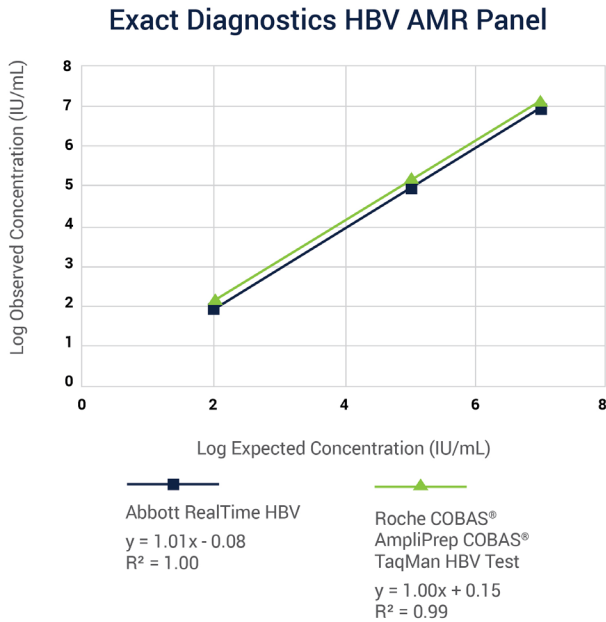






**РАБОТНИ ХАРАКТЕРИСТИКИ:**

Три уникални партиди от EDX HBV AMR Panel са тествани в три екземпляра от целите тестове, посочени в графиката по-долу.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**СПРАВКА ЗА СИМВОЛИТЕ:**



Каталожен номер



Партиден номер



За използване при ин витро диагностика



Биологични рискове



Срок на годност



Не използвайте повторно



Горна граница на температурата



Производител



Внимание



Прочетете инструкциите за употреба

**БИБЛИОГРАФИЯ:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission



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Съединени американски щати

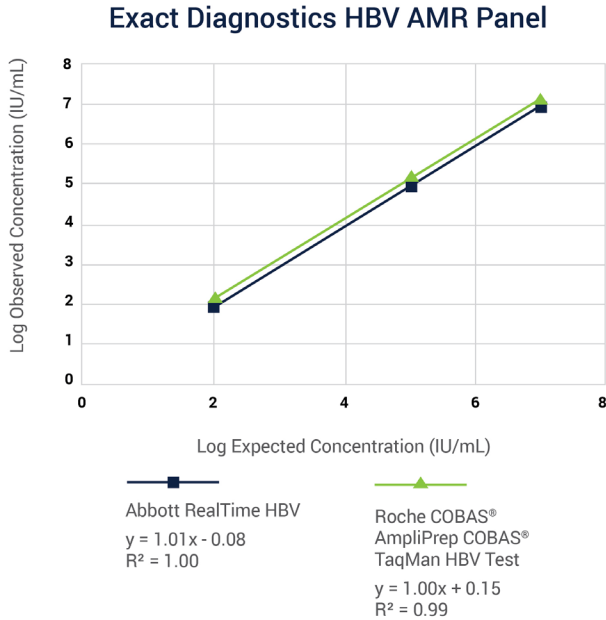






**VÝKONOVÁ CHARAKTERISTIKA:**

Tři unikátní šarže EDX HBV AMR Panel byly testovány ve třech provedeních napříč analýzami uvedenými v grafu níže.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**POUŽITÉ SYMBOLY:**

-  Katalogové číslo
-  Číslo šarže
-  Pro diagnostické použití in vitro
-  Biologická rizika
-  Datum expirace
-  Nepoužívejte opakovaně
-  Horní teplotní limit
-  Výrobce
-  Upozornění
-  Čtěte návod k použití

**ODKAZY:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU.  
<http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup> Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007  
Guideline for Isolation Precautions: Preventing Transmission



