



CanAg AFP EIA

REF

600-10

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	SEMNICIFICAȚIA 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/
Sunaudoti iki/Izlietot līdz/Houdbaar
tot/Brukes innen/Użyć przed/
Prazo de validade/Expiră la/
Использовать до/Använd före/
Použite'né do/ Uporabno do/
Upotrebljivo do/Son Kullanma Tarihi

LOT

Batch code/Номер на партида/
Číslo šarže/Lotnummer/
Chargenbezeichnung/Αριθμός
Παρτίδας/Código de lote/Partii
kood/Code du lot/Kod serije/
Sarzszám/Codice del lotto/
Partijos kodas/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/
Ημερομηνία παραγωγής/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

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/ Zdravotnícka pomôcka na
diagnostiku in vitro/In vitro diagnostični
pripomoček/Diagnostički medicinski
uređaj In Vitro/<96> testleri için yeterlilik
içerir

REF

Catalogue number/Каталожен номер/
Katalogové číslo/Katalognummer/
Bestellnummer/Αριθμός καταλόγου/
Número de catálogo/Katalogi number/
Numéro de catalogue/Katalogski 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/Katalogski broj/
Katalog numarası



Temperature limitation/
Температурни граници/
Теплотні обмеження/
Temperaturbegrænsning/
Temperaturbegrenzung/
Περιορισμοί θερμοκρασίας/
Limites de temperatura/
Temperatuuri piirang/
Limite de température/
Temperaturno ograničenje/
Hőmérsékletre vonatkozó korlátozás/
Limiti di temperatura/
Temperatūriniai apribojimai/
Temperatūras ierobežojums/
Temperatuurbepijking/
Temperaturbegrensninger/
Temperatury graniczne/
Limite de temperatura/
Limite de temperatură/
Температурный режим/
Temperaturbegrænsning/
Teplotné obmedzenie
Omejitve temperature/
Temperaturno ograničenje/
Sıcaklık sınırlaması/



Contains sufficient for <96> tests/Съдържа
достатъчно количество за тестове
<96>/Lze použít pro <96> testů/Ineholder
tilstrækkeligt/Inhalt ausreichend für <96>
Prüfungen/Περιεχόμενο 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/Obshaj postačuje na
tento počet testov: <96>/Vsebinsa zadostuje
za <96> testov/Sadržina dovoljna za <96>
testova/<96> testleri için yeterlilik içerir



Consult Instructions for Use/
Прочетете инструкцията за
употреба/Konzultujte s návodem
k použití/Se brugsanvisning/Siehe
Gebrauchsanweisung/Συμβουλευτείτε
της Οδηγίες σχετικά με τη χρήση/
Consulte las instrucciones de uso/
Vt kasutusjuhendit/Consulter le mode
d'emploi/Pročitajte upute za uporabu/
Olvassa el a használati útastást/
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/
Pročitajte uputstvo za upotrebu/
Kullanım Talimatlarını Bakınız

CONT

Contents of kit/Съдържание на набора/
Obsah soupravy/Kittets indhold/Inhalt
des Kits/Περιεχόμενα του κιτ/Contenido
del kit/Komplekt sisaladab/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/Vseбина kompleta/Sadržaj
opreme/Kitin içindekiler



Biological risks/Биологическа
опасност/Biologická rizika/Biologisk
fare/Biologische Gefahren/Biolογικοί
κίνδυνοι/Riesgos biológicos/
Biolooligised ohud/Risques biologiques/
Biolóskli rizici/Biológiai kockázatok/Rischi
biologici/Biologinis pavojus/Biológiskais
risks/Biologische risico's/Biologiske
risikoer/Zagroženie biologické/Riscos
biológicos/ Biologisk risk/Pericole
biologice/Biologическая опасность/
Biologický rizikové/Biologické riziká/
Biolóskli rizici/Biyołojik riskler

ORIG HUM

Human/C човешки произход/Lidské/
Human/Human/δείγματα αναφοράς/
Humano/Inimăritolu/Humaine/Ljudskog
porjekla/Humán/Origine Umana/
Žmogaus kilmės/Cilvēku izcelsmes/
Human/Menneske/Ludzka/Humano/
Origine umână/Человеческого
происхождения/Human/L'udské/
Humanega izvora/Ljudskog porekla/İnsan

