotinylated anti-HBsAg mouse monoclonal antibodies and black particles coated with anti-HBsAg mouse monoclonal antibodies. This mixture migrates along the solid phase to the immobilized avidin at the patient bar.
If HBsAg is present in the specimen, the antigen binds to the biotinylated anti-HBsAg mouse monoclonal antibodies and the black particles coated with anti-HBsAg mouse monoclonal antibodies. This complex binds to the immobilized avidin forming a black bar on the test strip. If HBsAg is not present, black particles flow past the patient bar and no black bar is formed on the test strip.
To ensure assay validity, a procedural control bar is incorporated in the assay device on the test strip. The red control bar will appear.

CONTENTS

- Determine HBsAg 2 20 Test (7D2942): 2 cards (10 tests/card)
- Determine HBsAg 2 100 Test (7D2943): 10 cards (10 tests/card)
- Determine HBsAg 2 SET (7D2943SET) 100 Test for testing whole blood samples
  - Determine HBsAg 2 (7D2943) 10 cards (10 tests/card)
  - Chase Buffer (7D2243) 1 bottle of 2.5 ml
  - EDTA Capillary Tubes (7D2222) 1 pack for 100 tests
  - Blood Lancet (sterilized) (7D2233) 1 box for 100 tests

ACCESSORIES (required)

For testing Whole Blood Samples
Chase Buffer (7D2243) 1 Bottle (2.5 mL) containing phosphate buffered saline, preservative and antimicrobial agent

For testing Whole Blood Samples (fingerstick assay)
Single use sterile lancet
EDTA capillary tube (7D2222)

Materials Required But Not Provided

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab, clean or sterile gauze pad

WARNING AND PRECAUTIONS

For *In Vitro* Diagnostic Use.
Use the Chase Buffer bottle with attention to avoid contamination of the nozzle. Don't touch nozzle to the sample or sample pad.
Safety data sheet available for professional users on request.

CAUTION:

When handling specimens and reagents, use appropriate biosafety practices[4,5]. 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[3,4].
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations[3,4].

STORAGE

Store Determine HBsAg 2 Test Cards and Chase Buffer at 2°C to 30°C until expiration date. Chase Buffer cap should be kept firmly sealed between each use to avoid evaporation or spillage.

- When handled and stored as directed, kit components are stable until 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 wet devices or damaged packages.

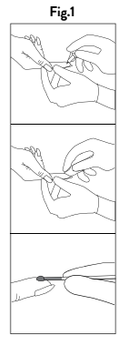
SPECIMEN COLLECTION

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 tube (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



EDTA CAPILLARY TUBES

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

1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused). Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
2. Clean fingertip with alcohol swab; allow to air dry.
3. Position the hand palm-side up. 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 clean or 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, avoiding the puncture wound.
6. Touch the tip of the capillary tube to the drop of blood. Avoid air bubbles. Fill the tube with whole blood up to between the two marked lines.

SPECIMEN STORAGE

- Store serum and plasma specimens at 2 °C to 8 °C and run the test within 7 days of collection. If testing is delayed more than 7 days, the specimens should be frozen (-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 min 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 °C to 8 °C. Do not freeze whole blood specimens. Run the test within 2 days (48 hours) of collection. Mix the specimen well by gentle inversion of the tube immediately before testing.
- For whole blood collected by fingerstick, test immediately.

TEST PROCEDURE

This test should be performed at 18 °C to 40 °C.

1. Remove the desired number of test strips from the 10-test card by bending and tearing at the perforation.
   - 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.
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 (30 minutes maximum) from addition of the sample and read result.

   For whole blood (venipuncture) samples:
   a. Apply 50 µL of sample (precision pipette) to the middle of the sample pad (marked by the arrow symbol).
   b. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   c. Wait a minimum of 15 minutes (30 minutes maximum) from addition of the sample and read result.

   For whole blood (fingerstick) samples using EDTA capillary tubes:
   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 all the 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 (30 minutes maximum) from addition of the sample and read result.

NOTE:

- Running the test in high temperature/low humidity may affect the appearance of the patient bar. If the test strip is partially dried and it is difficult to read the result at 15 to 30 minutes, 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. At 40 °C/ 40 % RH or low humidity conditions, the test strip dries at 30 minutes.
- 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.

QUALITY CONTROL

To ensure assay validity, a procedural control system is incorporated in the device. This red control bar will appear in the window. If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip. A visible control bar confirms a lateral flow through the membrane.

