

QuikRead go[®] Hb 10 µl Control, Cat. no. 153656

English

(English translation of the original instructions for use)

Intended use

QuikRead go[®] Hb 10 µl Control is intended for quality control of the Hb assays of the QuikRead go[®] wrCRP+Hb tests by the QuikRead go[®] instrument.
For *in vitro* diagnostic use.

Principles of the procedure

Use the control in the same way as unknown **whole blood** specimen would be used, following the instructions for the assay procedure.

Reagents

The control is from bovine origin. It should be handled in the same way as patient sample.

Preparation

The control is ready-to-use. Allow the material to stabilizie for 30 minutes at room temperature (18…25°C).
Mix well. Do not shake.

Storage

Stable until the expiry date when stored at 2…8°C.
Opened vial: Stable for 1 month at 2…8°C.
Do not use any vial that has visible evidence of microbial growth.

Expected values

The individual result should be within the range indicated on the control vial label. Each laboratory should establish its own mean and precision data.

(German translation of the original instructions for use)

QuikRead go[®] Hb 10 µl Control, Kat. -Nr. 153656

Hb 10 µl Kontrolle

(German translation of the original instructions for use)

Anwendung

QuikRead go[®] Hb 10 µl Control ist für die Qualitätskontrolle des QuikRead go[®] wrCRP+Hb-Testes bestimmt, gemessen mit dem QuikRead go[®] Instrument.
Nur für *in vitro* Diagnostik.

Testprinzip

Die Kontrolllösung wird unter Berücksichtigung der Bedienungsanleitung wie unbekanntes **Vollblut** verwendet.

Reagenzien

Die Kontrolllösung ist tierischen Ursprungs (Rind) und sollte genauso gehandhabt werden wie Patientenproben.

Vorbereitung

Die Kontrolle ist gebrauchsfertig. Vor Testdurchführung für ca. 30 min. bei 18…25°C stehen lassen,
gut mischen, nicht schütteln.

Lagerung

Bei 2…8°C ist die Kontrolle bis zu dem auf der Packung angegebenen Verfalldatum stabil.

Der Inhalt geöffneter Fläschchen ist bei 2…8°C für einen (1) Monat stabil.

Keine Fläschchen mit sichtbarer mikrobieller Verunreinigung verwenden.

Erwartete Werte

Die gemessene Konzentration sollte in dem auf dem Etikett angegebenen Meßbereich liegen. Darüberhinaus sollte jedes Labor eigene Mittelwerte und Standardabweichungen dokumentieren.

(French translation of the original instructions for use)

QuikRead go[®] Hb 10 µl Control, N^o réf. 153656

Français

(French translation of the original instructions for use)

(Spanish translation of the original instructions for use)

QuikRead go[®] Hb 10 µl Control, Cat. N. 153656

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153701-2

(English translation of the original instructions for use)

Warnings and precautions

• Avoid using the last drops of the control because opening of the vial many times may result in evaporation, which may bias the results. If the control is not in the acceptable range, take a new vial.

• Do not use the product after the expiry date marked on the outer package.

• Do not exceed the stability periods for opened reagents.
• QuikRead go Hb 10 µl Control is from bovine origin. As a precaution, handle QuikRead go Hb 10 µl Control as if capable of transmitting infectious agents.

Disposal

• Dispose of contents according to national and local law.
• Materials of the components
Paper: Instructions for use
Cardboard: Outer box
Glass: Control vials
Plastic: Vial caps
• When used in accordance with Good Laboratory Practice, good occupational hygiene and the instructions for use, the reagents supplied should not present a hazard to health.

(German translation of the original instructions for use)

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Hb 10 µl controllo

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QuikRead go® Hb 10 µl Control, Kat.č. 153656	Slovensky
Hb 10 µl kontrola	

Určený účel použitia

QuikRead go® Hb 10 µl Control je určená na kontrolu kvality merania hemoglobínu stanovovaného na prístroji QuikRead go® súpravami QuikRead go® wrCRP+Hb.
Pre použitie *in vitro*.