ORIG MOU

From mouse/C миши произход/Myši/
Fra mus/Maus/από ποντίκι/de ratón/
Hiirtelt/De souris/Mišjeg porjekla/
Egérbőli/Murino/Pelės kilmės/No peles/
Van muizen/Fra mus/Mysia/Do rato/De
la șoareci/Мышиного происхождения/
Från mus/Myšie/Mišjega izvora/Mišjeg
porekla/Fareden

ORIG BOV

Bovine/C говежди произход/
Hovězí/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/Hováðzie/Rogvejaga
izvora/Rogate krupne stoke/Bovin



Reconstitute with/Пазтваряне с/
Rozfedte pomoci/Rekonstituieres med/
Rekonstituieren mit/Ανασύσταση με/
Reconstituir con/Lahjendamine/
Reconstituer avec/Rekonstituiraite s/
Feloldáshoz/Ricostituire con/Atkurti,
ištirpdant su/Atšikaidīt ar/Reconstituie
met/Rekonstituieres med/Odtworzyć
za pomocą/Reconstituir com/A
se reconstitui cu/Пастворить в/
Rekonstituera med/Rozriedte pomocou/
Rekonstituiraite z/s/Ponovno formiranje
sa/Yeniden oluşturalur



Manufacturer/Производитель/Výrobce/
Producent/Hersteller/Κατασκευαστής/
Fabricante/Tootja/Fabricant/Proizvođač/
Gyártó/Fabbricante/Gamintojas/
Ražotājs/Fabrikant/Produsent/
Producent/Fabricante/Producător/
Производитель/Tilverkare/ Výrobca/
Izdelovalec/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 Material Sicherheitsdatenblätter (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 ohutuskaardid 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.

Veuillez 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 ineternetu, molimo da se obratite lokalnom distributeru ili Fujirebio Diagnostics AB za pomoć.

HU

HASZNÁLATI UTASÍTÁS

További nyelveken készült Használati utasítások találhat 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 találhatók. 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.

IT

ISTRUZIONI PER L'USO

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.

Seguire 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.

LT

NAUDOJIMO INSTRUKCIJOS

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 pateiktų instrukcijų viršelyje.

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

LV

LIETOŠANAS INSTRUKCIJA

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 iespiestajam 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. Instruks 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 sítio 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**.

Aby 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.

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, natisnjenemu 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.

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 UPO-ZORENJE 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.

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 AFP EIA

Instructions for use

Enzyme immunometric assay kit
For 96 determinations

INTENDED USE

The CanAg AFP EIA kit is intended for the quantitative determination of α -Fetoprotein (AFP) in human serum.

SUMMARY AND EXPLANATION OF THE ASSAY

α -Fetoprotein (AFP), the foetal equivalent to albumin, is a 67 kDa glycoprotein produced during embryonic development and found in high concentrations in foetal serum and amniotic fluid. In normal non-pregnant adults AFP is present in low concentrations in serum. However AFP may be markedly increased in the serum from patients with cancer of the liver, testis or ovary. Quantitative determination of AFP in serum may be valuable in the management of patients with suspected or diagnosed liver cancer or germ cell tumours of the testis or ovary (1, 2).

PRINCIPLE OF THE TEST

The CanAg AFP EIA is a solid-phase, non-competitive immunoassay based upon the direct sandwich technique. Calibrators, controls and patient samples are incubated together with biotinylated Anti-AFP monoclonal antibody and horseradish peroxidase (HRP) labelled Anti-AFP monoclonal antibody in Streptavidin coated microstrips. After washing, buffered Substrate/ Chromogen reagent (hydrogen peroxide and 3, 3', 5, 5' tetra-methylbenzidine) is added to each well and the enzyme reaction is allowed to proceed. During the enzyme reaction a blue colour will develop if antigen is present. The intensity of the colour is proportional to the amount of AFP present in the samples.

The colour 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 AFP concentrations of patient samples are then read from the calibration curve.

REAGENTS

- Each CanAg AFP 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
-----------	----------	---

MICROPLA

Microplate	1 Plate	2–8° C until expiry date stated on the plate
-------------------	---------	--

12 x 8 wells coated with Streptavidin. After opening, immediately return unused strips to the aluminium pouch, containing desiccant. Reseal carefully to keep dry.

