



CanAg CA19-9 EIA

REF 120-10

IVD



Instructions for use. 2022-06

Read highlighted changes

EN	EXPLANATION OF SYMBOLS
BG	ОБЯСНЕНИЕ НА СИМВОЛИТЕ
CS	VÝZNAM SYMBOLŮ
DA	SYMBOLFORKLARING
DE	ERKLÄRUNG DER SYMBOLE
EL	ΕΠΕΞΗΓΗΣΗ ΤΩΝ ΣΥΜΒΟΛΩΝ
ES	SIGNIFICADO DE LOS SÍMBOLOS
ET	SÜMBOLITE SELGITUS
FR	EXPLICATION DES SYMBOLES
HR	OBJAŠNJENJE SIMBOLA
HU	JELMAGYARÁZAT
IT	SPIEGAZIONE DEI SIMBOLI
LT	SIMBOLIŲ PAAIŠKINIMAI
LV	SIMBOLU SKAIDROJUMS
NL	VERKLARING DER SYMBOLEN
NO	SYMBOLFORKLARING
PL	OBJAŚNIENIE SYMBOLI
PT	EXPLICAÇÃO DOS SÍMBOLOS
RO	SEMNIȚAȚIA SIMBOLURILOR
RU	ОБОЗНАЧЕНИЯ
SV	SYMBOLFÖRKLARING
SK	VÝZNAM SYMBOLOV
SL	RAZLAGA SIMBOLOV
SR	OBJAŠNJENJE SIMBOLA
TR	SEMBOLLERİN AÇIKLAMALARI



Use By/Годно до/Použitelné do/
Holdbar til/Verwendbar bis/
Ημερομηνία λήξης/Fecha
de caducidad/Kölblik kuni/
Utiliser jusque/Rok valjanosti/
Felhasználható/Utilizzare entro/
Sunautoti iki/Izlietot līdz/Houdbaar
tot/Brukes innen/Użyć przed/
Prazo de validade/Expirã ă la/
Использовать до/Använd före/
Použite ăné do/ Uporabno do/
Upotrebljivo do/Son Kullanna Tarihi

LOT

Batch code/Номер на партида/
Číslo šarže/Lotnummer/
Chargenbezeichnung/Αριθμός
Παρτίδας/Código de lote/Partii
kood/Code du lot/Kod serije/
Sarzsám/Codice del lotto/
Partijas kods/Partijas kods/Lot
nummer/Partikode/Kod partii/
Código do lote/Număr de lot/
Номер лота/Lotnummer/Číslo
šarže/Številka serije/Kod partije/
Parti Kodu

Date of manufacture/Дата на производство/Datum výroby/
Produktionsdato/Herstellungsdatum/
Προϊκτιοης ηαροαυηής/Fecha de fabricación/Valmistamise kuupäev/
Date de fabrication/Datum proizvodnje/
Gyártási idő/Data di produzione/
Pagaminimo data/Ražošanas datums/
Productiedatum/Fremstillingsdato/
Data produkcji/Data de fabrico/Data fabricației/Дата производства/
Tillverkningsdatum/Dátum výroby/Datum izdelave/Datum proizvodnje/Úretim tarihi



Temperature limitation/
Температурни граници/
Теплотни омецени/
Temperaturbegränsning/
Temperaturbegrenzung/
Περιορισμοί θερμοκρασίας/
Limites de temperatura/
Temperatuuri piirang/
Limite de température/
Temperaturno ogranichenje/
Hőmérsékletre vonatkozó korlátozás/
Limiti di temperatura/
Temperatūriniai apribojimai/
Temperatūras ierobežojums/
Temperaturbepierking/
Temperaturbegrensniger/
Temperaturey graniczne/
Limite de temperatura/
Limite de temperatură/
Температурный режим/
Temperaturbegränsning/
Теплотне обмеженне
Omejeitev temperature/
Temperaturno ogranichenje/
Sıcaklık sınırlaması/

IVD

In Vitro Diagnostic Medical Device/
Медицински уред за диагностика
ин витро/Diagnostický zdravotnícký
prostředek in vitro/Medicinsk udstyr til
in vitro-diagnostik/In-vitro-Diagnostikum/
Ιατροτεχνολογικό προϊόν για διάγνωση
In Vitro/Dispositivo médico para
diagnóstico in vitro/In vitro diagnostiline
meditsiiniseade/Dispositif médical de
diagnostic in vitro/Diagnostički medicinski
uređaj In Vitro/In vitro orvosdiagnostikai
eszköz/Dispositivo medico per test
diagnostici in vitro/In Vitro Diagnostinė
Medicinos Priemonė/Medicínska ierice
in vitro diagnostikai/In vitro-diagnostisch
medisch instrument/In vitro diagnostisk
medisinsk utstyr/Wyrób medyczny do
diagnostyki in vitro/Dispositivo Médico
de Diagnóstico In Vitro/Dispozitiv medical
pentru diagnostic in vitro/Только для
диагностики In Vitro/Endast för in
vitro-diagnostik/ Zdravotnicka pomůcka na
diagnostiku in vitro/In vitro diagnostični
pripomoček/Diagnostički medicinski
uređaj In Vitro/<96> testleri için yeterlilik
içerir



Contains sufficient for <96> tests/Съдържа
достатъчно количество за тестове
<96>/Lze použít pro <96> testů/Ineholder
tilstrækkeligt/Inhalt ausreichend für <96>
Prüfungen/Περεχόμενο επαρκές για
«96» εξετάσεις/Contenido suficiente para
<96> ensayos/Kogusest piisab <96> testi
läbiviimiseks/Contenu suffisant pour «96»
tests/Sadržaj dovoljno za <96> testova/A
doboz tartalma <96> vizsgálat elvégzéséhez
elegendő/Contenuto sufficiente per «96»
saggi/Turiny's skirtas atlikti <96> tyrimus/
Satur's pietiekams <96> testiem/Inhoud
voldoende voor «96» testen/til «96» test/
Tilstrækkelig innhold for <96> prøver/
Wystarczy na wykonanie <96> testów/
Conteúdo suficiente para «96» ensaios/
Conținut suficient pentru 96 de teste/
Содержит достаточные количества для
«96» определений/Innehåller tillräckligt
till «96» antal tester/Obsah postačuje na
tento počet testov: <96>/Vsebinsa zadostuje
za <96> testov/Sadržina dovoljna za <96>
testova/<96> testleri için yeterlilik içerir

REF

Catalogue number/Каталожен номер/
Katalogové číslo/Katalognummer/
Bestellnummer/Αριθμός καταλόγου/
Número de catálogo/Katalogoi number/
Numéro de catalogue/Kataloški broj/
Katalógusszám/Numero di catalogo/
Katalogo numeris/Numurs katalogā/
Catalogusnummer/Katalognummer/
Numer katalogowy/Número do catálogo/
Număr de catalog/Номер по каталогу/
Produktnummer/Katalógové číslo/
Kataloška številka/Kataloški broj/
Katalog numarası



Consult Instructions for Use/
Прочетете инструкцията за
употреба/Konzultujte s návodem
k použití/Se brugsanvisning/Siehe
Gebrauchsanweisung/Συμβουλευτείτε
της Οδηγίας σχετικά με τη χρήση/
Consulte las instrucciones de uso/
Vt kasutusjuhendit/Consulter le mode
d'emploi/Pročítajte upute za uporabu/
Olvassa el a használati utasítást/
Consultare le istruzioni per l'uso/Dél
naudojimo žiūrėkite instrukcijas/Izlasiet
lietošanas instrukciju/Raadpleeg de
instructies voor gebruik/Les instruksene
for bruk/Sprawdzić w instrukcji użycia/
Consulte as Instruções de Utilização/
Consultați instrucțiunile de utilizare/
Обратитесь к инструкции по
применению/Se bruksanvisning/
Prečítajte si návod na používanie/
Pročítajte uputstvo za upotrebu/
Kullanım Talimatlarını Bakınız



