CanAg NSE EIA

REF 420-10

IVD

CE

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	SEMNIFICAŢIA SIMBOLURILOR
RU	ОБОНАЧЕНИЯ
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/Kõlblik kuni/ Utiliser jusque/Rok valjanosti/ Felhasználható/Utilizare 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/ Sarzsszám/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 fabricaţiei/Дата производства/ Tillverkningsdatum/Dátum výroby/Datum izdelave/Datum proizvodnje/Üretim tarihi

Temperature limitation/ Температурни граници/ Teplotní omezení/ Temperaturbegrænsning/ Temperaturbegrenzung/ Περιορισμοί θερμοκρασίας/ Límites de temperatura/ Temperatuuri piirang/ Limite de température/ Temperaturno ograničenje/ Hőmérsékletre vonatkozó korlátozás/ Limiti di temperatura/ Temperatūriniai apribojimai/ Temperatūras ierobežojums/ Temperatuurbeperking/ Temperaturbegrensninger/ Temperatury graniczne/ Limite de temperatura/ Limite de temperatură/ Температурный режим/ Temperaturbegränsning/ Teplotné obmedzenie Omejitev temperature/ Temperaturno ograničenje/ Sıcaklık sınırlaması/

IVD

In Vitro Diagnostic Medical Device/ Медицински уред за диагностика ин витро/Diagnostický zdravotnický 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 orvosdiagnosztikai eszköz/Dispositivo medico per test diagnostici in vitro/In Vitro Diagnostinė Medicinos Priemonė/Medicīniska ierīce 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

Contains sufficient for <96> tests/Съдържа достатъчно количество за тестове <96>/Lze použít pro <96> testů/Indeholder 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/Sadrži dovoljno za <96> testova/A doboz tartalma <96> vizsgálat elvégzéséhez elegendő/Contenuto sufficiente per “96” saggi/Turinys skirtas atlikti <96> tyrimus/ Saturs pietiekams <96> testiem/Inhoud voldoende voor “96” testen/til “96” test/ Tilstrekkelig innhold for <96> prøver/ Wystarczy na wykonanie <96> testów/ Conteúdo suficiente para “96” ensaios/ Conţinut suficient pentru 96 de teste/ Содержит достаточные количества для «96» определений/Innehåller tillräckligt till “96” antal tester/Obsah postačuje na tento počet testov: <96>/Vsebina 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/Kataloogi number/ Numéro de catalogue/Katološki broj/ Katalógusszám/Numero di catalogo/ Katalogo numeris/Numurs katalogā/ Katalogusnummer/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 τις 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 utasítást/ Consultare le istruzioni per l'uso/Dėl naudojimo žiūrėkite instrukcijas/Izlasiet lietošanas instrukciju/Raadpleeg de instructies voor gebruik/Les instruksene før bruk/Sprawdzić w instrukcji użycia/ Consulte as Instruções de Utilização/ Consultaţi instrucţiunile de utilizare/ Обратитесь к инструкции по применению/Se bruksanvisning/ Prečítajte si návod na používanie/ Pročitajte uputstvo za upotrebu/ Kullanım Talimatlarına Bakınız

CONT

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/Conţinutul setului/ Компоненты набора/Kit innehåll/ Obsah súpravy/Vsebina kompleta/Sadržaj opreme/Kitin içindekiler

Biological risks/Биологическа опасност/Biologická rizika/Biologisk fare/Biologische Gefahren/Βιολογικοί κίνδυνοι/Riesgos biológicos/ Bioloogilised ohud/Risques biologiques/ Biološkli rizici/Biológiai kockázatok/Rischi biologici/Biologinis pavojus/Bioloģiskais risks/Biologische risico's/Biologiske risikoer/Zagrożenie biologiczne/Riscos biológicos/ Biologisk risk/Pericole biologice/Биологическая опасность/ Biologicky rizikové/Biologické riziká/ Biološkli rizici/Biyolojik riskler