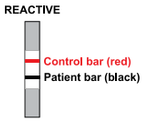
INTERPRETATION OF RESULTS (See pictures)

NOTE:

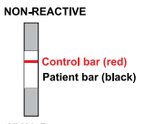
- Interpret any visible red bar (even very faint) in the window as a valid result.
- The test result is valid even if the black patient bar appears lighter or darker than the red control bar. Any visible black patient bar, no matter how faint, together with a red control bar is interpreted as reactive.
- Even if the color of control bar is dark red, it is valid.
- A test that has a very red background color making the patient and control bars difficult to read, as can occur with hemolytic specimens, should be considered invalid.
- If an invalid result occurs repeatedly, or for technical assistance, contact your local distributor or call the Advice Line.
- When a whole blood venipuncture or whole blood fingerstick result is reactive with Determine HBsAg 2, it is recommended

that the result is followed up with a plasma or serum Determine HBsAg 2 test or a laboratory reference test.

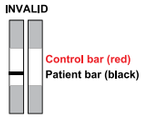
Reactive (Two bars: Red bar and Black bar)
Two bars: one red bar and one black bar appear in the window. The red bar corresponds to control bar and the black bar corresponds to patient bar, respectively.



Non-reactive (One bar: Red bar)
One red bar appears and no black bar appears in the window.



INVALID (No bar or One bar: Black bar)
If there is no red control bar in the window, and even if a black patient bar appears in the window, the result is invalid. Repeat the test using a new test strip.



LIMITATIONS OF THE PROCEDURES

- The Determine HBsAg 2 test is designed to detect Hepatitis B Surface Antigen (HBsAg) in human serum, plasma and whole blood. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the patient bar does not necessarily correlate with the titer of antigen in the specimen.
- No test provides absolute assurance that a sample does not contain low levels of HBsAg such as those present at a very early stage of infection.
- If the result is non-reactive at 15 minutes and reactive at 30 minutes, the patient has very low HBsAg below the detection limit.
- A non-reactive result at any time does not preclude the possibility of exposure to or infection with hepatitis B virus.
- The use of anticoagulants other than EDTA for whole blood or plasma specimens has not been validated for use with the Determine HBsAg 2 and may give incorrect results.
- For diagnostic purposes and to differentiate acute HBV infection from chronic HBV infection, the detection of HBsAg must be correlated with patient symptoms and other hepatitis B viral serological markers and nucleic acid testing (NAT).
- Biotin treatment higher than 5mg per day may lead to decreased patient bar intensity. Biotin concentrations up to 50 ng/mL in serum did not impact the sensitivity.

PERFORMANCE CHARACTERISTICS

Sensitivity
Sensitivity was evaluated by testing confirmed HBsAg positive specimens, commercial seroconversion panels, HBV genotype and serotype panels.

1. HBsAg Positive Specimens
A total of 437 confirmed HBsAg positive specimens were tested with Determine HBsAg 2 and a commercially available rapid HBsAg test (Table I). The sensitivity (95% CI) of Determine HBsAg 2 on this population of specimens was calculated to be 98.4% (96.7-99.4%). The non-reactive specimens with Determine HBsAg 2 were 0.06, 0.06, 0.09, 0.10, 0.13, 0.33 and 1.29 IU/mL by a quantitative HBsAg test kit.

Table I:
HBsAg Positive Specimens

Types	Number of Specimens tested	Reactive by Determine HBsAg 2	Reactive by alternative rapid HBsAg test
HBsAg positive specimens	369	362	294
HBV genotype determined specimens*	51	51	43
HBsAg serotype determined specimens**	17	17	17
Plasma sensitivity (95% CI)	369	98.6% (364/369) (96.9-99.6%)	81.3% (300/369) (76.9-85.2%)
Serum sensitivity (95% CI)	68	97.1% (66/68) (89.8-99.6%)	79.4%(54/68) (67.9-88.3%)
Total Sensitivity (95% CI)	437	98.4% (430/437) (96.7-99.4%)	81.0% (354/437) (77.0-84.6%)

* Genotypes: A, B, C, D, E, F, G, H, A/E, A/F, D/E, D/F and D/G
** Serotypes: adw2, adr, ayw2, ayw3 and ayw4 including 15 samples of # 6100/09 PEI Hepatitis B virus genotype panel

2. HBV seroconversion panels
The sensitivity of Determine HBsAg 2 was evaluated using 32 sets of seroconversion panels; each including early seroconversion panel members. The results were compared with the results of a commercially available rapid immunochromatographic HBsAg test kit and a quantitative HBsAg test kit (Chemiluminescent microparticle immunoassay (CMIA)). On all sets, Determine HBsAg 2 detected HBsAg earlier than a rapid immunochromatographic test kit. On 4 of 32 sets, Determine HBsAg 2 detected HBsAg earlier than a CMIA kit. Detection of 4 of 32 sets by Determine HBsAg 2 was delayed by 1 bleed date when compared to CMIA kit.
The first reactive date followed by continuously reactive results was compared with the first reactive date with the Determine HBsAg 2.