Princíp metódy

Používajte kontrolu rovnakým spôsobom ako by bola použitá neznáma vzorka **plnej krvi**, dodržujte návod na použitie.

Reagencie

Kontrola je materiál bovinného pôvodu. Malo by sa s ňou zaobchádzať rovnako ako s patientskou vzorkou.

Príprava

Kontrola je pripravená na použitie. Materiál nechajte temperovať 30 minút na izbovú teplotu (18...25°C). **Dobře premiešajte**. Netrepte.

Skladovanie

Kontrola je stabilná do dátumu expirácie, ak je skladovaná pri 2...8°C.
Otvorená fľaštička je stabilná 1 mesiac pri 2...8°C.
Fľaštičku, ktorá by vykazovala znaky mikrobiálneho rastu, vyhodte.

Očakávané hodnoty

Získané hodnoty by sa mali pohybovať v rozmedzí uvedenom na štítku fľaštičky s kontrolou. Každé laboratórium by si malo stanoviť vlastný priemer a presné údaje.

Upozornenia a varovania

- Nepoužívajte niekoľko posledných kvapiek kontrolného materiálu, pretože pri častom otváraní fľaštičky môže dôjsť k odpareniu tekutiny, čo môže spôsobiť skreslenie výsledkov. Pokiaľ nie je výsledok pri použití takejto kontroly v zodpovedajúcom rozmedzí, použite novú fľaštičku.
- Produkt nepoužívajte po uplynutí doby expirácie uvedenej na vonkajšom obale.
- Neprekráčajte dobu, po ktorú je zaručená stabilita pre otvorené reagencie.
- QuikRead go Hb 10 µl Control je materiál bovinného pôvodu. V rámci bezpečnostných opatrení je s QuikRead go Hb 10 µl Control nutné manipulovať ako s materiálom schopným prenášať infekčné agens.

Likvidácia

- Odstráňte obsah podľa národných a miestnych zákonov.
- Materiály komponentov
- Papier: Návod na použitie
- Karton: Vonkajšia škatuľa
- Sklo: Fľaštička s kontrolným roztokom
- Plast: Viečka fľaštičiek
- Ak sa systém používa v súlade so správnyimi laboratórnyimi postupmi, dodržiuje sa pracovná hygiena a návod na použitie, dodávané reagencie by nemali predstavovať zdravotné riziko.

QuikRead go® Hb 10 µl Control, Kat. št. 153656	Slovenščina
Hb 10 µl kontrola	

Namen

QuikRead go® Hb 10 µl Control je namenjena kontroli kvalitate testov Hb pri testih QuikRead go® wrCRP+Hb, ki jih izvajamo na analizatorju QuikRead go®.
Za *in vitro* diagnostiko.

Princip testa

Kontrolni test izvajajte po navodilih enako kot z vzorcem **polne krvi**.

Reagenti

Kontrola je govejega izvora. Z raztopino ravnajte enako kot z vzorci pacientov.

Príprava

Kontrola je pripravljena za uporabo. Pred uporabo naj stoji 30 minut pri sobni temperaturi (18...25°C). **Kontrolo dobro premešajte**, vendar je ne stresajte.

Shranjevanje

Kontrola je ob hranjenju pri temperaturi 2...8°C uporabna do datuma odtisnjenega na embalaži.
Odprta steklenička: 1 mesec stabilna pri temperaturi 2...8°C.
Stekleničke, v katerih opazite prisotnost mikroorganizmov, zavrzite.

Pričakovane vrednosti

Vrednost kontrole mora biti v območju, navedenem na nalepki stekleničke. Vsak laboratorij naj ugotavlja dejanske in povprečne vrednosti.

QuikRead go® Hb 10 µl Control, Art. Nr. 153656	Svenska
Hb 10 µl kontroll	

Avsedd användning

QuikRead go® Hb 10 µl Control är avsedd för kvalitetskontroll av Hb-analyser i QuikRead go® wrCRP+Hb-tester med QuikRead go®-instrumentet.
För *in vitro* diagnostik.