AFP Calibrators	6 vials	2–8° C until expiry date stated on the vials
------------------------	---------	--

CAL	AFP	0	0 µg/L	1 x 0.75 mL
CAL	AFP	5	5 µg/L	1 x 0.75 mL
CAL	AFP	25	25 µg/L	1 x 0.75 mL
CAL	AFP	100	100 µg/L	1 x 0.75 mL
CAL	AFP	250	250 µg/L	1 x 0.75 mL
CAL	AFP	500	500 µg/L	1 x 0.75 mL

Human AFP in a Tris-HCl buffered salt solution containing bovine serum albumin, an inert yellow dye and 0.01% methyl-isothiazolone (MIT) as preservative. Ready for use.

Component	Quantity	Storage and stability after first opening			
AFP Controls	2 vials	2–8° C until expiry date stated on the vials			
<table border="1"><tr><td>CONTROL</td><td>AFP</td><td>1</td></tr></table>	CONTROL	AFP	1	1 x 0.75 mL	
CONTROL	AFP	1			
<table border="1"><tr><td>CONTROL</td><td>AFP</td><td>2</td></tr></table>	CONTROL	AFP	2	1 x 0.75 mL	
CONTROL	AFP	2			

Human AFP in a Tris-HCl buffered salt solution containing bovine serum albumin, and 0.01% methyl-isothiazolone (MIT) as preservative. Ready for use.

<table><tr><td>BIOTIN</td><td>Anti-AFP</td></tr></table>	BIOTIN	Anti-AFP		
BIOTIN	Anti-AFP			
Biotin Anti-AFP	1 x 15 mL	2–8° C until expiry date stated on the vial		

Biotin Anti-AFP monoclonal antibody from mouse, approximately 1 µg/mL. Contains phosphate buffered saline (pH 7.2), bovine serum albumin, bovine immunoglobulin, blocking agents, Tween 20, an inert blue dye and 0.01% methyl-isothiazolone (MIT) as preservative. To be mixed with Tracer, HRP Anti-AFP before use.

CONJ	Anti-AFP		
Tracer, HRP Anti-AFP	1 x 0.75 mL	2–8° C until expiry date stated on the vial	

Stock solution of HRP Anti-AFP monoclonal antibody from mouse, approximately 20 µg/mL. Contains preservatives. To be mixed with Biotin Anti-AFP before use.

<table><tr><td>SUBS</td><td>TMB</td></tr></table>	SUBS	TMB		
SUBS	TMB			
TMB HRP-Substrate	1 x 12 mL	2–8° C until expiry date stated on the vial		

Contains buffered hydrogen peroxide and 3, 3', 5, 5' tetramethyl-benzidine (TMB). Ready for use.

Component	Quantity	Storage and stability after first opening
-----------	----------	---

STOP

STOP Solution	1 x 15 mL	2–8° C until expiry date stated on the vial
----------------------	-----------	---

Contains 0.12 M hydrochloric acid. Ready for use.

WASHBUF 25X

Wash Concentrate	1 x 50 mL	2–8° C until expiry date stated on the bottle
-------------------------	-----------	---

A Tris-HCl buffered salt solution with Tween 20. Contains Germall II as preservative. To be diluted with water 25 times before use.

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.

- For professional use only.
- Please refer to the US Department of Health and Human Services (Bethesda, Md., US) publication No. (CDC) 88-8395 on laboratory safety or any other local or national regulation.
- Handle all patient specimens as potentially infectious.
- 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-1/2 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.

Protocol Sheet

CanAg AFP EIA REF 600-10

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

Step	Vial/Plate	Procedure
1. Prepare Wash Solution	WASHBUF25X	Dilute 50 mL of Wash Concentrate with 1200 mL of distilled water or deionized water.
	CONJAnti-AFP	
	BIOTINAnti-AFP	
Prepare Antibody Solution		Mix 50 µL of Tracer, HRP Anti-AFP, with 1 mL of Biotin Anti-AFP per strip:
	No. of Strips	Tracer, HRP Anti-AFP (µL)Biotin Anti-AFP (mL)
	1	501
	2	1002
	3	1503
	4	2004
	5	2505
	6	3006
	7	3507
	8	4008
	9	4509
	10	50010