3. Analytical sensitivity of HBsAg
The analytical sensitivity of Determine HBsAg 2 was evaluated by testing WHO International Standard for HBsAg (NIBSC code 12/226). The results demonstrated that the test could detect a concentration of 0.1 IU/mL HBsAg.

4. HBsAg Mutant Detection
HBsAg mutant susceptibility was evaluated with Determine HBsAg 2. A panel consisting of 14 different recombinant HBsAg mutant panels was tested. The mutant panel consisted of following mutations, P120Q, T123A, T126N, T126S, Q129R, Q129H, Q129L, M133H, M133L, K141E, P142S, T143K, D144A and G145R. All 14 samples were detected with Determine HBsAg 2 at 0.25 IU/ml, and 11 out of 14 samples at 0.125 IU/ml.

Specificity
A total of 1736 confirmed negative serum or plasma specimens were tested with the Determine HBsAg 2 and the specificity (95% CI) was determined (Table II). The specificity was 99.53 (99.1 - 99.8%).

Table II:
HBsAg Negative Specimens

Population	Determine HBsAg 2		Rapid HBsAg Test	
	total	Non-reactive	total	Non-reactive
Seronegative specimens*	1027	1027	1027	1027
Clinical specimens	213	209	213	210
Pregnant women	211	210	206	205
Potentially cross-reacting specimens**	285	282	204	202
Plasma specificity (95% CI)	542	100% (542/542) (99.3-100%)	522	100% (522/522) (99.3-100%)
Serum specificity (95% CI)	1194	99.3% (1186/1194) (98.7-99.7%)	1128	99.5% (1122/1128) (98.8-99.8%)
Total Specificity (95% CI)	1736	99.5% (1728/1736) (99.1-99.8%)	1650	99.6% (1644/1650) (99.2-99.8%)

* Including specimens collected in USA (1240) and Africa (20)

**Disease states other than HBV and potentially interfering substances: Rheumatoid factor (20/20), antinuclear antibody (15/15), systemic lupus erythematosus (15/15), high cholesterol (9/9), high bilirubin (10/10), high total protein (3/3), high IgM (10/10), high IgG (4/4), human anti-mouse IgG (20/20), other infections - Hepatitis A virus (6/6), Hepatitis C virus (15/15), Hepatitis E virus (5/5), HTLV I (9/9), Cytomegalovirus (10/10), Toxoplasma IgG (10/10), Syphilis (8/8), Herpes simplex virus 1/2 (10/10), Epstein-Barr virus (9/10), Flu vaccinated patients (10/10), non-virus liver disease (19/20), Measles (5/6), Influenza A (5/5), Influenza B (5/5), Varicella zoster virius (5/5), HIV-1 (5/5), HIV-2 (5/5), malaria (5/5), Visceral Leishmaniasis (5/5), Gonorrhoea (5/5), Trichomonas (5/5), Schistosomiasis (5/5), and dialysis patient specimens (10/10). The following diseases have not been tested: multiple blood transfusions, sickle-cell disease, yellow fever, human African trypanosomiasis and and yellow fever vaccination.

Interference
- 20mg/dL bilirubin, 500mg/dL hemoglobin, 3300mg/dL triglyceride, and 12g/dL protein did not interfere with test results.
- At 15g/dL protein, no interference was observed with HBsAg negative sample, and HBsAg positive sample at 0.2IU/ml or more. With HBsAg positive sample at 0.1IU/ml, the test result presented false negative at 15 minutes reading time, but showed positive results at 30 minutes reading time.

Sample type
All specimen matrices (serum, plasma, whole blood venipuncture and whole blood fingerstick) were tested.

Table III:
HBsAg sensitivity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

Population	No. of matched specimens tested		Type of Specimens and No. of reactive or non-reactive by Determine HBsAg 2			
			Serum	Plasma	Whole blood venipuncture	Whole blood fingerstick**
HBsAg positive	145	Reactive	142	143	141	141
		Non-reactive	3	2	4	4
		Sensitivity (95% CI)	97.9% (94.1-99.6%)	98.6% (95.1-99.8%)	97.2%*** (93.1-99.2%)	97.2%*** (93.1-99.2%)
HBsAg negative	203	Reactive	1	0	0 <3**>	0 <3**>
		Non-reactive	202	202*	203 <200**>	203 <200**>
		Specificity (95% CI)	99.5% (97.3-100%)	100% (98.2-100%)	100% <98.5%**> (98.2-100%)	100% <98.5%**> (98.2-100%)

* There was no plasma result for 1 study subject.
** EDTA capillary tubes were used for 225 specimens. MICROSAFE® Tubes were used for 123 specimens. Prospective multiple (matched) specimens of whole blood, serum and plasma from 348 individuals (145 HBsAg positive) in European countries were tested with Determine HBsAg 2 (Table III). Whole blood initially reactive results were adjudicated utilizing the serum or plasma results; all were non-reactive on serum and plasma testing. The final assessment is that the samples were nonreactive. The true negative but initially reactive whole blood results are listed in parentheses <

> in Table III.