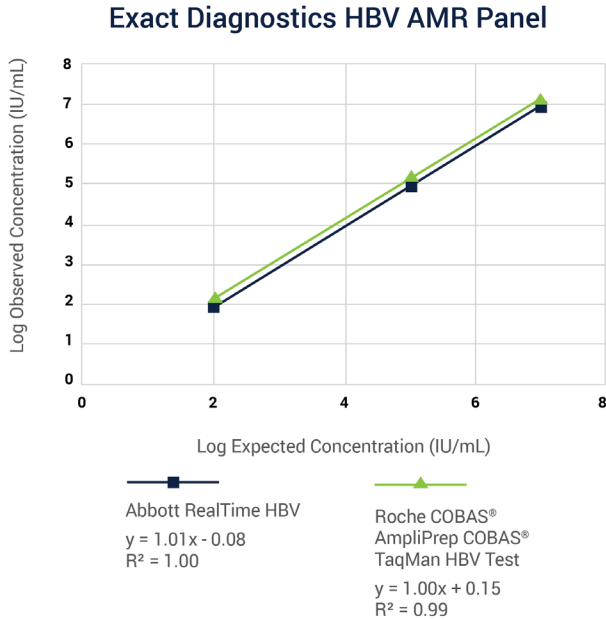
Exact Diagnostics LLC  
3400 Camp Bowie Blvd CBH-214  
Fort Worth, Texas 76107  
Spojené státy















**YDELSESEGENSKABER:**

Tre unikke lot EDX HBV AMR Panel blev testet i triplikat for de analyser, der er anført i diagrammet herunder.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**SYMBOLFORKLARING:**

-  REF Katalognummer
-  LOT Lotnummer
-  IVD Til in vitro-diagnostisk brug
-  Biologiske risici
-  Holdbarhedsdato
-  Må ikke genbruges
-  Øvre temperaturgrænse
-  Producent
-  Forsigtig
-  Se brugsanvisningen

**REFERENCER:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission



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USA

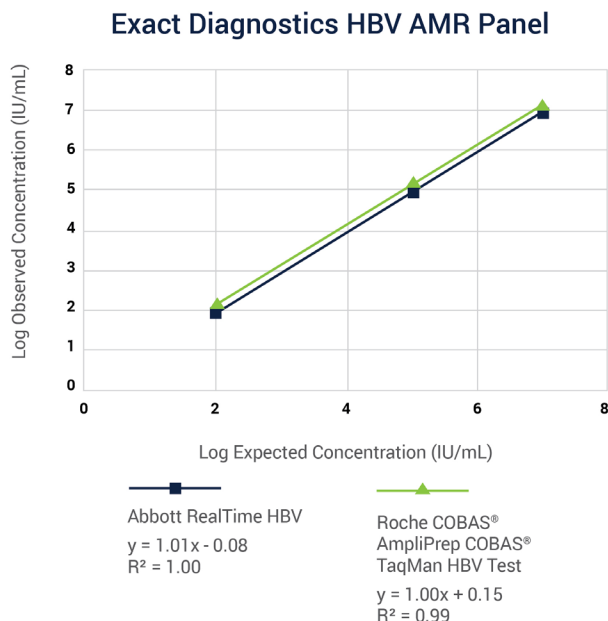






## SOORITUSNÄITAJAD

Alltoodud graafikul näidatud analüüside raames testiti kolme EDX HBV AMR Panel'i partiid kolmes eksemplaris.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

## VIITED

<sup>1</sup> The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup> Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

## TINGMÄRGID



Katalooginumber



Partii number



Kasutamiseks *in vitro* diagnostikas



Bioloogiline oht



Kõlblikkusaja lõpp



Ärge kasutage korduvalt



Temperatuuri ülempiir



Tootja



Ettevaatust!



Tutvuge kasutusjuhistega



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Fort Worth TX 76107  
Ameerika Ühendriigid

Tootja: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107

Abi saamiseks ja tellimuste esitamiseks võtke ühendust aadressil  
[customerservice@exactdiagnostics.com](mailto:customerservice@exactdiagnostics.com) või telefonil **817-989-9262**

[www.exactdiagnostics.com](http://www.exactdiagnostics.com)

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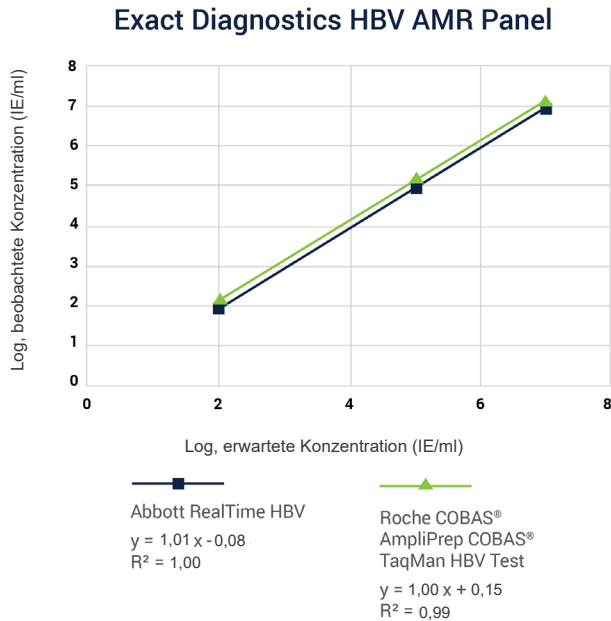