2.	Wash	MICROPLA	Wash each well once with wash solution
3.	Add calibrators, controls and samples	CAL AFP 0, 5, 25, 100, 250, 500 CONTROL AFP	25 µL in each well
4.	Add Antibody Solution	ANTIBODY SOLUTION	100 µL in each well
5.	Incubate	MICROPLA	1 hour shaking at room temperature
6.	Wash	MICROPLA	Wash each well six times with wash solution
7.	Add TMB HRP-Substrate	SUBS	100 µL in each well
8.	Incubate	MICROPLA	30 min shaking at room temperature
9.	Read absorbance	MICROPLA	620 nm
Alt.9	Add Stop Solution	STOP	100 µL in each well
Alt.10	Incubate	MICROPLA	1 min shaking at room temperature
Alt.11	Read absorbance	MICROPLA	Read at 405 nm within 5 min

SPECIMEN COLLECTION AND HANDLING

The CanAg AFP 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 2 days. For longer periods it is recommended to store the samples at –20° C or below. Avoid repeated freezing and thawing of the samples. Allow frozen samples to thaw slowly, preferably 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 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 to deliver microlitre and millilitre volumes.

An 8-channel pipette or dispenser pipette with disposable plastic tips for delivery of 100 µL is useful but not essential.

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 AFP 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 should be brought to room temperature slowly and must be gently but thoroughly mixed after thawing.
3. Before starting to pipette calibrators, controls 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 wash cycles 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

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

Antibody Solution	3 weeks at 2–8° C
--------------------------	-------------------

Prepare the required quantity of Antibody Solution by mixing 50 µL of Tracer, HRP Anti-AFP with 1 mL of Biotin Anti-AFP per strip (see table below and the Protocol Sheet).

No. of Strips	Tracer, HRP Anti-AFP (µL)	Biotin Anti-AFP (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 the Antibody Solution.

Alternative: Pour the content of the Tracer, HRP Anti-AFP into the vial of Biotin Anti-AFP and mix gently. Make sure that all of the Tracer, HRP Anti-AFP is transferred to the vial of Biotin Anti-AFP.

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

Assay procedure

Perform each determination in duplicate for calibrators, controls 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 Antibody 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 AFP Calibrators (CAL 0, 5, 25, 100, 250, 500), controls (C1, C2) and patient samples (unknowns-Unk) into the strip wells according to the following scheme:

	1	2	3	4	5	6	7 etc
A	Cal 0	Cal 250	Unk 1				
B	Cal 0	Cal 250	Unk 1				
C	Cal 5	Cal 500	Unk 2				
D	Cal 5	Cal 500	Unk 2				
E	Cal 25	C1	etc.				
F	Cal 25	C1					
G	Cal 100	C2					
H	Cal 100	C2					

4. Add 100 µL of Antibody Solution 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 the surface of the liquid.
5. Incubate the frame containing the strips for 1 hour ($\pm$ 5 min) at room temperature (20–25°C) with constant shaking of the plate using a microplate shaker.
6. Wash each strip 6 times, using the wash procedure described in Procedural notes item 4.

7. Add 100 µL of TMB HRP-Substrate to each well using the same pipetting procedure as in item 4. The TMB HRP-Substrate should be added to the wells as quickly as possible and the time between the addition to the first and last well should not exceed 5 min.
8. Incubate for 30 min ($\pm$ 5 min) at room temperature with constant shaking. Avoid direct sunlight.
9. Immediately read the absorbance at 620 nm in a microplate spectrophotometer.

Option

If the laboratory does not have access to a microplate spectrophotometer capable of reading at 620 nm, the absorbance can be determined as follows:

- Alt. 9. Add 100 µL of Stop Solution. Mix and read the absorbance at 405 nm in a microplate spectrophotometer within 5 minutes after addition of Stop Solution.

Measurement range

The CanAg AFP EIA measures concentrations between 0.5 and 500 µg/L. If AFP concentrations above the measuring range are to be expected, it is recommended to dilute samples with normal human serum prior to analysis. **NOTE:** The serum used for dilution should also be measured in order to determine the endogenous AFP concentration (see "Calculation of results").

Quality control

AFP Control 1 and 2 may 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 in addition prepare its own serum pools at different levels, which can be used as internal controls in order to assure the accuracy of the assay.

Reference material

The 1st International Standard IS 72/225 may be used as a reference standard. Values for AFP Calibrators and Controls were assigned against a set of in-house reference standards whose values are traceable to IS 72/225 using the conversion factor 0.83, i.e. 1 µg/L corresponds to 0.83 kIU/L.