The results obtained from all specimen matrices showed correlation, except for the following.

One positive specimen (0.27 IU/mL) was reactive with plasma but non-reactive with serum, venipuncture whole blood and fingerstick. One positive specimen (0.14 IU/mL) was reactive with serum and plasma but non-reactive with venipuncture whole blood and fingerstick. Two seropositive specimens (0.08 IU/ml and 0.14 IU/ml) were non-reactive with all specimen matrices at 15 minutes. At 30 minutes, results for serum and plasma were reactive.

One negative specimen was non-reactive with plasma, venipuncture whole blood and fingerstick but reactive with serum. Three negative venipuncture whole blood specimens were reactive. Three negative fingerstick specimens were reactive.

*** When using the cut-off 0.13 IU/mL, the sensitivity at 15 and at 30 minutes for fingerstick and venous whole blood samples was 97.9%.

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3. Clinical and Laboratory Standards Institute. Collection of Capillary Blood Specimens; GP42 7th Edition September 2020
4. Clinical and Laboratory Standards Institute, Clinical Laboratory Waste Management: Approved Guideline-Third Edition, GP05-A3. January 2011
5. EPA Guide for Infectious Waste Management: Publication No. EPA/530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986:1-1-5, R1-R3, A1-A24.

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

Advice Line

For further information, please contact your distributor, or call 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

Glossary of Symbols	
	Temperature limit (2°C to 30°C)
	Catalogue number
	Do not reuse
	*In vitro* diagnostic medical device
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Contains Sufficient for n tests
	Consult instructions for use
	Batch Code
	Use-by date
	Unique device identification
	Manufacturer


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

February 2025
D10140469_AC

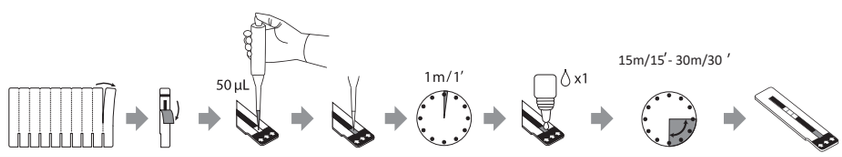
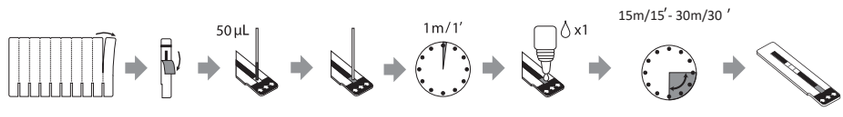
Abbott