Contents of kit/Съдържание на набора/
Obsah soupravy/Kittets indhold/Inhalt
des Kits/Περιεχόμενα του κιτ/Contenido
del kit/Komplekt sisaldab/Contenu du
kit/Sadržaj opreme/A készlet tartalma/
Contenuto del kit/Rinkinio turinys/
Komplekta saturs/Inhoud van de set/
Settets innhold/Zawartość zestawu/
Conteúdo do kit/Conținutul setului/
Компоненты набора/Kit innehåll/
Obsah súpravy/Vsebina kompleta/Sadržaj
opreme/Kitin içindekiler



Biological risks/Биологическа
опасност/Biológická rizika/Biologisk
fare/Biologische Gefahren/Bιολογικοί
κίνδυνοι/Riesgos biológicos/
Biolooilised ohud/Risques biologiques/
Biolóskli rizici/Biológiai kockázatok/Rischi
biologici/Biologinis pavojus/Biológiskais
risks/Biologische risico's/Biologische
risikoer/Zagroženie biologiczne/Riscos
biológicos/ Biologisk risk/Pericole
biologice/Биологическая опасность/
Biologický rizikové/Biologické riziká/
Biolóskli rizici/Biyolojik riskler



US: For use by or on the order of a
physician only



Human/C човешки производ/Ľidské/
Human/Human/δείγματα αναφοράς/
Humano/Inimpãritolu/Humaine/Ljudskog
porjekla/Humàn/Origine Umana/
Žmogaus kilmės/Cilvēku izcelsmes/
Human/Menneske/Ludzka/Humano/
Origine umână/Человеческого
происхождения/Human/Ludské/
Humanega izvora/Ljudskog porekla/İnsan



From mouse/C миши производ/Мыši/
Fra mus/Maus/από πογτίκι/de ratón/
Hiirtelt/De souris/Mišijeg porjekla/
Egérbdli/Murino/Pelés kilmés/No peles/
Van muizen/Fra mus/Mysia/Do rato/De
la șoareci/Мышиного происхождения/
Från mus/Мыšije/Mišjega izvora/Mišijeg
porekla/Fareden



Bovine/C говежди производ/
Hovézi/Bovin/Rind/από βοοειδή/
Bovino/Veistelt/Bovine/Rogate stoke/
Szarvasmarha/Bovino/Jaučio/No
liellopa/Bovien/Bovin/Wolowy/Bovino/
Origine bovină/крупного рогатого
скота/Från ko/Hovädzie/Rogovega
izvora/Rogate krupne stoke/Bovin



Reconstitute with/Разтваряне с/
Rozfedte pomoci/Rekonstitueres med/
Rekonstituieren mit/Ανασύσταση με/
Reconstituir con/Lahjendamine/
Rekonstituer avec/Rekonstituiraite s/
Feloldáshoz/Ricostituire con/Atkurti,
ištirpdant su/Atšķaidīt ar/Reconstituite
met/Rekonstitueres med/Odtworzyć
za pomocą/Reconstituir com/A
se reconstitui cu/Разтворить в/
Rekonstituera med/Rozriedte pomocou/
Rekonstituiraite z/s/Ponovno formiranje
sa/Yeniden oluşturular



Manufacturer/Производител/Výrobce/
Producent/Hersteller/Κατασκευαστής/
Fabricante/Tootja/Fabricant/Proizvođač/
Gyártó/Fabbricante/Gamintojas/
Ražotājs/Fabrikant/Produsent/
Producent/Fabricante/Producător/
Производитель/Tilverkare/ Výrobca/
Izdevalaiec/Proizvođač/Üretici

INSTRUCTIONS FOR USE

EN

INSTRUCTIONS FOR USE

Please visit our website www.fdi.com/ifu to obtain the Instructions For Use (IFU) in additional languages.

To ensure that you download the correct IFU for your kit lot, please select the revision corresponding to the issue date printed on the front page of the IFU provided with this kit.

Please follow the IFU carefully. Instructions for safe handling are found in the WARNINGS AND PRECAUTIONS section. Material Safety Data Sheets (MSDS) are available on our website www.fdi.com. If you do not have access to the internet, please contact your local distributor, or Fujirebio Diagnostics AB for assistance.

CS

NÁVOD K POUŽITÍ

Návod k použití v dalších jazycích najdete na našich webových stránkách www.fdi.com/ifu.

Abyste se ujistili, že jste si stáhli správný návod k použití pro vaši šarži sady, vyberte revizi odpovídající datu vydání vytištěnému na přední straně návodu k použití dodanému s touto sadou.

Návod k použití přesně dodržujte. Pokyny pro bezpečnou manipulaci najdete v části VAROVÁNÍ A UPOZORNĚNÍ. Tabulky údajů o bezpečnosti materiálu (MSDS) najdete na stránkách www.fdi.com. Nemáte-li přístup k Internetu, požádejte o pomoc místního distributora nebo společnost Fujirebio Diagnostics AB.

DA

BRUGSANVISNINGER

Gå ind på vores hjemmeside www.fdi.com/ifu for at hente brugsanvisninger på andre sprog.

For at sikre at du henter den rette brugsanvisning til det pågældende kitlot, skal du vælge det revisionsnummer, der svarer til den udgivelsesdato, der er trykt på forsiden af den brugsanvisning, der følger med kittet.

Følg brugsanvisningen omhyggeligt. Vejledning i sikker håndtering findes i afsnittet ADVARSLER OG FORSIGTIGHEDSREGLER. Sikkerhedsdataark (MSDS) kan hentes på vores hjemmeside www.fdi.com/ifu. Hvis du ikke har adgang til internettet, kan du kontakte den lokale distributør eller Fujirebio Diagnostics AB for assistance.

GEBRAUCHSANWEISUNG

Auf unserer Website www.fdi.com/ifu finden Sie die Gebrauchsanweisung in weiteren Sprachen.

Um sicherzustellen, dass Sie die richtige Gebrauchsanweisung für Ihre Kit-Charge herunterladen, wählen Sie bitte die Version, die mit dem Veröffentlichungsdatum auf der Titelseite der mit diesem Kit mitgelieferten Gebrauchsanweisung übereinstimmt.

Halten Sie sich bitte genau an die Gebrauchsanweisung. Anweisungen für den sicheren Umgang finden Sie im Abschnitt „SICHERHEITSHINWEISE UND VORSICHTSMASSNAHMEN“. Die Materialsicherheitsdatenblätter (MSDS) finden Sie auf unserer Website www.fdi.com. Sollten Sie keinen Zugang zum Internet haben, so wenden Sie sich bitte an Ihren örtlichen Vertriebshändler oder an Fujirebio Diagnostics AB.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Για να λάβετε τις Οδηγίες χρήσης και σε άλλες γλώσσες, επισκεφθείτε την τοποθεσία μας στο web www.fdi.com/ifu.

Για να διασφαλίσετε ότι κάνετε λήψη των σωστών Οδηγιών χρήσης για την παρτίδα του kit σας, επιλέξτε την αναθεώρηση που αντιστοιχεί στην ημερομηνία έκδοσης που αναγράφεται στην μπροστινή σελίδα των Οδηγιών χρήσης αυτού του kit.