**LEISTUNGSMERKMALE:**

Drei verschiedene Chargen des EDX HBV AMR Panel wurden im Dreifachansatz Ausfertigung über die in der folgenden Grafik dargestellten Assays hinweg getestet.



Die bereitgestellten Daten dienen nur zu Informationszwecken. Erwartete Ergebnisse sind vom Endanwender für das betreffende Assay-System festzulegen.

**SYMBOLVERWEISE:**

-  REF Katalognummer
-  LOT Chargennummer
-  IVD In-vitro-Diagnostikum
-  Biologische Risiken
-  Haltbarkeitsdatum
-  Nicht wiederverwenden
-  Obere Temperaturgrenze
-  Hersteller
-  Achtung
-  Gebrauchsanleitung beachten

**LITERATUR:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

BIO-RAD und DROPLET DIGITAL PCR sind Marken von Bio-Rad Laboratories, Inc. in bestimmten Rechtssprechungen.

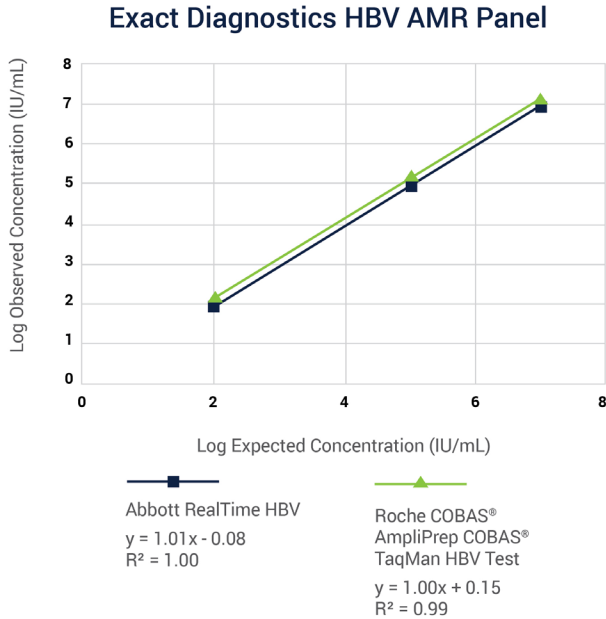


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USA



**ΧΑΡΑΚΤΗΡΙΣΤΙΚΑ ΑΠΟΔΟΣΗΣ:**

Έγιναν δοκιμές σε τρεις μοναδικές παρτίδες του EDX HBV AMR Panel εις τριπλούν για τις διαδικασίες προσδιορισμού που αναφέρονται στο διάγραμμα που ακολουθεί.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**ΑΝΑΦΟΡΕΣ ΣΥΜΒΟΛΩΝ:**

Αριθμός καταλόγου



Αριθμός παρτίδας



Για διαγνωστική χρήση in vitro



Βιολογικοί κίνδυνοι



Ημερομηνία λήξης



Μην επαναχρησιμοποιείτε



Άνω όριο θερμοκρασίας



Κατασκευαστής



Προσοχή



Συμβουλευθείτε τις οδηγίες χρήσης

**ΒΙΒΛΙΟΓΡΑΦΙΑ:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU.  
<http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007  
Guideline for Isolation Precautions: Preventing Transmission