REF 7D2943SET

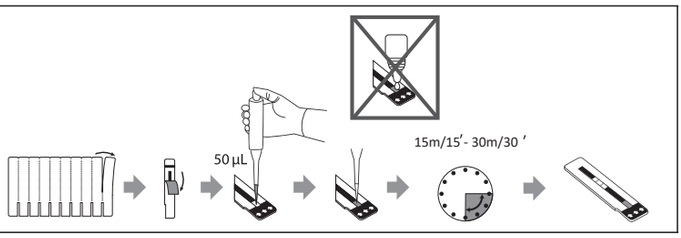
Read Highlighted Changes

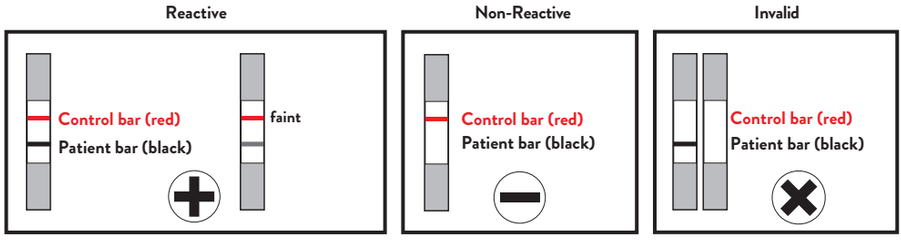
DETERMINE™ HBsAg 2

Whole Blood / Sangre Total / Sang Total / Sangue Total

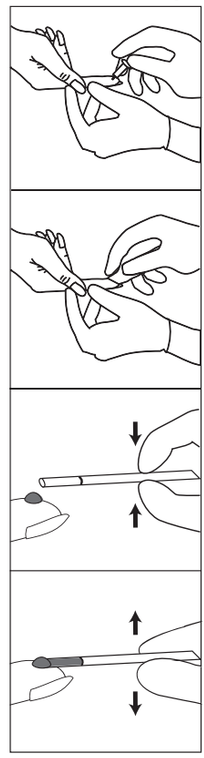
Pipette Pipeta Pipette Pipeta	
Capillary Tubes Tubos capilares Tubes capillaires Tubos Capilares	

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

Pipette Pipeta Pipette Pipeta	



Whole Blood Collection by Fingerstick



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EN

This instruction for use must be read carefully prior to use. All procedures must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this IFU.

NAME AND INTENDED USE

Determine™ HBsAg 2 is an *in vitro,* visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid in the diagnosis of HBV infection through detection of HBsAg from infected individuals. The test is not intended for screening blood donors. The test is for professional use only.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis B virus (HBV), is a DNA virus transmitted percutaneously, sexually and perinatally. Worldwide it causes deaths from cirrhosis, liver failure and hepatocellular carcinoma[1]. HBsAg seropositivity is the first serological marker to appear in acute HBV infection[2].

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine HBsAg 2 is an immunochromatographic test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg).
A specimen is added to the sample pad. The specimen mixes with biotinylated anti-HBsAg mouse monoclonal antibodies and black particles coated with anti-HBsAg mouse monoclonal antibodies. This mixture migrates along the solid phase to the immobilized avidin at the patient bar.
If HBsAg is present in the specimen, the antigen binds to the biotinylated anti-HBsAg mouse monoclonal antibodies and the black particles coated with anti-HBsAg mouse monoclonal antibodies. This complex binds to the immobilized avidin forming a black bar on the test strip. If HBsAg is not present, black particles flow past the patient bar and no black bar is formed on the test strip.
To ensure assay validity, a procedural control bar is incorporated in the assay device on the test strip. The red control bar will appear.

CONTENTS

Determine HBsAg 2 SET (7D2943SET) (100 test for testing whole blood samples)

- Determine HBsAg 2 Test Card, 20 cards (containing 5 tests/ card)
- Chase Buffer (7D2243) 1 Bottle (2.5ml) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.
- Capillary Tubes
- Blood Lancet

Materials Required But Not Provided

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab, clean or sterile gauze pad

WARNING AND PRECAUTIONS

For *In Vitro* Diagnostic Use.
Use the Chase Buffer bottle with attention to avoid contamination of the nozzle. Don't touch nozzle to the sample or sample pad.
Safety data sheet available for professional users on request.

CAUTION:

The package insert is placed in the kit box. **DO NOT** put the package insert inside the foil pouch. When handling specimens and reagents, use appropriate biosafety practices[4,5]. 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[3,4].
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations[3,4].

STORAGE

Store Determine HBsAg 2 Test Cards and Chase Buffer at 2°C to 30°C until expiration date. Chase Buffer cap should be kept firmly sealed between each use to avoid evaporation or spillage.

- When handled and stored as directed, kit components are stable until 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 wet devices or damaged packages.

SPECIMEN COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture

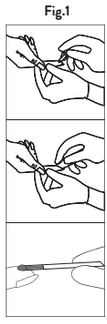
Use EDTA collection tubes for whole blood and plasma specimens.

- 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)

1. Before collecting a fingerstick specimen, place a capillary tube and a lancet on a clean dry surface. After taking a capillary tube, seal to close the plastic bag and store the remaining capillary tubes in the kit box to avoid sunlight.
   Do not use a capillary tube that is dirty or bent.
   Do not touch the open end of the capillary tubes before use.
2. Ask the patient to increase blood circulation by rubbing the hands together.
3. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused). Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
4. Clean the fingertip with alcohol swab and allow to air-dry. Position the hand, palm-side up. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin.
   Dispose of the lancet in an appropriate biohazard sharps container.
5. Wipe away the first drop of blood with a clean or sterile gauze pad.

Fig.1



6. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times, avoiding the puncture wound.
7. Confirm the location of the line on the capillary tube. Squeeze the body of capillary tube by using your index finger and thumb. Let the open end of the capillary tube touch the blood bead, release the finger slowly - blood will be sucked into the capillary tube.
8. Collect the blood up to the line and do not collect the blood above the line. Reliability of assay results cannot be guaranteed if blood is collected below or above the line.
9. If the sample is not enough to fill up to the line of the capillary tube, apply gentle pressure to the finger again to make a drop of blood and take the blood until the line is reached.
10. Confirm no air bubble is present in the sample. If an air bubble is present, or if blood is collected below or above the line after completion of collection, discard the capillary tube with the sample and do not use it.
11. Immediately proceed to Testing Procedure 4 for whole blood (fingerstick) samples.