ORIG | HUM

Human/С човешки произход/Lidské/ Humant/Human/δείγματα αναφοράς/ Humano/Inimpäritolu/Humaine/Ljudskog porjekla/Humán/Origine Umana/ Žmogaus kilmės/Cilvēku izcelsmes/ Human/Menneske/Ludzka/Humano/ Origine umană/Человеческого происхождения/Human/Ľudské/ Humanega izvora/Ljudskog porekla/İnsan

ORIG | MOU

From mouse/С миши произход/Myší/ Fra mus/Maus/απο ποντίκι/de ratón/ Hiirtelt/De souris/Mišijeg porjekla/ Egérből/Murino/Pelės kilmės/No peles/ Van muizen/Fra mus/Mysia/Do rato/De la şoareci/Мышиного происхождения/ Från mus/Myšie/Mišjega izvora/Mišijeg porekla/Fareden

ORIG | BOV

Bovine/С говежди произход/ Hovězí/Bovin/Rind/από βοοειδή/ Bovino/Veistelt/Bovine/Rogate stoke/ Szarvasmarha/Bovino/Jaučio/No liellopa/Bovien/Bovin/Wołowy/Bovino/ Origine bovină/крупного рогатого скота/Från ko/Hovädzie/Govejega izvora/Rogate krupne stoke/Bovin

Reconstitute with/Разтваряне с/ Rozřeďte pomocí/Rekonstitueres med/ Rekonstituieren mit/Ανασύσταση με/ Reconstituir con/Lahjendamine/ Reconstituer avec/Rekonstituirajte s/ Feloldáshoz/Ricostituire con/Atkurti, ištirpdant su/Atšķaidīt ar/Reconstitutie met/Rekonstitueres med/Odtworzyć za pomocą/Reconstituir com/A se reconstitui cu/Растворить в/ Rekonstituera med/Rozrieďte pomocou/ Rekonstituirajte z/s/Ponovno formiranje sa/Yeniden oluşturulur

Manufacturer/Производител/Výrobce/ Producent/Hersteller/Κατασκευαστής/ Fabricante/Tootja/Fabricant/Proizvođač/ Gyártó/Fabbricante/Gamintojas/ Ražotājs/Fabrikant/Produsent/ Producent/Fabricante/Producător/ Производитель/Tillverkare/ 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 you 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 pøesnì dodržujte. Pokyny pro bezpeènou manipulaci najdete v èásti VAROVÁNÍ A UPOZORNÌNÍ. Tabulky údajù o bezpeènosti materiálu (MSDS) najdete na stránkách **www.fdi.com**. Nemáte-li pøístup k Internetu, požádejte o pomoc místního distributora nebo spoleènost 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.

DE

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.

EL

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 κιτ σας, επιλέξτε την αναθεώρηση που αντιστοιχεί στην ημερομηνία έκδοσης που αναγράφεται στην μπροστινή σελίδα των Οδηγιών χρήσης αυτού του κιτ.

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.

ES

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 töltse le, válassza a kithez 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 distribiutorių 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 VOORZORGS-MAATREGELEN. 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. Instrukser for sikker håndtering fins i avsnittet ADVARSLER OG FORHOLDSREGLER. Materialesikkerhetsdatasider (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.

PT

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.

RO

INSTRUCŢIUNI DE UTILIZARE

Vizitaţi site-ul nostru Web **www.fdi.com/ifu** pentru a obţine instrucţiunile de utilizare (IFU) în alte limbi.

Pentru a vă asigura că descărcaţi instrucţiunile de utilizare corecte pentru lotul acestui kit, selectaţi revizia corespunzătoare cu data emiterii, imprimată pe prima pagină a instrucţiunilor de utilizare furnizate cu acest kit.

Urmaţi cu atenţie instrucţiunile de utilizare. Instrucţiunile pentru o manevrare în siguranţă se regăsesc în secţiunea AVERTISMENTE ŞI PRECAUŢII. Fişele de date despre siguranţa materialelor (Material Safety Data Sheets - MSDS) sunt disponibile pe site-ul nostru Web **www.fdi.com**. Dacă nu aveţi acces la Internet, contactaţi pentru asistenţă distribuitorul dvs. local sau Fujirebio Diagnostics AB.