Ακολουθήστε τις Οδηγίες χρήσης με προσοχή. Μπορείτε να βρείτε οδηγίες για ασφαλή χειρισμό στην ενότητα ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ. Στην τοποθεσία μας στο web www.fdi.com διατίθενται Φύλλα δεδομένων ασφαλείας υλικών (MSDS). Εάν δεν έχετε πρόσβαση στο internet, επικοινωνήστε με το διανομέα της περιοχής σας ή με την Fujirebio Diagnostics AB για βοήθεια.

INSTRUCCIONES DE USO

Visite nuestro sitio web www.fdi.com/ifu para obtener instrucciones de uso (IFU) en otros idiomas.

Para asegurarse de que descarga las instrucciones de uso adecuadas a su lote de kits, seleccione el número de revisión que corresponda a la fecha de emisión impresa en la primera página de las instrucciones de uso suministradas con este kit.

Por favor, siga las instrucciones atentamente. Las instrucciones relativas a la seguridad en la manipulación figuran en el apartado ADVERTENCIAS Y PRECAUCIONES. Las fichas de seguridad de los materiales (MSDS) también están disponibles en nuestro sitio web: www.fdi.com. Si no tiene acceso a Internet, póngase en contacto con su distribuidor local o con Fujirebio Diagnostics AB para obtener ayuda.

ET

KASUTUSJUHEND

Erinevates keeltes kasutusjuhend on kättesaadav meie veebilehel www.fdi.com/ifu.

Komplekti partiile vastava kasutusjuhendi allalaadimise tagamiseks valige versioon, mis vastab komplektile lisatud kasutusjuhendi esilehel toodud väljaandmise kuupäevale.

Palun järgige kasutusjuhendit hoolikalt. Ohutusjuhised on toodud HOIATUSTE JA ETTEVAATUSABINÕUDE osas. Materjali ohutuskardid on kättesaadavad meie veebilehel www.fdi.com. Kui Teil ei ole võimalik Internetti kasutada, pöörduge abi saamiseks kohaliku esindaja või Fujirebio Diagnostics AB poole.

FR

MODE D'EMPLOI

Visitez notre site Web, www.fdi.com/ifu, pour obtenir le mode d'emploi dans d'autres langues.

Pour être sûr que vous téléchargez le mode d'emploi correspondant à votre lot de kit, sélectionnez la version correspondant à la date de publication imprimée sur la première page du mode d'emploi joint à ce kit.

Veillez suivre soigneusement les indications du mode d'emploi. Les instructions de manipulation sans risque se trouvent dans la section AVERTISSEMENTS ET PRÉCAUTIONS. Des fiches de données de sécurité (MSDS) sont disponibles sur notre site Web, www.fdi.com. Si vous n'avez pas accès à Internet, veuillez contacter votre distributeur local ou Fujirebio Diagnostics AB pour obtenir de l'aide.

HR

UPUTA ZA UPORABU

Molimo posjetite naše stranice www.fdi.com/ifu radi preuzimanja Upute za uporabu (IFU) na ostalim jezicima.

Da biste osigurali preuzimanje ispravnih IFU za vaš komplet, molimo odaberite reviziju koja odgovara datumu izdavanja otisnutim na prednjoj stranici IFU koje ste dobili s kompletom.

Molimo slijedite IFU pažljivo. Uputstva za sigurno rukovanje nalaze se u odjeljku UPOZORENJA I MJERE OPREZA. Sigurnosno-tehnički listovi (MSDS) su dostupni na našim stranicama www.fdi.com. Ako nemate pristup internetu, molimo da se obratite lokalnom distributeru ili Fujirebio Diagnostics AB za pomoć.

HU

HASZNÁLATI UTASÍTÁS

További nyelveken készült Használati utasítások található a www.fdi.com/ifu honlapon.

Annak biztosítása érdekében, hogy az Ön kit tételének megfelelő Használati utasítást töltsse le, válassza a kithoz mellékelt Használati utasítás első oldalán lévő kibocsátási dátumnak megfelelő módosítást.

Kérjük, tartsa be a Használati utasítás előírásait. A biztonságos kezelésre vonatkozó utasítások a FIGYELMEZTETÉSEK ÉS ÓVINTÉZKEDÉSEK című fejezetben található. A Biztonsági adatlapok (MSDS) honlapunkon (**www.fdi.com**) elérhetőek. Amennyiben Ön nem rendelkezik internet hozzáféréssel, forduljon segítségért helyi értékesítőjéhez vagy a Fujirebio Diagnostics AB-hez.

ISTRUZIONI PER L'USO

IT

Istruzioni per l'uso in altre lingue sono disponibili sul nostro sito web **www.fdi.com/ifu**.

Per scaricare le Istruzioni per l'uso corrispondenti al lotto del proprio kit, selezionare la revisione corrispondente alla data di emissione stampata sulla prima pagina delle Istruzioni per l'uso fornite insieme al kit.

Sequire attentamente le Istruzioni per l'uso. Le istruzioni per una gestione sicura sono contenute nella sezione AVVERTENZE E PRECAUZIONI. Sul nostro sito web **www.fdi.com** sono disponibili le schede tecniche relative alla sicurezza dei materiali. Qualora fosse impossibile accedere a Internet, contattare il proprio distributore locale oppure rivolgersi a Fujirebio Diagnostics AB.

NAUDOJIMO INSTRUKCIJOS

LT

Kad gautumėte naudojimo instrukcijas kitomis kalbomis, apsilankykite mūsų tinklalapyje: **www.fdi.com/ifu**.

Kad atsisiųstumėte instrukcijas, kurios tikrai tinka Jūsų komplektui, pasirinkite peržiūros datą, kuri atitinka pagaminimo datą, atspausdintą su šiuo komplektu pateiktą instrukcijų viršelyje.

Atidžiai laikykitės instrukcijų. Saugaus naudojimo instrukcijos yra skyriuje PERSPĖJIMAI IRATSARGUMO PRIEMONĖS. Medžiagų saugos duomenų lapus (MSDS) rasite mūsų tinklalapyje **www.fdi.com**. Jeigu neprieinate prie interneto, kreipkitės pagalvos į savo vietinį distributorių arba į „Fujirebio Diagnostics AB“.

LIETOŠANAS INSTRUKCIJA

LV

Lai iegūtu lietošanas instrukciju (LI) citās valodās, lūdzu, apmeklējiet mūsu vietni **www.fdi.com/ifu**.

Lai lejupielādētu pareizo LI savam komplektam, lūdzu, izvēlieties versiju, kas atbilst šim komplektam pievienotās LI pirmajā lappusē iespēstajam izdošanas datumam.

Lūdzu, rūpīgi iepazīstieties ar LI un ievērojiet to. Norādījumi drošai lietošanai sniegti sadaļā BRĪDINĀJUMI UN PIESARDZĪBAS PASĀKUMI. Materiālu drošības datu lapas (MDDL) ir pieejamas mūsu vietnē **www.fdi.com**. Ja jums nav pieejams internets, lūdzu, sazinieties ar vietējo izplatītāju vai Fujirebio Diagnostics AB, lai iegūtu palīdzību.

NL

INSTRUCTIES VOOR GEBRUIK

Ga naar onze website **www.fdi.com/ifu** voor de Instructies voor gebruik in andere talen.

Om ervoor te zorgen dat u de juiste Instructie voor gebruik downloadt voor uw setpartij, selecteert u de revisie die overeenkomt met de uitgavedatum die afgedrukt staat op de voorpagina van de Instructies voor gebruik die bij deze kit bijgeleverd zijn.