SPECIMEN STORAGE

- Store serum and plasma specimens at 2 °C to 8 °C and run the test within 7 days of collection. If testing is delayed more than 7 days, the specimens should be frozen (-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 min 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 °C to 8 °C. Do not freeze whole blood specimens. Run the test within 2 days (48 hours) of collection. Mix the specimen well by gentle inversion of the tube immediately before testing.
- For whole blood collected by fingerstick, test immediately.

TEST PROCEDURE

This test should be performed at 18 °C to 40 °C.

1. Remove the desired number of test strips from the 5-test card by bending and tearing at the perforation.
   - The lot number and expiration date are printed on the back of each test strip and on the foil pouch.
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 (30 minutes maximum) from addition of the sample and read result.

   For whole blood (venipuncture) samples:
   a. Apply 50 µL of sample (precision pipette) to the middle of the sample pad (marked by the arrow symbol).
   b. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   c. Wait a minimum of 15 minutes (30 minutes maximum) from addition of the sample and read result.

   For whole blood (fingerstick) samples:
   a. Squeeze the body of the capillary tube expelling the blood onto the sample pad of the test device. Apply all blood in the capillary tube onto the sample pad. Do not splash the blood.
   b. Dispose of the used capillary tubes as biohazardous material according to local regulations.
   c. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically. The tip of Chase Buffer should be 1 cm distance away (same as nozzle length) from the sample pad to avoid contamination.
   d. Close the cap after using the chase buffer every time.
   e. If sample splashes onto an adjacent test strip or chase buffer nozzle, discard the strip or chase buffer.
   f. Store the remaining capillary tubes to avoid sunlight.
   g. Wait a minimum 15 minutes (30 minutes maximum) from addition of the sample and read result.

NOTE:

- Running the test in high temperature/low humidity may affect the appearance of the patient bar. If the test strip is partially dried and it is difficult to read the result at 15 to 30 minutes, 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. At 40 °C/ 40 % RH or low humidity conditions, the test strip dries at 30 minutes.
- 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.
- Recap and store the Chase Buffer at 2-30°C to avoid evaporation or spillage. The procedural control demonstrates that sample and Chase Buffer addition and flow are correct.

QUALITY CONTROL

To ensure assay validity, a procedural control system is incorporated in the device. This red control bar will appear in the window. If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip. A visible control bar confirms a lateral flow through the membrane.

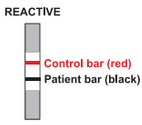
INTERPRETATION OF RESULTS (See pictures)

NOTE:

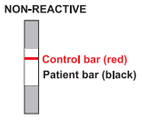
- Interpret any visible red bar (even very faint) in the window as a valid result.
- The test result is valid even if the black patient bar appears lighter or darker than the red control bar. Any visible black patient bar, no matter how faint, together with a red control

bar is interpreted as reactive.
- Even if the color of control bar is dark red, it is valid.
- A test that has a very red background color making the patient and control bars difficult to read, as can occur with hemolytic specimens, should be considered invalid.
- If an invalid result occurs repeatedly, or for technical assistance, contact your local distributor or call the Advice Line.
- When a whole blood venipuncture or whole blood fingerstick result is reactive with Determine HBsAg 2, it is recommended that the result is followed up with a plasma or serum Determine HBsAg 2 test or a laboratory reference test.

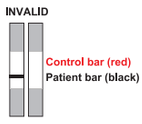
Reactive (Two bars: Red bar and Black bar)
Two bars: one red bar and one black bar appear in the window. The red bar corresponds to control bar and the black bar corresponds to patient bar, respectively.



Non-reactive (One bar: Red bar)
One red bar appears and no black bar appears in the window.



INVALID (No bar or One bar: Black bar)
If there is no red control bar in the window, and even if a black patient bar appears in the window, the result is invalid. Repeat the test using a new test strip.