Testprincip

Använd kontrollen på samma sätt som ett okänt **helblodsprov**, genom att samma analysprincip följs.

Reagens

Kontrollen är av bovint ursprung. Det skall behandlas på samma sätt som ett patientprov.

Förberedelse

Kontrollen är färdig att använda. Låt kontrollmaterialet stabiliseras i 30 minuter i rumstemperatur (18...25°C).
Blanda väl. Skaka inte flaskan.

Förvaring

Kontrollen är hållbar till utgångsdatum vid förvaring vid 2...8°C.
Öppnad flaska: Hållbar i 1 månad vid 2...8°C.
Använd ej kontrollen om den har misstänkt/synlig bakterieväxt.

Förväntade värden

Det enskilda kontrollresultatet bör falla inom de gränsvärden som ges på kontrollflaskans etikett. Varje laboratorium skall upprätta sitt eget medelvärde och tillåten avvikelse.

QuikRead go® Hb 10 µl Control, Kat. nummer 153656	Norsk
Hb 10 µl kontroll	

Bruksområde

QuikRead go® Hb 10 µl Control er ment for kvalitetskontroll av Hb analysen på QuikRead go® wrCRP+Hb testen utført på QuikRead go® instrumentene.
For *in vitro* diagnostisk bruk.

Prosedyre

Bruk kontrollen på samme måte som en **fullblodprøve**, følg instruksjonen for testprosedyren.

Reagenser

Kontrollen er av bovin opprinnelse. Den skal behandles på samme måte som pasientprøver.

Forberedelser

Kontrollen er klar til bruk. La kontrollen stabiliseres ved (18...25°C) i 30 minutter.
Bland godt. Ikke rist.

Oppbevaring

Kontrollen er stabil inntil utløpsdato når den er oppbevart ved 2...8°C.
Åpnet flaske: Stabil i 1 måned ved 2...8°C.
Ikke bruk kontrollen hvis den viser tydelig tegn på mikrobiologisk vekst.

Forventede verdier

Det enkelte resultat skal ligge innenfor de verdier som er angitt på etiketten på flasken. Hvert laboratorium bør etablere sin egen gjennomsnittsverdi og presisjonsdata.

QuikRead go® Hb 10 µl Control, Varenummer 153656	Dansk
Hb 10 µl kontrol	

Påtaknt anvendelse

QuikRead go® Hb 10 µl Control, er påtakent til kvalitetskontrol af Hb analysen af QuikRead go® wrCRP+Hb kittene, ved hjælp af QuikRead go® instrumentet.
Til *in vitro* diagnostisk brug.

Testprocedure

Anvend kontrollen på samme måde som en ukendt **fuldblodsprøve**, ved at følge vejledningen for testproceduren.

Reagenser

Kontrollen stammer fra kvæg og skal behandles på samme måde som en patientprøve.

Forholdsregler

Kontrollen er klar-til-brug. Kontrollen skal stabiliseres i 30 min. ved stuetemperatur (18...25°C).
Blandes grundigt, men ikke rystes.

Opbevaring

Holdbar inntil udløbsdatoen, hvis den opbevares ved 2...8°C.
Åbnet flaske: Stabil i 1 måned ved 2...8°C.
Anvend aldrig en kontrol, som har tydelig tegn på mikrobiel vækst.

Forventede værdier

Det individuelle resultat bør være indenfor området vist på kontrolflaskens etiket. Hvert laboratorium bør etablere deres eget referenceområde for kontrollen.

QuikRead go® Hb 10 µl Control, Tuotenumro 153656	Suomi
Hb 10 µl kontrolli	

Käyttötarkoitus

QuikRead go® Hb 10 µl Control on tarkoitettu QuikRead go® -laitteella tehtävien QuikRead go® wrCRP+Hb -testien hemoglobiini­mää­ritysten laaduntarkkailuun.
***In vitro* -diagno­stii­kkaan.**

Määrittysperiaate

Kontrollia käytetään kuten **kokoverinäytettä** ja testi suoritetaan reagenssipakkauksen ohjeiden mukaisesti.