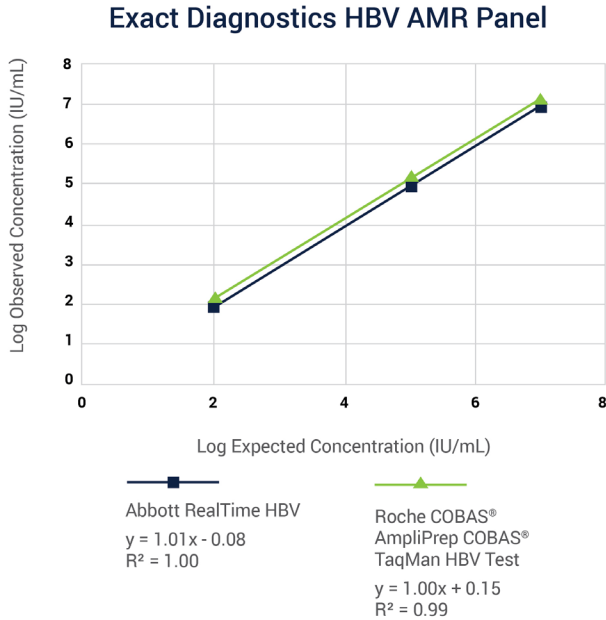


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Η.Π.Α.



**TELJESÍTMÉNYJELLEMZŐK:**

Az EDX HBV AMR Panel három egyedi tétele három példányban volt tesztelve az alábbi ábrán látható próbával.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**JELMAGYARÁZAT:**

-  Katalógusszám
-  Tételszám
-  In vitro diagnosztikai felhasználásra
-  Biológiai kockázatok
-  Lejárati dátum
-  Ne használja újra.
-  Hőmérséklet felső határa
-  Gyártó
-  Figyelem
-  Olvassa el a Használati utasítást

**IRODALOMJEGYZÉK:**

<sup>1</sup>A Hepatitis B 3. WHO nemzetközi szabványa (10/264) IFU.  
<http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007  
Guideline for Isolation Precautions: Preventing Transmission



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Fort Worth TX 76107  
USA

Gyártó: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107

Ha segítségre van szüksége, vagy szeretne utánrendelni, lépjen velünk kapcsolatba:

customerservice@exactdiagnostics.com vagy **817.989.9262**

[www.exactdiagnostics.com](http://www.exactdiagnostics.com)

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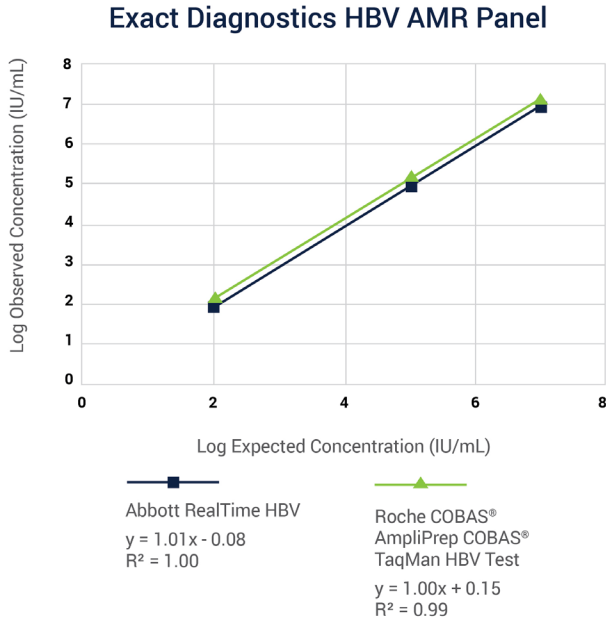






**METROLOGINĖS CHARAKTERISTIKOS:**

Trys unikalios „EDX HBV AMR Panel“ partijos buvo išbandytos kartu tyrimuose, nurodytuose toliau pateiktame grafike.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**SIMBOLIŲ NUORODOS:**

-  Katalogo numeris
-  Partijos numeris
-  Skirta in vitro diagnostikos tyrimams
-  Biologinė rizika
-  Galiojimo data
-  Nenaudoti pakartotinai
-  Viršutinė temperatūros riba
-  Gamintojas
-  Perspėjimas
-  Žiūrėti naudojimo instrukciją

**BIBLIOGRAFIJA:**

<sup>1</sup>3-iasis PSO tarptautinis standartas dėl hepatito B (10/264), naudojimo instrukcija.  
<http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L ir „Healthcare Infection Control Practices Advisory Committee“, 2007 m. „Guideline for Isolation Precautions: Preventing Transmission“