SK

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.

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, 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.

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.

TR

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'ının 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. Internet erişiminiz bulunmuyorsa, destek için lütfen yerel distribütörünüz veya Fujirebio Diagnostics AB ile temasa geçin.

EN

CanAg NSE EIA

Instructions for use

Enzyme immunometric assay kit
For 96 determinations

INTENDED USE

The CanAg NSE EIA kit is intended for the quantitative determination of NSE in human serum.

SUMMARY AND EXPLANATION OF THE ASSAY

The glycolytic enzyme enolase (2-phospho-D-glycerate hydrolase, EC 4.2.1.11) exists as several dimeric isoenzymes ($\alpha\alpha$, $\alpha\beta$, $\alpha\gamma$, $\beta\beta$ and $\gamma\gamma$) composed of three distinct subunits α, β and γ. The γ unit is found either in a homologous $\gamma\gamma$- or in a heterologous $\alpha\gamma$-isoenzyme and is known as neuron-specific enolase (NSE). The monoclonal antibodies used in the CanAg NSE EIA bind to the γ-subunit of the enzyme and thereby detects both the $\gamma\gamma$ and the $\alpha\gamma$ forms (1, 2). The NSE levels are low in healthy subjects and subjects with benign diseases. Elevated levels are commonly found in patients with malignant tumours with neuroendocrine differentiation, especially small cell lung cancer (SCLC) (3) and neuroblastoma (4). Quantitative determination of NSE in serum may be valuable in the management of patients with suspected or diagnosed SCLC or neuroblastoma, to aid in the differential diagnosis and to monitor the effect of treatment (5, 6).

PRINCIPLE OF THE TEST

The CanAg NSE EIA is a solid phase, non-competitive immunoassay based on two monoclonal antibodies (derived from mice) directed against two separate antigenic determinants of the NSE molecule. The monoclonal antibodies (MAb) used bind to the γ-subunit of the enzyme and thereby detects both the $\gamma\gamma$ and the $\alpha\gamma$ form. Calibrators and patient samples are incubated together with biotinylated Anti-NSE MAb E21 and horseradish peroxidase (HRP) labelled Anti-NSE MAb E17 in streptavidin coated micro strips. After washing, buffered Substrate/Chromogen reagent (hydrogen peroxide and 3, 3', 5, 5' tetramethylbenzidine) 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 development is proportional to the amount of NSE 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 NSE concentrations of patient samples are then read from the calibration curve.

REAGENTS

- Each CanAg NSE 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 breakable wells coated with streptavidin. After opening, immediately return unused strips to the aluminium pouch containing desiccant and reseal carefully to keep dry.		
NSE Calibrators	5 vials, lyophilised	4 weeks at 2–8 °C 3 months at –20 °C
CAL NSE A	1 x 0.75 mL	
CAL NSE B	1 x 0.75 mL	
CAL NSE C	1 x 0.75 mL	
CAL NSE D	1 x 0.75 mL	
CAL NSE E	1 x 0.75 mL	

The lyophilised calibrators contain human NSE in a protein matrix with 0.01 % of a non-azide preservative. To be reconstituted with 0.75 mL distilled water before use.

NOTE: The exact NSE concentration is lot specific and is indicated on the label of each vial.

Component	Quantity	Storage and stability after first opening
BIOTIN **Anti-NSE**		
Biotin Anti-NSE	1 x 15 mL	2–8 °C until expiry date stated on the vial

Biotin Anti-NSE monoclonal antibody from mouse, approximately 2 µg/mL. Contains phosphate buffer (pH 7.1), bovine serum albumin, blocking agents, an inert blue dye and 0.01 % methyl-isothiazolone (MIT) as preservative. To be mixed with Tracer, HRP Anti-NSE before use.