Volg de Instructie voor gebruik zorgvuldig op. U vindt de instructies voor een veilig hanteren in het gedeelte **WAARSCHUWINGEN EN VOORZORGSMAATREGELEN**. Op onze website **www.fdi.com** zijn ook Veiligheidsinformatiebladen (MSDS) beschikbaar. Als u geen toegang hebt tot het internet, neemt u dan contact op met uw plaatselijke distributeur of met Fujirebio Diagnostics AB voor assistentie.

NO

BRUKSINSTRUKSER

Bruksinstrukser (IFU) på andre språk kan lastes ned fra vår hjemmeside **www.fdi.com/ifu**.

For å sikre at du laster ned den riktige IFU-en for ditt settparti, vennligst velg oppdateringen som svarer til utstedelsesdatoen på forsiden av IFU-en levert med settet ditt.

Vennligst følg IFU-instruksene nøye. Instruksjer for sikker håndtering fins i avsnittet **ADVARSLER OG FORHOLDSREGLER**. Materialesikkerhetsdatabaser (MSDS) kan lastes ned fra vår hjemmeside **www.fdi.com**. Dersom du ikke har adgang til internettet, vennligst kontakt din lokalforhandler eller Fujirebio Diagnostics AB for å få hjelp.

PL

INSTRUKCJA UŻYCIA

Instrukcje użycia (IFU) w innych językach znaleźć można na naszej stronie internetowej **www.fdi.com/ifu**.

Aby mieć pewność, że pobierasz instrukcję użycia właściwą dla partii zestawu, wybierz wersję odpowiadającą dacie wydania nadrukowanej na okładce IFU dostarczonej z zestawem.

Należy ściśle przestrzegać zaleceń zawartych w instrukcji użycia. Instrukcje dotyczące bezpiecznej pracy znaleźć można w części **OSTRZEŻENIA I ŚRODKI OSTROŻNOŚCI**. Karty charakterystyki substancji (MSDS) dostępne są na naszej stronie internetowej **www.fdi.com**. W przypadku braku dostępu do Internetu, pomoc można uzyskać u lokalnego dystrybutora lub w firmie Fujirebio Diagnostics AB.

INSTRUÇÕES DE UTILIZAÇÃO

Visite o nosso sitio da Internet **www.fdi.com/ifu** para obter Instruções de Utilização (IDU) em idiomas adicionais.

Para assegurar que descarrega as IDU correctas para o lote do seu kit, seleccione a revisão correspondente à data de emissão impressa na capa das IDU fornecida com este kit.

Siga as IDU cuidadosamente. É possível encontrar instruções para um manuseamento seguro na secção ADVERTÊNCIAS E PRECAUÇÕES. As Fichas de Dados de Segurança do Material (FDSM) estão disponíveis em **www.fdi.com**. Se não tiver acesso à Internet, contacte o seu distribuidor local ou a Fujirebio Diagnostics AB para obter ajuda.

INSTRUCȚIUNI DE UTILIZARE

Vizitați site-ul nostru Web **www.fdi.com/ifu** pentru a obține instrucțiunile de utilizare (IFU) în alte limbi.

Pentru a vă asigura că descărcați instrucțiunile de utilizare corecte pentru lotul acestui kit, selectați revizia corespunzătoare cu data emiterii, imprimată pe prima pagină a instrucțiunilor de utilizare furnizate cu acest kit.

Urmați cu atenție instrucțiunile de utilizare. Instrucțiunile pentru o manevrare în siguranță se regăsesc în secțiunea AVERTISMENTE ȘI PRECAUȚII. Fișele de date despre siguranța materialelor (Material Safety Data Sheets - MSDS) sunt disponibile pe site-ul nostru Web **www.fdi.com**. Dacă nu aveți acces la Internet, contactați pentru asistență distribuitorul dvs. local sau Fujirebio Diagnostics AB.

NÁVOD NA POUŽITIE

Návod na použitie v ďalších jazykoch nájdete na našej webovej lokalite **www.fdi.com/ifu**.

Abý ste sa uistili, že ste prevzali správny návod na použitie pre danú šaržu súpravy, vyberte revíziu zodpovedajúcu dátumu vydania vytlačenému na prednej strane návodu na použitie dodanému s touto súpravou.

Návod na použitie presne dodržujte. Pokyny na bezpečnú manipuláciu nájdete v časti VÝSTRAHY A UPOZORNENIA. Tabuľky údajov o bezpečnosti materiálu (MSDS) nájdete na stránkach **www.fdi.com**. Ak nemáte prístup na internet, požiadajte o pomoc miestneho distribútora alebo spoločnosť Fujirebio Diagnostics AB.

SL

NAVODILA ZA UPORABO

Če si želite ogledati navodila za uporabo v drugih jezikih, obiščite spletno mesto **www.fdi.com/ifu**.

Če želite zagotoviti, da ste prenesli ustrezna navodila za uporabo za vašo serijo kompleta, izberite različico, ki ustreza datumu izdaje, natisnjnemu na sprednji strani navodil za uporabo, priloženih temu kompletu.

Prosimo vas, da skrbno upoštevate navodila za uporabo. Navodila za varno ravnanje so v poglavju OPOZORILA IN PREVIDNOSTNI UKREPI. Varnostni listi (MSDS) so na naši spletni strani **www.fdi.com**. Če nimate dostopa do interneta, se za pomoč obrnite na svojega lokalnega distributerja ali družbo Fujirebio Diagnostics AB.

SR

UPUTSTVO ZA UPOTREBU

Molimo Vas da posetite naš sajt **www.fdi.com/ifu** kako biste dobili Uputstvo za upotrebu na ostalim jezicima.

Da biste bili sigurni da ste skinuli odgovarajuće Uputstvo za upotrebu za Vaš set proizvoda, molimo Vas da odaberete odeljak koji odgovara datumu odštampanom na prednjoj strani Uputstva za upotrebu koje ste dobili uz proizvod.

Molimo Vas da pažljivo sledite uputstva data u Uputstvu za upotrebu. Uputstva za bezbedno korišćenje su data u odeljku pod naslovom UPOZORENJE I OPREZ. Informacije vezane za bezbedno korišćenje materijala su dostupne na sajtu **www.fdi.com**. Ako nemate pristup Internetu, molimo Vas da stupite u kontakt sa lokalnim distributerom ili se telefonom obratite Fujirebio Diagnostics službi za davanje informacija.

SV

BRUKSANVISNING

Bruksanvisning (IFU) på andra språk finns att ladda ner från vår hemsida, **www.fdi.com/ifu**.

Säkerställ att du laddar ner rätt bruksanvisning för din kit lot genom att välja samma revisionsdatum som anges på framsidan av den bruksanvisning som medföljer denna förpackning.

Vänligen följ noga anvisningarna i bruksanvisningen. Instruktioner för säker användning finns i stycket VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER. Säkerhetsdatablad (MSDS) finns att ladda ner från vår hemsida, **www.fdi.com**. Om du inte har tillgång till internet, vänligen kontakta din lokala distributör eller Fujirebio Diagnostics AB för att få hjälp.

KULLANIM TALIMATLARI

İlave dillerde Kullanım Talimatlarını (KT) almak için lütfen www.fdi.com/ifu adresindeki web sitemizi ziyaret edin.

Kit partiniz için doğru KT'nı indirdiğinizden emin olmak için lütfen bu kitle birlikte verilen KT'nın ön sayfasında yazılı düzenlenme tarihiyle eşleşen gözden geçirmeyi seçin.