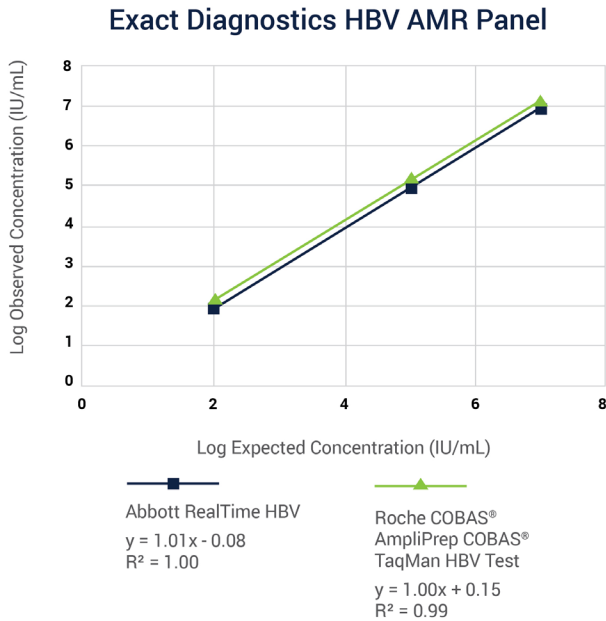


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**КАРАКТЕРИСТИКИ НА УЧИНОК:**

Три уникатни серии на EDX HBV AMR Panel беа тестирани во три примероци во анализи идентификувани во графиконот подолу.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**РЕФЕРЕНЦИ СИМБОЛИ:**



Каталошки број



Број на серија



За ин витро дијагностичка употреба



Биолошки ризици



Рок на траење



Не смее повторно да се употребува



Горна граница на температура



Производител



Внимание



Прочитајте ги упатствата за користење

**РЕФЕРЕНЦИ:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

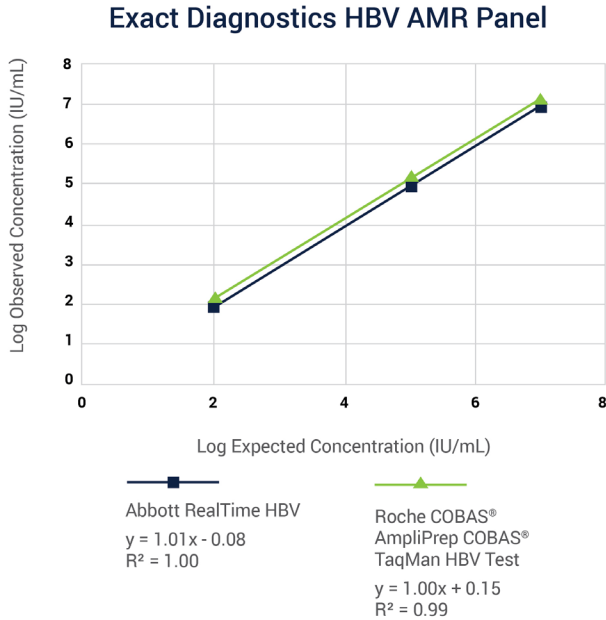


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Соединети Држави













**YTELSESEGENSKAPER:**

Tre ulike partier av EDX HBV AMR Panel ble testet i tre eksemplarer på tvers av analysene identifisert i grafen nedenfor.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**SYMBOLREFERANSER:**

-  Katalognummer
-  Partnummer
-  Til in vitro-diagnostisk bruk
-  Biologiske risikoer
-  Utløpsdato
-  Må ikke gjenbrukes
-  Øvre temperaturgrense
-  Produsent
-  Forsiktig
-  Se bruksanvisningen

**REFERANSER:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission



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United States



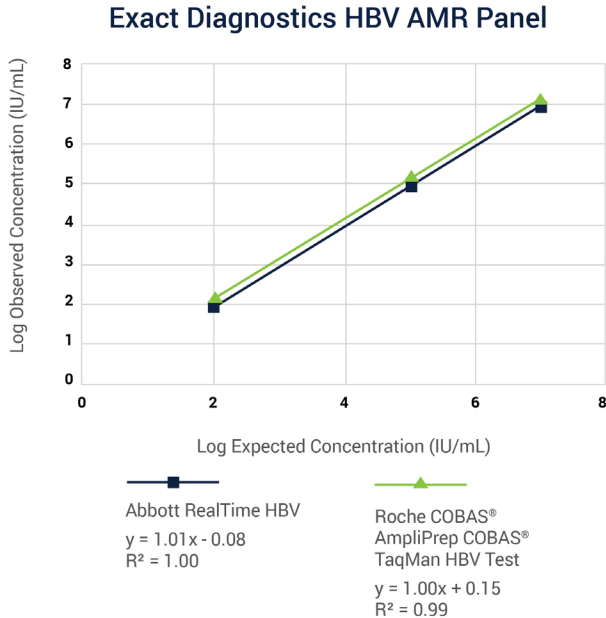













**CARACTERÍSTICAS DE DESEMPENHO:**

Foram testados três lotes únicos de EDX HBV AMR Panel em triplicado nos ensaios identificados no gráfico abaixo.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**REFERÊNCIAS DOS SÍMBOLOS:**