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

Stock solution of HRP Anti-NSE monoclonal antibody from mouse, approximately 40 µg/mL. To be mixed with Biotin Anti-NSE prior to use. Contains 0.02 % methyl-isothiazolone (MIT), 0.02 % bromonitrodioxane and 20 ppm Proclin™ 300 as preservatives.

SUBS **TMB**		
TMB HRP-Substrate	1 x 12 mL	2–8 °C until expiry date stated on the vial

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

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
Ready for use. Contains 0.12 M hydrochloric acid.		
WASHBUF | **25X**		
Wash Concentrate	1 x 50 mL	2–8 °C until expiry date stated on the bottle
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

- For Professional Use Only
- Please refer to the U.S. 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

Each donor unit 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.

Protocol Sheet

CanAg NSE EIA REF 420-10

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

Step		Vial/Plate	Procedure
1.	Prepare NSE Calibrators	CAL | NSE A, B, C, D, E	Add 0.75 mL of distilled water to each vial and mix gently. Allow to stand for at least 15 minutes. **NOTE:** The exact concentration of each calibrator is stated on the label. This value of the calibrators should be used for calculations.
2.	Prepare Wash Solution	WASHBUF | 25X	Dilute 50 mL of Wash Concentrate with 1200 mL of distilled water or deionized water.
3.	Prepare Antibody Solution	CONJ | Anti-NSE BIOTIN | Anti-NSE	Mix 50 µL of Tracer, HRP Anti-NSE with 1 mL of Biotin Anti-NSE per strip:

No. of Strips	HRP Anti-NSE (µL)	Biotin Anti-NSE (mL)
1	50	1
2	100	2
3	150	3
4	200	4
5	250	5

		5	250	5
		6	300	6
		7	350	7
		8	400	8
		9	450	9
		10	500	10
		11	550	11
		12	600	12
4.	Wash	MICROPLA	Wash each well once with Wash Solution
5.	Add calibrators and samples	CAL | NSE A, B, C, D, E	25 µL in each well
6.	Add Antibody Solution	ANTIBODY SOLUTION	100 µL in each well
7.	Incubate	MICROPLA	1 hour shaking at room temperature
8.	Wash	MICROPLA	Wash each well six times with Wash Solution
9.	Add TMB HRP-Substrate	SUBS | TMB	100 µL in each well
10.	Incubate	MICROPLA	30 min shaking at room temperature
11.	Read absorbance	MICROPLA	620 nm
Alt.11	Add Stop Solution	STOP	100 µL in each well
Alt.12	Incubate	MICROPLA	1 min shaking at room temperature
Alt.13	Read absorbance	MICROPLA	Read at 405 nm within 5 min

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 NSE EIA is intended for use with serum. Collect blood by venipuncture and separate the serum according to common procedures. Serum should be separated from the clot within 60 minutes of collection to avoid leaking of NSE from blood cells. Do not use haemolysed samples. Plasma is not recommended since significant amounts of NSE can be released from platelets. 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. Bring frozen samples to room temperature and mix THOROUGHLY by gently inverting multiple times before analysis. Samples that contain gross particulates should be centrifuged at 10.000 x g for 10 minutes, prior to use to eliminate any particulate matter that may have developed from the thawing process. Analyze thawed samples within one hour.

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 for dispensing microlitre volumes. An 8-channel pipette or respenser 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 reconstitution of NSE Calibrators and for preparation of diluted wash solution.

Procedural notes

1. A thorough understanding of this package insert is necessary to ensure proper use of the CanAg NSE 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 sera 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 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
NSE Calibrators	4 weeks at 2–8 °C 3 months at -20 °C

Add exactly 0.75 mL of distilled water to each vial and mix gently. Allow standing for at least 15 minutes to reconstitute. **NOTE:** The concentration of the calibrators is stated on the labels and should be used for calculation of the results.