Lütfen KT'nı dikkatli bir şekilde izleyin. Güvenli kullanımla ilgili talimatlar UYARILAR VE ÖNLEMLER bölümünde bulunmaktadır. Malzeme Güvenliği Veri Sayfaları (MGVS) www.fdi.com adresindeki web sitemizde bulunmaktadır. İnternet erişiminiz bulunmuyorsa, destek için lütfen yerel distribütörünüz veya Fujirebio Diagnostics AB ile temasa geçin.

CanAg CA19-9 EIA

Instructions for use

Enzyme immunometric assay kit
For 96 determinations

INTENDED USE

The CanAg CA19-9 EIA kit is intended for the quantitative determination of the cancer associated antigen CA19-9 in serum.

SUMMARY AND EXPLANATION OF THE ASSAY

The CanAg CA19-9 EIA is based on a mouse monoclonal antibody, C192, highly specific for the sialyl Lewis^a epitope, also known as CA19-9 antigen (1). In adults, the epitope is typically expressed in trace amounts on mucosal cells of gastrointestinal epithelia. In patients with malignant disease, the epitope may appear associated with high molecular weight mucin in blood. Assays for CA19-9 are frequently used to monitor gastrointestinal malignancies such as pancreatic, gall bladder, gastric, and colorectal cancers (2, 3).

PRINCIPLE OF THE TEST

The CanAg CA19-9 EIA is a solid-phase, non-competitive immunoassay based upon the direct sandwich technique. Calibrators, controls and patient samples are incubated together with a biotinylated Anti-CA19-9 monoclonal antibody (MAb) C192 (derived from mice) in streptavidin coated microstrips. CA19-9 present in calibrators or samples is adsorbed to the streptavidin coated microstrips by the biotinylated Anti-CA19-9 MAb during the incubation. The strips are then washed and incubated with HRP labeled Anti-CA19-9 MAb C192. After washing, buffered Substrate/Chromogen reagent (hydrogen peroxide and 3, 3', 5, 5' tetra-methyl-benzidine) is added to each well and the enzyme reaction is allowed to proceed. During the enzyme reaction a blue color will develop if antigen is present. The intensity of the color is proportional to the amount of CA19-9 present in the samples.

The color intensity is determined in a microplate spectrophotometer at 620 nm (or optionally at 405 nm after addition of Stop Solution).

Calibration curves are constructed for each assay by plotting absorbance value versus the concentration for each calibrator. The CA19-9 concentrations of patient samples are then read from the calibration curve.

REAGENTS

- Each CanAg CA19-9 EIA kit contains reagents for 96 tests.
- The expiry date of the kit is stated on the label on the outside of the kit box.
- Do not use the kit beyond the expiry date.
- Do not mix reagents from different kit lots.
- Store the kit at 2–8° C. Do not freeze.
- Opened reagents are stable according to the table below provided they are not contaminated, stored in resealed original containers and handled as prescribed. Return to 2–8° C immediately after use.

Component	Quantity	Storage and stability after first opening
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MICROPLA

Microplate	1 Plate	2–8° C until expiry date stated on the plate
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12 x 8 breakable wells coated with streptavidin. After opening, immediately return unused strips to the aluminium pouch, containing desiccant. Reseal carefully to keep dry.

CA19-9 Calibrators	6 vials	2–8° C until expiry date stated on the vials
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CAL	CA19-9	0	0 U/mL	1 x 8 mL
CAL	CA19-9	15	15 U/mL	1 x 0.75 mL
CAL	CA19-9	30	30 U/mL	1 x 0.75 mL
CAL	CA19-9	60	60 U/mL	1 x 0.75 mL
CAL	CA19-9	120	120 U/mL	1 x 0.75 mL
CAL	CA19-9	240	240 U/mL	1 x 0.75 mL

CA19-9 antigen in a Tris-HCl buffered salt solution containing bovine serum albumin, an inert yellow dye and 0.05 % sodium azide as preservative. Ready for use.

CAL	CA19-9	0
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 should also be used for dilution of samples.

Component	Quantity	Storage and stability after first opening
CA19-9 Controls	2 vials	2–8° C until expiry date stated on the vials
CONTROL CA19-9 1	1 x 0.75 mL	
CONTROL CA19-9 2	1 x 0.75 mL	

CA19-9 antigen in a Tris-HCl buffered salt solution containing bovine serum albumin and 0.05 % sodium azide as preservative. Ready for use.

BIOTIN	Anti-CA19-9
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Biotin Anti-CA19-9	1 x 15 mL	2–8° C until expiry date stated on the vial
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Biotin Anti-CA19-9 monoclonal antibody from mouse, approximately 2 µg/mL. Contains phosphate citrate-buffer (pH 7.5), bovine serum albumin, blocking agents, Tween 40, an inert red dye, and 0.01 % methyl-isothiazolone (MIT) as preservative. Ready for use.

CONJ	Anti-CA19-9
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Tracer, HRP Anti-CA19-9	1 x 0.75 mL	2–8° C until expiry date stated on the vial
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Stock Solution of HRP Anti-CA19-9 monoclonal antibody from mouse, approximately 40 µg/mL. Contains preservatives. To be diluted with Tracer Diluent prior to use.

DIL	CONJ
------------	-------------

Tracer Diluent	1 x 15 mL	2–8° C until expiry date stated on the vial
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Phosphate citrate-buffer (pH 7.5) with bovine serum albumin, blocking agents, Tween 40, an inert blue dye, and 0.01 % methyl-isothiazolone (MIT) as preservative. Ready for use.

Component	Quantity	Storage and stability after first opening
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SUBS	TMB
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TMB HRP-Substrate	1 x 12 mL	2–8° C until expiry date stated on the vial
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Contains buffered hydrogen peroxide and 3, 3', 5, 5' tetra-methylbenzidine (TMB). Ready for use.

STOP

Stop Solution	1 x 15 mL	2–8° C until expiry date stated on the vial
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Ready for use. Contains 0.12 M hydrochloric acid.

WASHBUF	25X
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Wash Concentrate	1 x 50 mL	2–8° C until expiry date stated on the bottle
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To be diluted with water 25 times before use. A Tris-HCl buffered salt solution with Tween 20. Contains Germall II as preservative.

Indications of instability

The TMB HRP-Substrate should be colourless or slightly bluish. A blue colour indicates that the reagent has been contaminated and should be discarded.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use

- Please refer to the U.S. Department of Health and Human Services (Bethesda, Md., USA) publication No. (CDC) 88–8395 on laboratory safety procedures or any other local or national regulation.
- Handle all patient specimens as potentially infectious.
- Avoid contact with reagents containing hydrogen peroxide or hydrochloric acid. In case of contact with any of these reagents, wash thoroughly with water.
- Reagents contain sodium azide (NaN_3) as a preservative. Sodium azide may

Protocol Sheet

CanAg CA19-9 EIA REF 120-10

Mix the components directly before use. Use shaking conditions according to the Instructions.