-  REF Número de catálogo
-  LOT Número do lote
-  IVD Para utilização em diagnóstico in vitro
-  Riscos biológicos
-  Data de validade
-  Não reutilizar
-  Limite de temperatura máximo
-  Fabricante
-  Precaução
-  Consulte as Instruções de Utilização

**REFERÊNCIAS:**

<sup>1</sup>A 3.ª Norma Internacional da OMS para a Hepatite B (10/264) IU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

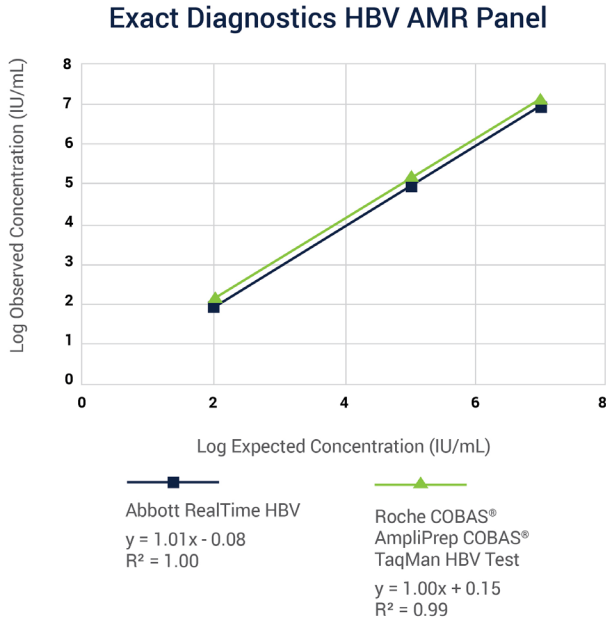


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Fort Worth TX 76107  
EUA



**CARACTERISTICI DE PERFORMANȚĂ:**

Trei loturi unice de EDX HBV AMR Panel au fost testate în trei exemplare în cadrul testelor identificate în graficul de mai jos.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**REFERINȚE:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

**REFERINȚE SIMBOLURI:**

-  Număr de catalog
-  Număr lot
-  Pentru utilizare în diagnosticul in vitro
-  Riscuri biologice
-  Data expirării
-  A nu se reutiliza
-  Limită superioară de temperatură
-  Producător
-  Atenție
-  Consultați instrucțiunile de utilizare



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 Fort Worth TX 76107  
 Statele Unite ale Americii















EDX HBV AMR Panel Sammanfattning	
Artikelnummer	HBVAMR
Analyt	Inaktiverad HBV
Matris	True EDTA Plasma
Konserveringsmedel	ProClin® 300
Lagring	-20 °C eller lägre
Fyllningsvolym	1,0 mL
Antal flaskor per uppsättning	3 flaskor
Antal användningar	För engångsbruk
Hållbarhet	36 månader efter tillverkningsdatum
Spårbarhet	WHO:s tredje internationella standard
Försiktighetsåtgärder	Biologiska risker
Gällande status	För in vitro-diagnostiskt bruk

**AVSEDD ANVÄNDNING:**

EDX HBV Analytical Measurement Range (AMR) Panel är en standard för olika molekyllära analyser. EDX HBV AMR Panel är kalibrerad mot WHO:s tredje internationella standard för Hepatit B (10/264)<sup>1</sup>. EDX HBV AMR Panel används för att fastställa referenspunkter (kvalitativt och kvantitativt) för mätning av Hepatit B virus (HBV) DNA. Rutinmässig användning av EDX HBV AMR Panel gör det möjligt för laboratorier att utvärdera den dagliga variationen och "lot-to-lot" -variationen i sin molekyllära analys samt testa operatörens kompetens.