Reagenssit

Kontrolli on nautaperäistä materiaalia. Sitä tulee käsitellä kuten mitä tahansa potilasnäytettä.

Esivalmistelut

Kontrolli on käyttövalmista. Anna kontrollin stabiloitua 30 minuuttia huone­lämmössä (18...25°C) ennen käyttöä.
Sekoita hyvin. Älä ravista.

Säilytys

Kontrolli säilyy aava­mattomana 2...8°C:ssa pakkaukseen merkityyn vanhenemis­päivämäärään saakka. Avattu pullo säilyy 1 kuukauden jääkaapissa (2...8°C) huolellisesti suljetuna. Älä käytä kontrollia, jossa on havaittavissa mikrobikasvu.

Viitearvot

Tuloksen tulisi olla alueella, joka on ilmoitettu kontrollipullon etiketissä. On suositeltavaa, että kukin laboratorio määrittäisi omat keskiarvo- ja tavoiterajansa.

Advarsler og forholdsregler

- Unngå å bruke de siste dråpene av kontrollvæsken, da åpning av flasken gjentatte ganger kan føre til fordamping som kan påvirke resultatet. Hvis kontrollen viser resultater utenfor resultatområdet, benytt en ny flaske.
- Produktet skal ikke brukes etter utløpsdatoen som er oppført på emballasjen.
- Ikke overskrid stabilitetstiden for åpnede reagenser.
- QuikRead go Hb 10 µl Control er av bovin opprinnelse. For sikkerhets skyld skal QuikRead go Hb 10 µl Control håndteres som om det inneholder smitteoffer.

Avhending






- Innholdet skal avhendes i samsvar med nasjonal og lokal lovgivning.
- Materialer i komponentene
 - Papir: pakningsvedlegg
 - Papp: utsiden av esken
 - Glass: kontrollflasker
 - Plast: korker på flasker
- Når testen utføres i samsvar med god laboratoriepraksis, god hygiene og pakningsvedlegget, skal reagensene som følger med i pakken, ikke representere noen helsefare.

Advarsler og forholdsregler

- Undgå at bruge de sidste dråber af kontrollen, da de mange åbninger af hætteglasset kan resultere i fordampning, hvilket kan forstyrre resultaterne. Hvis kontrollen ikke er indenfor det acceptable område, bedes en ny kontrol tages i brug.
- Produktet må ikke anvendes efter den udløbsdato, der er trykt på den ydre emballage.
- Åbnede reagenser må ikke anvendes ud over stabilitetsperioden.
- QuikRead go Hb 10 µl Control stammer fra kvæg. QuikRead go Hb 10 µl Control skal som en sikkerhedsforanstaltning håndteres, som om det kan være smittebærende.

Bortskaffelse

- Indholdet/beholderen bortskaffes i overensstemmelse med nationale og lokale bestemmelser.
- Materiale i komponenterne
 - Papir: Brugsanvisning
 - Karton: Ydre æske
 - Glas: Kontrolhætteglas
 - Plastik: Låg til hætteglas
- Hvis god laboratoriepraksis, gode hygiejnestandarder og brugsvejledningen følges, bør de medfølgende reagenser ikke udgøre en sundhedsrisiko.