Step	Vial/Plate	Procedure																																							
1. Prepare Wash Solution	WASHBUF 25X	Dilute 50 mL of Wash Concentrate with 1200 mL of distilled or deionized water.																																							
	CONJ Anti-CA19-9																																								
Prepare Tracer working solution	DIL CONJ	Mix 50 μ L of Tracer, HRP Anti-CA19-9 with 1 mL of Tracer Diluent per strip:																																							
		<table border="1"><thead><tr><th>No. of Strips</th><th>Tracer, HRP Anti-CA19-9 (μL)</th><th>Tracer Diluent (mL)</th></tr></thead><tbody><tr><td>1</td><td>50</td><td>1</td></tr><tr><td>2</td><td>100</td><td>2</td></tr><tr><td>3</td><td>150</td><td>3</td></tr><tr><td>4</td><td>200</td><td>4</td></tr><tr><td>5</td><td>250</td><td>5</td></tr><tr><td>6</td><td>300</td><td>6</td></tr><tr><td>7</td><td>350</td><td>7</td></tr><tr><td>8</td><td>400</td><td>8</td></tr><tr><td>9</td><td>450</td><td>9</td></tr><tr><td>10</td><td>500</td><td>10</td></tr><tr><td>11</td><td>550</td><td>11</td></tr><tr><td>12</td><td>600</td><td>12</td></tr></tbody></table>	No. of Strips	Tracer, HRP Anti-CA19-9 (μ L)	Tracer Diluent (mL)	1	50	1	2	100	2	3	150	3	4	200	4	5	250	5	6	300	6	7	350	7	8	400	8	9	450	9	10	500	10	11	550	11	12	600	12
No. of Strips	Tracer, HRP Anti-CA19-9 (μ L)	Tracer Diluent (mL)																																							
1	50	1																																							
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4	200	4																																							
5	250	5																																							
6	300	6																																							
7	350	7																																							
8	400	8																																							
9	450	9																																							
10	500	10																																							
11	550	11																																							
12	600	12																																							
2. Wash	MICROPLA	Wash each well once with Wash Solution. Use manual or automatic washer.																																							

3. Add calibrators, controls and samples	<table border="1"> <tr> <td data-bbox="10 713 51 873">CAL</td> <td data-bbox="51 713 124 873">CA19-9</td> </tr> <tr> <td colspan="2" data-bbox="10 655 124 713">0, 15, 30, 60, 120, 240</td> </tr> <tr> <td data-bbox="10 655 51 873">CONTROL</td> <td data-bbox="51 655 124 873">CA19-9</td> </tr> </table>	CAL	CA19-9	0, 15, 30, 60, 120, 240		CONTROL	CA19-9	25 µL in each well
CAL	CA19-9							
0, 15, 30, 60, 120, 240								
CONTROL	CA19-9							
1,2								
4. Add Biotin Anti-CA 19-9	<table border="1"> <tr> <td data-bbox="186 713 227 873">BIOTIN</td> <td data-bbox="227 713 341 873">Anti-CA19-9</td> </tr> </table>	BIOTIN	Anti-CA19-9	100 µL in each well				
BIOTIN	Anti-CA19-9							
5. Incubate	<table border="1"> <tr> <td data-bbox="248 713 290 873">MICROPLA</td> </tr> </table>	MICROPLA	2 hour shaking at room temperature					
MICROPLA								
6. Wash	<table border="1"> <tr> <td data-bbox="310 713 352 873">MICROPLA</td> </tr> </table>	MICROPLA	Wash each well three times with Wash Solution. Use manual or automatic washer.					
MICROPLA								
7. Add Tracer working solution	<table border="1"> <tr> <td data-bbox="372 713 445 873">TRACER WORKING SOLUTION</td> </tr> </table>	TRACER WORKING SOLUTION	100 µL in each well					
TRACER WORKING SOLUTION								
8. Incubate	<table border="1"> <tr> <td data-bbox="466 713 507 873">MICROPLA</td> </tr> </table>	MICROPLA	1 hour shaking at room temperature					
MICROPLA								
9. Wash	<table border="1"> <tr> <td data-bbox="528 713 569 873">MICROPLA</td> </tr> </table>	MICROPLA	Wash each well six times with Wash Solution. Use manual or automatic washer.					
MICROPLA								
10. Add TMB HRP-Substrate	<table border="1"> <tr> <td data-bbox="590 713 631 873">SUBS</td> <td data-bbox="631 713 652 873">TMB</td> </tr> </table>	SUBS	TMB	100 µL in each well				
SUBS	TMB							
11. Incubate	<table border="1"> <tr> <td data-bbox="673 713 714 873">MICROPLA</td> </tr> </table>	MICROPLA	30 min shaking at room temperature					
MICROPLA								
12. Read absorbance	<table border="1"> <tr> <td data-bbox="735 713 777 873">MICROPLA</td> </tr> </table>	MICROPLA	620 nm					
MICROPLA								
Alt.12 Add Stop Solution	<table border="1"> <tr> <td data-bbox="797 713 839 873">STOP</td> </tr> </table>	STOP	100 µL in each well					
STOP								
Alt.13 Incubate	<table border="1"> <tr> <td data-bbox="859 713 901 873">MICROPLA</td> </tr> </table>	MICROPLA	1 min shaking at room temperature					
MICROPLA								
Alt.14 Read absorbance	<table border="1"> <tr> <td data-bbox="922 713 953 873">MICROPLA</td> </tr> </table>	MICROPLA	Read at 405 nm within 5 min					
MICROPLA								

react with lead and copper plumbing to form highly explosive metal azides.
On disposal, flush with a large volume of water to prevent azide build-up.

- Follow local guidelines for disposal of all waste material.

Caution

Material used in the preparation of human source reagent has been tested and found to be Non Reactive for HIV 1 and 2 Antibody, HCV Antibody and Hepatitis B Surface Antigen (HBsAg). Since no method can completely rule out the presence of blood borne diseases, the handling and disposal of human source reagents from this product should be made as if they were potentially infectious.

CLP (1272/2008) HAZARD CLASSIFICATION

Information about CLP (1272/2008) HAZARD CLASSIFICATION can be found at the end of this document.

SPECIMEN COLLECTION AND HANDLING

The CanAg CA19-9 EIA is intended for use with serum. Collect blood by venipuncture and separate the serum according to common procedures. Samples can be stored at 2–8°C for 24 hours. For longer periods store samples at -70°C or below. Samples should not be stored in a self-defrosting freezer and not be thawed and refrozen before analysis. Allow frozen samples to thaw slowly at 2–8°C over night and then bring the samples to room temperature before analysis.

PROCEDURE

Materials required but not supplied with the kit

1. Microplate shaker

Shaking should be medium to vigorous, approximately 700-1100 oscillations/min.

2. Microplate wash device

Automatic plate washer capable of performing 1, 3 and 6 washing cycles with a minimal fill volume of 350 µL/well/washcycle.

An 8-channel pipette with disposable plastic tips for delivery of 350 µL is recommended if an automatic microplate washer is not used.

3. Microplate spectrophotometer

With a wavelength of 620 nm and/or 405 nm, and an absorbance range of 0 to 3.0.

4. Precision pipettes

With disposable plastic tips for dispensing microlitre volumes. An 8-channel pipette or resenser pipette with disposable plastic tips for delivery of 100

µL is useful but not essential. Pipettes for dispensing millilitre volumes.

5. Distilled or deionized water

For preparation of Wash Solution.