LIMITATIONS OF THE PROCEDURES

- The Determine HBsAg 2 test is designed to detect Hepatitis B Surface Antigen (HBsAg) in human serum, plasma and whole blood. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the patient bar does not necessarily correlate with the titer of antigen in the specimen.
- No test provides absolute assurance that a sample does not contain low levels of HBsAg such as those present at a very early stage of infection.
- If the result is non-reactive at 15 minutes and reactive at 30 minutes, the patient has very low HBsAg below the detection limit.
- A non-reactive result at any time does not preclude the possibility of exposure to or infection with hepatitis B virus.
- The use of anticoagulants other than EDTA for whole blood or plasma specimens has not been validated for use with the Determine HBsAg 2 and may give incorrect results.
- For diagnostic purposes and to differentiate acute HBV infection from chronic HBV infection, the detection of HBsAg must be correlated with patient symptoms and other hepatitis B viral serological markers and nucleic acid testing (NAT).
- Biotin treatment higher than 5mg per day may lead to decreased patient bar intensity. Biotin concentrations up to 50 ng/mL in serum did not impact the sensitivity.

PERFORMANCE CHARACTERISTICS

Sensitivity

Sensitivity was evaluated by testing confirmed HBsAg positive specimens, commercial seroconversion panels, HBV genotype and serotype panels.

1. HBsAg Positive Specimens

A total of 437 confirmed HBsAg positive specimens were tested with Determine HBsAg 2 and a commercially available rapid HBsAg test (Table I). The sensitivity (95% CI) of Determine HBsAg 2 on this population of specimens was calculated to be 98.4% (96.7-99.4%). The non-reactive specimens with Determine HBsAg 2 were 0.06, 0.06, 0.09, 0.10, 0.13, 0.33 and 1.29 IU/mL by a quantitative HBsAg test kit.

Table I:
HBsAg Positive Specimens

Types	Number of Specimens tested	Reactive by Determine HBsAg 2	Reactive by alternative rapid HBsAg test
HBsAg positive specimens	369	362	294
HBV genotype determined specimens*	51	51	43
HBsAg serotype determined specimens**	17	17	17
Plasma sensitivity (95% CI)	369	98.6% (364/369) (96.9-99.6%)	81.3% (300/369) (76.9-85.2%)
Serum sensitivity (95% CI)	68	97.1% (66/68) (89.8-99.6%)	79.4%(54/68) (67.9-88.3%)
Total Sensitivity (95% CI)	437	98.4% (430/437) (96.7-99.4%)	81.0% (354/437) (77.0-84.6%)

* Genotypes: A, B, C, D, E, F, G, H, A/E, A/F, D/E, D/F and D/G
** Serotypes: adw2, adr, ayw2, ayw3 and ayw4 including 15 samples of # 6100/09 PEI Hepatitis B virus genotype panel

2. HBV seroconversion panels

The sensitivity of Determine HBsAg 2 was evaluated using 32 sets of seroconversion panels; each including early seroconversion panel members. The results were compared with the results of a commercially available rapid immunochromatographic HBsAg test kit and a quantitative HBsAg test kit (Chemiluminescent microparticle immunoassay (CMIA)). On all sets, Determine HBsAg 2 detected HBsAg earlier than a rapid immunochromatographic test kit. On 4 of 32 sets, Determine HBsAg 2 detected HBsAg earlier than a CMIA kit. Detection of 4 of 32 sets by Determine HBsAg 2 was delayed by 1 bleed date when compared to CMIA kit.

The first reactive date followed by continuously reactive results was compared with the first reactive date with the Determine HBsAg 2.

3. Analytical sensitivity of HBsAg

The analytical sensitivity of Determine HBsAg 2 was evaluated by testing WHO International Standard for HBsAg (NIBSC code 12/226). The results demonstrated that the test could detect a concentration of 0.1 IU/mL HBsAg.

4. HBsAg Mutant Detection

HBsAg mutant susceptibility was evaluated with Determine HBsAg 2. A panel consisting of 14 different recombinant HBsAg mutant panels was tested. The mutant panel consisted of following mutations, P120Q, T123A, T126N, T126S, Q129R, Q129H, Q129L, M133H, M133L, K141E, P142S, T143K, D144A and G145R. All 14 samples were detected with Determine HBsAg 2 at 0.25 IU/ml, and 11 out of 14 samples at 0.125 IU/ml.

Specificity

A total of 1736 confirmed negative serum or plasma specimens were tested with the Determine HBsAg 2 and the specificity (95% CI) was determined (Table II). The specificity was 99.53 (99.1 - 99.8%).