Explanation of symbols • Zeichenerklärung • Explication des symboles • Explicación de los símbolos • Spiegazione dei simboli • Vysvětlení symbolů															
	English	Deutsch	Français	Español	Italiano	Česky	Magyar	Polski	Slovensky	Slovenščina	Svenska	Norsk	Dansk	Suomi	
I V D	<i>In vitro</i> diagnostic medical device	<i>In-vitro</i> -Diagnostikum	Dispositif médical de diagnostic <i>in vitro</i>	Producto sanitario para diagnóstico <i>in vitro</i>	Dispositivo medico-diagnostico <i>in vitro</i>	Diagnostický zdravotnický prostředek <i>in vitro</i>	<i>In vitro</i> diagnosztikai orvostechnikai eszköz	Wyrób medyczny do diagnozy <i>in vitro</i>	Diagnostická zdravotnícka pomôcka <i>in vitro</i>	<i>In vitro</i> diagnostični medicinski pripomoček	Medicinteknisk produkt avsedd för <i>in vitro</i> -diagnostik	Medisinsk utstyr for <i>in vitro</i> -diagnostikk	Medicinsk udstyr til <i>in vitro</i> -diagnostik	<i>In vitro</i> -diagnostiikkaan tarkoitettu lääkinnällinen laite	
REF	Catalogue number	Bestellnummer	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Katalogové číslo	Katalógusszám	Numer katalogowy	Katalógové číslo	Kataloška številka	Listnummer	Bestillingsnummer	Bestillingsnummer	Luettelonumero	
LOT	Batch code	Loscode	Code du lot	Código de lote	Codice di lotto	Kód šarže	Gyártási tételszám	Kod partii	Číslo šarže	Številka serije	Satsnummer	Lotnummer	Batchkode	Eräkoodi	
	Use by	Verwendbar bis	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Spotřebujte do	Lejárati napja	Użyć przed	Použiteľné do	Uporablajte do	Används före	Brukes innen	Udløbsdato	Käytettävä viimeistään	
	Temperature limitation	Temperaturbegrenzung	Limites de température	Limitación de temperatura	Limiti di temperatura	Teplotní omezení	Megengedett hőmérséklet	Zakres temperatur	Templotné rozmedzie	Temperaturne meje	Temperaturbegränsning	Temperaturbegränsning	Temperaturbegränsning	Lämpötilarajat	
	Shelf life after opening 1 month	Nach dem Öffnen haltbar bis 1 Monat	Stabilité du flacon ouvert 1 mois	Caducidad a los 1 mes tras la apertura	Validità del kit dopo l'apertura 1 mese	Skladovací doba po otevření 1 měsíc	Eltarthatóság felbontás után 1 hónapig	Okres trwałości po otwarciu 1 miesiąc	Skladovacia doba po otvorení 1 mesiac	Rok uporabe po odprtju 1 mesec	1 månad hållbarhet efter öppnande	Holdbarhet etter åpning 1 måned	Holdbarhed efter åbning er 1 måned	Säilyvyys avaamisen jälkeen 1 kuukausi	
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter la notice d'utilisation	Consultare las instrucciones de uso	Consultare le istruzioni per l'uso	Viz návod k použití	Olvassa el a használati utasítást	Sprawdź w instrukcji obsługi	Pozri návod na použitie	Sledi navodilu za uporabo	Läs bruksanvisningen	Se bruksanvisningen	Se bruksanvisningen	Katso käyttöohjetta	
	Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante	Výrobce	Gyártó	Wytwórca	Výrobca	Proizvajalec	Tilverkare	Produsent	Fabrikant	Valmistaja	
CONT	Contents	Inhalt	Contenu	Contenido	Contenuto	Obsah	Tartalomjegyzék	Zawartość	Obsah	Vsebina	Innehåll	Innhold	Indhold	Sisältö	
CONTROL	Control	Kontrolle	Contrôle	Control	Controllo	Kontrola	Kontroll	Kontrola	Kontrola	Kontrola	Kontroll	Kontrol	Kontrol	Kontrolli	
ORIG BOV	Origin: bovine	Ursprung: Rind	Origine: bovine	Origen: bovino	Origine: bovina	Původ: bovinní	Eredet: marha	Pochodzenie: bydłace	Pôvod: bovinný	Izvor: goveji	Ursprung: bovint	Opprinnelse: bovin	Oprindelse: kvæg	Alkuperä: nauta	