**PRODUKTBESKRIVNING:**

EDX HBV AMR Panel innehåller hela, intakta virus som har värmeinaktiverats. EDX HBV AMR Panel är avsedd att testa hela processen för en molekyllära analys inklusive extraktion, detektion och amplifiering.

EDX HBV AMR Panel rapporteras i internationella enheter per milliliter (IU/mL). EDX HBV AMR Panel är tillverkad enligt ISO 17511:2003. EDX HBV AMR Panel är formulerad i True EDTA Plasma som är icke-reaktiv för HBV DNA, HCV RNA, HIV-1 RNA, HBsAg och antikroppar för HIV-1/2 och HCV.

EDX HBV AMR-komponenter	Koncentration
EDX HBV AMR Panelmedlem 1	100 IU/mL
EDX HBV AMR Panelmedlem 2	100 000 IU/mL
EDX HBV AMR Panelmedlem 3	10 000 000 IU/mL

**PROCEDUR:**

EDX HBV AMR Panel kräver ett extraktionssteg. Panelen måste behandlas på liknande sätt som andra testade prover. Detta gör det möjligt för operatören att utvärdera sin extraktionsteknik. EDX HBV AMR Panel ska testas i enlighet med analystillverkarens eller testlaboratoriets anvisningar och rekommendationer.

**FÖRVARING OCH HANTERING:**

EDX HBV AMR Panel bör förvaras vid -20 °C eller lägre.

Tina EDX HBV AMR Panel i rumstemperatur och rör snabbt om innan användning.

Väl upptinad är EDX HBV AMR Panel stabil i 24 timmar vid lagring vid 2-8 °C. Allt återstående material måste kasseras efter användning. Får ej återanvändas. Får ej spädas ut.

Använd inte EDX HBV AMR Panel efter angivet utgångsdatum.

**BEGRÄNSNINGAR:**

För in vitro-diagnostiskt bruk.

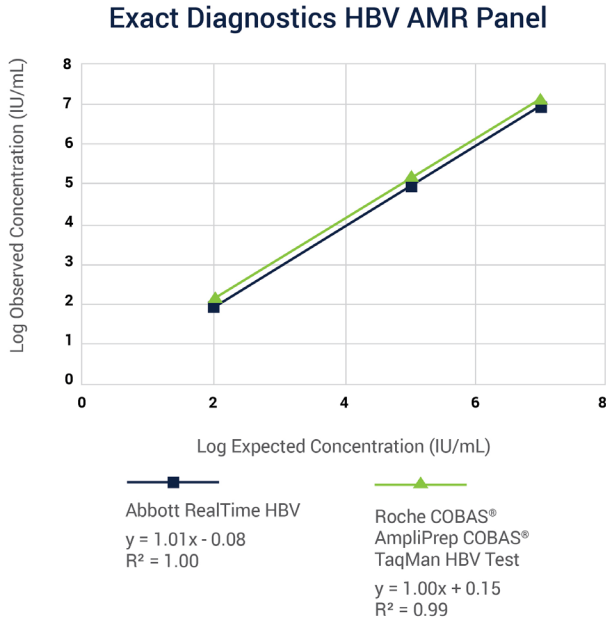
**VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER:**

EDX HBV AMR Panel innehåller virus som har värmeinaktiverats, men bör betraktas som biologiskt riskmaterial. Universella försiktighetsåtgärder och korrekt avfallshantering bör tillämpas<sup>2</sup>. Munpipettera ej. Rök, ät och drick inte i områden där testprov hanteras.

Kassera produkten om förpackningen är skadad eller läcker. Desinficera vätskor, material eller spill med en 0,5 % natriumhypokloritlösning. Kassera alla material och vätskor som används i proceduren som om de innehöll patogena medel.

**PRESTANDAEGENSKAPER:**

Tre unika partier av EDX HBV AMR Panel testades i tre exemplar över de analyser som identifierats i diagrammet nedan.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**SYMBOLREFERENSER:**

-  REF Artikelnummer
-  LOT Batchnummer
-  IVD För in vitro-diagnostiskt bruk
-  Biologiska risker
-  Utgångsdatum
-  Får ej återanvändas
-  Övre temperaturgräns
-  Tillverkare
-  Varning
-  Se bruksanvisningen

**REFERENSER:**

<sup>1</sup>The 3<sup>rd</sup> WHO International Standard for Hepatitis B (10/264) IFU. <http://www.nibsc.org/documents/ifu/10-264.pdf>

<sup>2</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission



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