CALCULATION OF RESULTS

If a microplate spectrophotometer reader with built-in data calculation program is used, refer to the manual for the plate reader and create a program using the concentration stated on the labels of each of the AFP Calibrators.

For automatic calculation of AFP 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 µg/L.
- 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 µg/L.
- Quadratic curve fit method. Calibrator 0 should be included in the curve with the value 0 µg/L.

NOTE: 4-parametric or linear regression should not be used.

For manual evaluation, a calibration curve is constructed by plotting the absorbance (A) values obtained for each AFP calibrator against the corresponding AFP concentration (in µg/L), see figure below. The unknown AFP 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 AFP levels higher than 500 µg/L the samples should be diluted 1/10 and 1/100 with normal human serum and reanalyzed to obtain the accurate AFP concentration. **NOTE:** The sample used for dilution should also be measured in order to determine the endogenous AFP concentration.

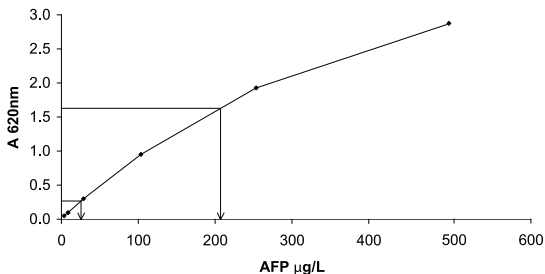
The AFP concentration of the undiluted sample is then obtained as follows:

$$\text{Dilution 1/10:} \quad 10 \times ([\text{AFP}]_{\text{Diluted sample}} - (0.9 \times [\text{AFP}]_{\text{Normal serum}}))$$

$$\text{Dilution 1/100:} \quad 100 \times ([\text{AFP}]_{\text{Diluted sample}} - (0.99 \times [\text{AFP}]_{\text{Normal serum}}))$$

Example of results

Specimen			Calibrator values	Mean abs value (A)	AFP (µg/L)
CAL	AFP	0	0 µg/L	0.036	
CAL	AFP	5	5 µg/L	0.083	
CAL	AFP	25	25 µg/L	0.282	
CAL	AFP	100	100 µg/L	0.938	
CAL	AFP	250	250 µg/L	1.914	
CAL	AFP	500	500 µg/L	2.854	
Specimen A				0.220	19.4
Specimen B				1.686	208



Example (do not use this curve or table above to determine actual assay results).

LIMITATIONS OF THE PROCEDURE

The level of AFP cannot be used as absolute evidence for the presence or absence of malignant disease, and the AFP 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 AFP test should not replace any established clinical examination.

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 buffer.

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 (8,9). In a study by Grimsey et al. (8) 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 (10).

EXPECTED VALUES

AFP was measured in 40 apparently healthy men and 93 apparently healthy women. The mean value obtained was 2.8 µg/L with a standard deviation of 2.6. 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:

Fraction	Reference limit (µg/L)	90% confidence interval
2.5 th (lower)	0.1	0.0–0.3
97.5 th (upper)	10	8.7–14.6

It is recommended that each laboratory establish their own normal range to account for such local environmental factors as diet, climate, living conditions, patient selection, etc. As AFP levels have been shown to increase with age, the use of age-specific reference intervals have been suggested (2, 3). It should also be borne in mind that the individual patient's own baseline results provides the most important reference point for interpretation of marker results (3, 4).

PERFORMANCE CHARACTERISTICS

Precision

Total precision was calculated according to NCCLS guideline EP5-A (6) using four levels of frozen pooled human serum containing added AFP and nine different CanAg AFP EIA reagent combinations. Each sample was randomly pipetted (n=2/analysis) and analysed twice each day over 20 days.