Procedural notes

1. A thorough understanding of this package insert is necessary to ensure proper use of the CanAg CA19-9 EIA kit. The reagents supplied with the kit are intended for use as an integral unit. Do not mix identical reagents from kits having different lot numbers. Do not use the kit reagents after the expiry date printed on the outside of the kit box.
2. Reagents should be allowed to reach room temperature (20–25°C) prior to use. The assay should only be performed at temperatures between 20–25°C to obtain accurate results. Frozen specimens must be gently but thoroughly mixed after thawing.
3. Before starting to pipette calibrators and patient specimens it is advisable to mark the strips to be able to clearly identify the samples during and after the assay.
4. The requirement for efficient and thorough washing for separation of bound and unbound antigen and reagents from the solid-phase bound antibody-antigen complexes is one of the most important steps in an EIA. In order to ensure efficient washing make sure that all wells are completely filled to the top edge with wash solution during each wash cycle, that wash solution is dispensed at a good flow rate, that the aspiration of the wells between and after the washcycles is complete and that the wells are empty. If there is liquid left, invert the plate and tap it carefully against absorbent paper.
 - Automatic strip washer: Follow the manufacturer's instructions for cleaning and maintenance diligently and wash the required number of wash cycles prior to and after each incubation step. It's highly recommended to use *strip* process mode and *overflow* wash mode with a dispensing volume of 800 µL. The aspiration/wash device should not be left standing with the Wash Solution for long periods, as the needles may get clogged resulting in poor liquid delivery and aspiration.
5. The TMB HRP-Substrate is very sensitive for contamination. For optimal stability of the TMB HRP-Substrate, pour the required amount from the vial to a carefully cleaned reservoir or preferably a disposable plastic tray to avoid contamination of the reagent. Be sure to use clean disposable plastic pipette tips (or respenser pipette tip).
6. Be sure to use clean disposable plastic pipette tips and a proper pipetting technique when handling samples and reagents. Avoid carry-over by holding the pipette tip slightly above the top of the well and avoid touching the plastic strip or surface of the liquid. A proper pipetting technique is of particular importance when handling the TMB HRP-Substrate solution.

Preparation of reagents	Stability of prepared reagent
Wash Solution	2 weeks at 2–25° C in a sealed container
Tracer working solution	3 weeks at 2–8° C in a sealed container

Pour the 50 mL Wash Concentrate into a clean container and dilute 25-fold by adding 1200 mL of distilled or deionised water to give a buffered Wash Solution.

Prepare the required quantity of Tracer working solution by mixing 50 µL of Tracer, HRP Anti-CA19-9 with 1 mL of Tracer Diluent per strip (see table below):

No. of Strips	Tracer, HRP Anti-CA19-9 (µL)	Tracer Diluent (mL)
1	50	1
2	100	2
3	150	3
4	200	4
5	250	5
6	300	6
7	350	7
8	400	8
9	450	9
10	500	10
11	550	11
12	600	12

Be sure to use a clean plastic or glass bottle for preparation of Tracer working solution.

Alternative: Pour the content of the Tracer, HRP Anti-CA19-9 into the vial of Tracer Diluent and mix gently. Make sure that the entire content of the Tracer, HRP Anti-CA19-9 is transferred to the vial of Tracer Diluent.

NOTE: The Tracer working solution is stable for 3 weeks at 2–8° C. Do not prepare more Tracer working solution than will be used within this period and make sure that it is stored properly.

Assay procedure

Perform each determination in duplicate for both calibrators and patient samples. A calibration curve should be run with each assay. All reagents and samples must be brought to room temperature (20–25° C) before use.

1. Start to prepare Wash Solution and Tracer working solution. It is important to use clean containers. Follow the instructions carefully.
2. Transfer the required number of microplate strips to a strip frame. (Immediately return the remaining strips to the aluminium pouch containing a desiccant and reseal carefully). Wash each strip once with the Wash Solution. Do not wash more strips than can be handled within 30 min.
3. Pipette 25 µL of the CA19-9 Calibrators (CAL 0, 15, 30, 60, 120, 240), CA19-9 Controls (C 1, C 2) and patient specimens (unknowns-Unk) into the strip wells according to the following scheme:

	1	2	3	4	5	6	7 etc
A	Cal 0	Cal 120	1st Unk				
B	Cal 0	Cal 120	1st Unk				
C	Cal 15	Cal 240	2nd Unk				
D	Cal 15	Cal 240	2nd Unk				
E	Cal 30	C1	etc.				
F	Cal 30	C1					
G	Cal 60	C2					
H	Cal 60	C2					

4. Add 100 µL of Biotin Anti-CA19-9 to each well using a 100 µL precision pipette (or an 8-channel 100 µL precision pipette). Avoid carry-over by holding the pipette tip slightly above the top of the well and avoid touching the plastic strip or surface of the liquid.
5. Incubate the plate for 2 hours (\pm 5 min) at room temperature (20-25° C) with constant shaking of the plate using a microplate shaker.

6. After the first incubation aspirate and wash each strip 3 times using the wash procedure described in Procedural notes, item 4.
7. Add 100 μ L of Tracer working solution to each well. Use the same pipetting procedure as in item 4 above.
8. Incubate the frame for 1 hour (\pm 5 min) at room temperature (20–25° C) with constant shaking.
9. After the second incubation aspirate and wash each strip 6 times, using the wash procedure described in Procedural notes, item 4.
10. Add 100 μ L of TMB HRP-Substrate to each well using the same pipetting technique as in item 4. The TMB HRP-Substrate should be added to the wells as quickly as possible and the time between addition to the first and last well should not exceed 5 min.
11. Incubate for 30 min (\pm 5 min) at room temperature with constant shaking. Avoid exposure to direct sunlight.
12. Immediately read the absorbance at 620 nm in a microplate spectrophotometer.

Option

If the laboratory does not have access to a microplate reader capable of reading at 620 nm, the absorbance can be determined as in item alternative 12:

- Alt. 12. Add 100 μ L of Stop Solution, mix and read the absorbance at 405 nm in a microplate spectrophotometer within 5 min after addition of Stop Solution.

Measurement range

The CanAg CA19-9 EIA measures concentrations between 1 and 240 U/mL. If CA19-9 concentrations above the measuring range are to be expected, it is recommended to dilute samples with CA19-9 Calibrator 0 prior to analysis.

Quality control

CA19-9 Control 1 and 2 should be used for validation of the assay series. Ranges of expected results are indicated on the vial labels. If values outside of the specified range are obtained, a complete check of reagents and reader performance should be made and the analysis repeated. Each laboratory may also prepare its own serum pools at different levels, which can be used as internal controls in order to assure the precision of the assay.

Reference materials

Since no common reference material is available for CA19-9 antigen, CanAg CA19-9 EIA Calibrator values are assigned against a set of in-house reference standards.

CALCULATION OF RESULTS

If a microplate spectrophotometer with built-in data calculation program is used, refer to the manual for the spectrophotometer and create a program using the concentration stated on the label of each of the CA19-9 calibrators.

For automatic calculation of CA19-9 results it is recommended to use either of the following methods:

- Cubic spline curve fit method. Calibrator 0 should be included in the curve with the value 0 U/mL.
- Spline smoothed curve fit method. Calibrator 0 should be used as plate blank.
- Interpolation with point-to-point evaluation. Calibrator 0 should be included in the curve with the value 0 U/mL.
- Quadratic curve fit method. Calibrator 0 should be included in the curve with the value 0 U/mL.

NOTE: 4-Parametric or Linear regression evaluation methods should not be used.

For manual evaluation, a calibration curve is constructed by plotting the absorbance (A) values obtained for each CA19-9 calibrator against the corresponding CA19-9 concentration (in U/mL), see figure below. The unknown CA19-9 concentrations can then be read from the calibration curve using the mean absorbance value of each patient specimen.

If samples in an initial analysis give CA19-9 levels higher than 240 U/mL the samples should be diluted 1/10 and 1/100 with CA19-9 Calibrator 0 to obtain the accurate CA19-9 concentration of the samples.