Table II:
HBsAg Negative Specimens

Population	Determine HBsAg 2		Rapid HBsAg Test	
	total	Non-reactive	total	Non-reactive
Seronegative specimens*	1027	1027	1027	1027
Clinical specimens	213	209	213	210
Pregnant women	211	210	206	205
Potentially cross-reacting specimens**	285	282	204	202
Plasma specificity (95% CI)	542	100% (542/542) (99.3-100%)	522	100% (522/522) (99.3-100%)
Serum specificity (95% CI)	1194	99.3% (1186/1194) (98.7-99.7%)	1128	99.5% (1122/1128) (98.8-99.8%)
Total Specificity (95% CI)	1736	99.5% (1728/1736) (99.1-99.8%)	1650	99.6% (1644/1650) (99.2-99.8%)

* Including specimens collected in USA (1240) and Africa (20)

**Disease states other than HBV and potentially interfering substances: Rheumatoid factor (20/20), antinuclear antibody (15/15), systemic lupus erythematosus (15/15), high cholesterol (9/9), high bilirubin (10/10), high total protein (3/3), high IgM (10/10), high IgG (4/4), human anti-mouse IgG (20/20), other infections - Hepatitis A virus (6/6), Hepatitis C virus (15/15), Hepatitis E virus (5/5), HTLV I (9/9), Cytomegalovirus (10/10), Toxoplasma IgG (10/10), Syphilis (8/8), Herpes simplex virus 1/2 (10/10), Epstein-Barr virus (9/10), Flu vaccinated patients (10/10), non-virus liver disease (19/20), Measles (5/6), Influenza A (5/5), Influenza B (5/5), Varicella zoster virus (5/5), HIV-1 (5/5), HIV-2 (5/5), malaria (5/5), Visceral Leishmaniasis (5/5), Gonorrhoea (5/5), Trichomonas (5/5), Schistosomiasis (5/5), and dialysis patient specimens (10/10). The following diseases have not been tested: multiple blood transfusions, sickle-cell disease, yellow fever, human African trypanosomiasis and and yellow fever vaccination.

Interference

- 20mg/dL bilirubin, 500mg/dL hemoglobin, 3300mg/dL triglyceride, and 12g/dL protein did not interfere with test results.

- At 15g/dL protein, no interference was observed with HBsAg negative sample, and HBsAg positive sample at 0.2IU/ml or more. With HBsAg positive sample at 0.1IU/ml, the test result presented false negative at 15 minutes reading time, but showed positive results at 30 minutes reading time.

Sample type

All specimen matrices (serum, plasma, whole blood venipuncture and whole blood fingerstick) were tested.

Table III:
HBsAg sensitivity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

Population	No. of matched specimens tested		Type of Specimens and No. of reactive or non-reactive by Determine HBsAg 2			
			Serum	Plasma	Whole blood venipuncture	Whole blood fingerstick**
HBsAg positive	145	Reactive	142	143	141	141
		Non-reactive	3	2	4	4
		Sensitivity (95% CI)	97.9% (94.1-99.6%)	98.6% (95.1-99.8%)	97.2%*** (93.1-99.2%)	97.2%*** (93.1-99.2%)
HBsAg negative	203	Reactive	1	0	0 <3**>	0 <3**>
		Non-reactive	202	202*	203 <200**>	203 <200**>
		Specificity (95% CI)	99.5% (97.3-100%)	100% (98.2-100%)	100% <98.5%**> (98.2-100%)	100% <98.5%**> (98.2-100%)

* There was no plasma result for 1 study subject.
** EDTA capillary tubes were used for 225 specimens. MICROSAFE® Tubes were used for 123 specimens. Prospective multiple (matched) specimens of whole blood, serum and plasma from 348 individuals (145 HBsAg positive) in European countries were tested with Determine HBsAg 2 (Table III). Whole blood initially reactive results were adjudicated utilizing the serum or plasma results; all were non-reactive on serum and plasma testing. The final assessment is that the samples were nonreactive. The true negative but initially reactive whole blood results are listed in parentheses < > in Table III.

The results obtained from all specimen matrices showed correlation, except for the following.

One positive specimen (0.27 IU/mL) was reactive with plasma but non-reactive with serum, venipuncture whole blood and fingerstick. One positive specimen (0.14 IU/mL) was reactive with

serum and plasma but non-reactive with venipuncture whole blood and fingerstick. Two seropositive specimens (0.08 IU/ml and 0.14 IU/ml) were non-reactive with all specimen matrices at 15 minutes. At 30 minutes, results for serum and plasma were reactive.

One negative specimen was non-reactive with plasma, venipuncture whole blood and fingerstick but reactive with serum. Three negative venipuncture whole blood specimens were reactive. Three negative fingerstick specimens were reactive.

*** When using the cut-off 0.13 IU/mL, the sensitivity at 15 and at 30 minutes for fingerstick and venous whole blood samples was 97.9%.

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5. EPA Guide for Infectious Waste Management: Publication No. EPA/530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986:1-1-5, R1-R3, A1-A24.

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

Advice Line

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

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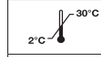	Temperature limit (2°C to 30°C)
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