Sample	Replicates	Mean (µg/L)	Within-run SD (µg/L)	Within-run CV %	Between-day SD (µg/L)	Between-day CV %
AFP 1	80	7.8	0.2	2.0	0.1	1.8
AFP 2	80	23.2	0.4	1.8	0.3	1.4
AFP 3	80	207	3.5	1.7	3.5	1.7
AFP 4	80	416	6.6	1.6	8.5	2.0

Detection limit

The detection limit of the CanAg AFP EIA is ≤ 0.5 µg/L defined as the concentration corresponding to the mean of the absorbance values of the AFP calibrator 0 plus 2 standard deviations according to formula:

$$\frac{2 \times \text{SD CAL } 0}{\text{OD CAL } 5 - \text{OD CAL } 0} \times 5 \text{ µg/L}$$

Recovery

Spiked serum samples were prepared by adding aliquots of a sample with highly elevated AFP to normal serum samples. The recovery of the added antigen was in the range 90–106 %. **NOTE:** Recovery studies should **not** be performed using the kit calibrators.

Hook effect

No hook effect has been noticed for samples up to 40 000 µg/L. However, since patients with advanced hepatocellular carcinoma may show extremely high levels, false low results due to a high dose hook effect may be seen in specimens from these patients. In order to avoid reporting misleadingly low results due to a hook effect at higher concentrations, particularly in patients for whom markers are being measured for the first time, or when very high AFP values may be expected, it is recommended to assay specimens at two dilutions (i.e. neat and diluted 1:100 with normal human serum).

Linearity

Patient samples were diluted with normal human serum and analysed. The obtained values were within $\pm 10\%$ of the expected values.

Specificity

The CanAg AFP EIA is based on two mouse monoclonal antibodies, AFPK51 and AFPK57, targeting two separate antigenic determinants on the AFP molecule (5). The NCCLS guideline EP7-P (7) 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	2 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 AFP concentration was determined for each sample and the percent recovery for each biotin concentration was calculated using the formula: Recovery (%) = 100x (Mean AFP concentration w. biotin added/Mean AFP concentration w. diluent only added).

AFP analyte level	Biotin test conc. (ng/mL)	Expected AFP conc. ($\mu\text{g/L}$)	Observed AFP conc. ($\mu\text{g/L}$)	Recovery (%)
Low	15	22,5	22,4	99
High	15	223	216	97
Low	30	22,5	22,4	100
High	30	224	214	96
Low	60	23,1	20,6	89
High	60	226	194	86
Low	200	22,8	5,28	23
High	200	227	53,5	24

Based on linear regression analysis, the lowest concentration of biotin found to influence test results ($\geq 10\%$) was 45 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.

REFERENCES

1. Johnson, P.J, (2002) Tumor Markers in Primary Malignancies of the liver. In "Tumor Markers: Physiology, pathobiology, technology and clinical applications", ed. Dimandis E.P. AACC Press, Washington pp 269-276.
2. Stenman, U-H and Alfthan, H. (2002) Markers for Testicular Cancer. In "Tumor Markers: Physiology, pathobiology, technology and clinical applications", ed. Dimandis E.P. AACC Press, Washington, pp 351-359.
3. Christiansen, M., Hogdall, C.K., Andersen, J.R. and Norgaard-Pedersen, B. (2001) Alpha-fetoprotein in plasma and serum of healthy adults: preanalytical, analytical and biological sources of variation and construction of age-dependent reference intervals. *Scand J Invest* 61: 205-216.
4. Trapé, J., Botargues, J.M., Porta, F., Ricós, C., Badal, J.M., Salinas, R., Sala, M., and Roca, A. (2003) Reference change value for α -Fetoprotein and its application in early detection of hepatocellular carcinoma in patients with hepatic disease. *Clin Chem* 49(7): 1209-1211.
5. Nustad, K., Paus, E., Kierulf, B., and Borner, O.P. (1998) Specificity and affinity of 30 monoclonal antibodies against Alpha-Fetoprotein. *Tumor Biol* 19: 293-300.
6. National Committee for Clinical Laboratory Standards, Evaluation of Precision Performance of Clinical Chemistry Devices. Approved Guideline EP5-A (1999).
7. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation protocol Number 7, Vol. 6, No 13, August (1986).
8. Grimsey P et al. Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. *J Pharmacokinet.* 2017; 2(4); 247-256.
9. Jenkins Colon P, Greene D.N. Biotin Interference in Clinical Immunoassays. *JALM* 2018; 2(6); 941-951.
10. Chun KY. Biotin Interference in Diagnostic Tests. *Clinical Chemistry* 2017; 63; 619-620.



CanAg[®] is a registered trademark of Fujirebio Diagnostics AB

Fujirebio Diagnostics AB
Elof Lindälv's 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