1/10 dilution = 50 μ L of specimen + 450 μ L of CA19-9 Calibrator 0

1/100 dilution = 50 μ L of 1/10 dilution + 450 μ L of CA19-9 Calibrator 0

The CA19-9 concentration of the undiluted sample is then calculated as:

Dilution 1/10: 10 x measured value

Dilution 1/100: 100 x measured value

Example of results

Specimen			Calibrator values	Mean abs value (A)	CA19-9 U/mL
CAL	CA19-9	0	0 U/mL	0.036	
CAL	CA19-9	15	15 U/mL	0.276	
CAL	CA19-9	30	30 U/mL	0.508	
CAL	CA19-9	60	60 U/mL	0.928	
CAL	CA19-9	120	120 U/mL	1.665	
CAL	CA19-9	240	240 U/mL	2.583	

Specimen A

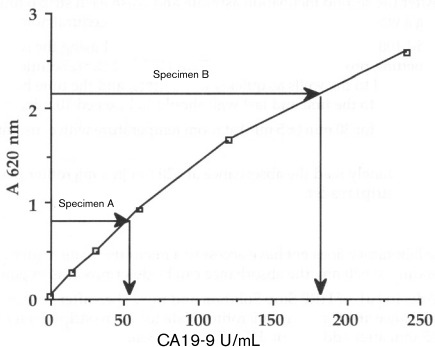
0.815

52

Specimen B

2.130

181



Example, do not use this curve to determine assay results.

LIMITATIONS OF THE PROCEDURE

The level of CA19-9 cannot be used as absolute evidence for the presence or absence of malignant disease and the CA19-9 test should not be used in cancer screening. The results of the test should be interpreted only in conjunction with other investigations and procedures in the diagnosis of disease and the management of patients, and the CA19-9 test should not replace any established clinical examination.

Benign conditions such as acute or chronic pancreatitis or cholelithiasis may cause elevated levels of CA19-9. Patients with a Le^{a+/b-} phenotype do not express the CA19-9 reactive epitope. Anti-reagent antibodies (human anti-mouse antibody (HAMA) or heterophilic antibodies) in the patient sample may occasionally interfere with the assay, even though specific blocking agents are included in the buffers.

Biotin may interfere with the assay giving false low results. This should be taken into consideration for patients taking dietary supplements or receiving therapy containing high (> 5mg/day) or extremely high (300 mg/day) biotin doses. Peak serum levels have been reported to occur 1-3h post ingestion and a physiological half-life of 8-16h depending on renal function (6,7). In a study by Grimsey et al. (6) a specimen concentration of 30 ng/mL was reached 8h following intake of 10 mg of biotin. For patients on very high doses of biotin it is recommended to stop taking biotin for at least 2 days before blood draw (8).

EXPECTED VALUES

CA19-9 was measured in 100 healthy blood donors, 36 women and 64 men. The mean value obtained was 6.5 U/mL with a standard deviation of 6.4. The median value was 4.5 U/mL, range 0 – 29 U/mL. The lower and upper extremes of the normal range were examined using IFCC recommended non-parametric statistical treatment. The reference interval contains the central 95% fraction of the reference distribution. Reference limits may accordingly be estimated as the 2.5% (lower) and 97.5% (upper) fractiles. These limits cut off a fraction of 2.5% of the values in each tail of the reference distribution. Non-parametric estimates: N=100

Fraction	Reference limit (U/mL)
2.5 th (lower)	0
97.5 th (upper)	25

100% of the healthy subjects had assay values below 37 U/mL.

It is recommended that each laboratory establish its own normal range to account for such local environmental factors as diet, climate, living conditions, patient selection, etc.

PERFORMANCE CHARACTERISTICS

Precision

Total precision was determined according to NCCLS guideline EP5-A (4) using four levels of frozen pooled human serum containing added ascitespool. Each sample was randomly pipetted (n=2/analysis) and analysed twice each day over 20 days. The analyses were undertaken during a period of 53 months, by \geq three different technicians and using 20 different CanAg CA19-9 EIA kit batches.

Sample	Replicates	Mean U/mL	Within-run SD (U/mL)	Within-run CV %	Between-day SD (U/mL)	Between-day CV %
CA19-9 1	80	15.4	0.6	3.8	1.0	6.8
CA19-9 2	80	56.3	1.9	3.3	3.6	6.3
CA19-9 3	80	99.8	4.5	4.5	6.2	6.2
CA19-9 4	80	182	7.9	4.4	12	7.0

Detection limit

The detection limit of the CanAg CA19-9 EIA assay is < 1 U/mL defined as the concentration corresponding to the mean of the absorbance values for the CA19-9 Calibrator 0 plus 2 standard deviations according to the formula:

$$\frac{2 \times \text{SD CAL 0}}{\text{OD CAL 15} - \text{OD CAL 0}} \times 15 \text{ U/mL}$$

Recovery

Spiked serum samples were prepared by adding different levels of human CA19-9 antigen to normal serum samples. The recovery of the antigen was in the range 90–110%.

Hook effect

No hook effect has been noticed with samples up to 50 000 U/mL. **NOTE:** In very high samples the color of the substrate will change from blue to greenish (and eventually yellow in extremely high samples). This will lead to a falsely low absorbance at 620 nm, and in extreme cases the absorbance may fall within the calibration curve range and noticed as a hook.

Linearity

Eight patient samples were serially diluted with CA19-9 Calibrator 0 and analyzed. The obtained values were between 96–105 % of the expected values in the range 10–200 U/mL.

Specificity

The monoclonal antibody used (C192) is highly specific for the sialyl Lewis^a epitope (1). The NCCLS guideline EP7-P (5) was followed to determine possible sources of interference. The following substances and concentrations were tested and found not to interfere with the test.

	Concentration with no significant (\pm 10%) interference
Lipemia (Intralipid [®])	10 mg/mL
Bilirubin, unconjugated	0.6 mg/mL
Hemoglobin	5 mg/mL

Biotin interference

A study was conducted to evaluate biotin interference. Low and high serum control samples were spiked to final biotin concentrations of 15, 30, 60, and 200 ng/mL. The mean CA19-9 concentration was determined for each sample and the percent recovery for each biotin concentration was calculated using the formula: Recovery (%) = 100x (Mean CA19-9 concentration w. biotin added/ Mean CA19-9 concentration w. diluent only added).

CA19-9 analyte level	Biotin test conc. (ng/mL)	Expected CA19-9 conc. (U/mL)	Observed CA19-9 conc. (U/mL)	Recovery (%)
Low	15	17,6	17,7	100
High	15	143	144	101
Low	30	17,8	17,7	99
High	30	145	146	101
Low	60	18,0	17,4	97
High	60	147	145	99
Low	200	17,9	9,71	54
High	200	146	90,0	62

Based on linear regression analysis, the lowest concentration of biotin found to influence test results (\geq 10%) was 73 ng/mL.

CLP (1272/2008) HAZARD CLASSIFICATION

The following warnings and precautions apply to

SUBS TMB

Hazard pictograms:



Signal word:	Danger
Hazard Statement:	Repr. 1B: H360D May damage the unborn child.
Prevention statement:	P202 Do not handle until all safety precautions have been read and understood.
Prevention:	P280 Wear protective gloves / protective clothing / eye protection / face protection.
Precautionary statement response:	P308+P313 IF exposed or concerned get medical advice/attention.
Precautionary statement disposal:	P501 Dispose of contents / container to an approved hazardous / special waste disposal facility in accordance with local and national regulations.

Restricted to professional users.

Hazardous substances: 2- Pyrrolidone

Other hazards

None of the mixtures in the kit contains any substances considered to meet the criteria classifying them as PBT and/or vPvB.

WARRANTY

The performance data presented here were obtained using the assay procedure indicated. Any change or modification of the procedure not recommended by Fujirebio Diagnostics may affect the results, in which event Fujirebio Diagnostics disclaims all warranties expressed, implied or statutory including the implied warranty of merchantability and fitness for use.

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Fujirebio Diagnostics AB
Elof Lindälvs gata 13
SE-414 58 Göteborg
Sweden
Phone + 46 31 85 70 30
Fax + 46 31 85 70 40
info@fdab.com
www.fdab.com