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 deionised 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-NSE with 1 mL of Biotin Anti-NSE per strip (see table below):

No. of Strips	Tracer, HRP Anti-NSE (µL)	Biotin Anti-NSE (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 Antibody Solution.
Alternative: Pour the content of the Tracer, HRP Anti-NSE into the vial of Biotin Anti-NSE and mix gently. Be sure that all content of the Tracer is transferred to the vial of Biotin Anti-NSE.
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 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 NSE Calibrators, 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 NSE Calibrators (CAL A, B, C, D, E) and patient specimens (unknowns-Unk) into the strip wells according to the following scheme:

	1	2	3	4	5	6	7 etc
A	Cal A	Cal E	4th Unk				
B	Cal A	Cal E	etc				
C	Cal B	1st Unk					
D	Cal B	1st Unk					
E	Cal C	2nd Unk					
F	Cal C	2nd Unk					
G	Cal D	3rd Unk					
H	Cal D	3rd Unk					

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 surface of the liquid.
5. Incubate the plate for 1 hour (± 10 min) at room temperature (20-25 °C) with constant shaking of the plate using a microplate shaker.
6. After the incubation aspirate and wash each strip 6 times.

7. Add 100 µL of TMB HRP-Substrate to each well using the same procedure 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.
8. Incubate for 30 min (± 5 min) at room temperature with constant shaking. Avoid exposure to 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 in item 10.

10. Add 100 µL 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 NSE EIA measures concentrations between 1 and approximately 150 µg/L. If NSE 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 NSE concentration (see "Calculation of results").

Quality control

CanChek Tumor Marker Control Sera Levels 1 and 2 (available separately, REF 107-20) are recommended for validation of the assay series. If values outside of the specified range are obtained, a complete check of reagents and reader performance should be made and the analysis repeated.

Reference materials

Since no common reference material is available for NSE antigen, CanAg NSE 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 NSE calibrators.
For automatic calculation of NSE results it is recommended to use either of the following methods:

- Cubic spline curve fit method. Calibrator A should be included in the curve

with the value 0 µg/L.
- Spline smoothed curve fit method. Calibrator A should be used as plate blank.
- Interpolation with point-to-point evaluation. Calibrator A should be included in the curve with the value 0 µg/L.
- Quadratic curve fit method. Calibrator A should be included in the curve with the value 0 µg/L.

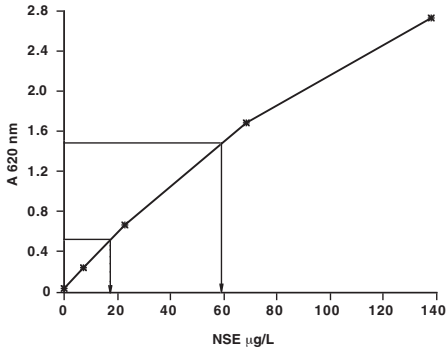
NOTE: 4-Parametric or Linear regression evaluation methods should not be used.

For manual evaluation, a calibration curve is constructed by plotting the absorbance (A) values obtained for each NSE Calibrator against the corresponding NSE concentration (in µg/L), see figure. The unknown NSE 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 NSE levels above the concentration of calibrator E, it is necessary to dilute the sample 1/10 with normal human serum in order to obtain accurate results. The result should then be calculated according to the following procedure:

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

Example of results

Specimen	Calibrator values	Mean abs value (A)	NSE µg/L
CAL NSE A	0 µg/L	0.037	
CAL NSE B	7.5 µg/L	0.238	
CAL NSE C	22.9 µg/L	0.663	
CAL NSE D	68.4 µg/L	1.688	
CAL NSE E	138.0 µg/L	2.720	
Specimen 1		0.518	17.5
Specimen 2		1.474	57.8



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

The exact NSE concentration is indicated on the label of each calibrator vial.

LIMITATIONS OF THE PROCEDURE

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

Elevated NSE values not due to tumours may occur in dialysis patients and patients with leukaemic diseases.

Serum should not contain visible haemolysis (the absorbance at 500 nm for non-turbid sample should not exceed 0.3) since erythrocytes contain significant amounts of NSE (7). Prolonged storage of whole blood can cause release of NSE from the blood cells.

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 (10,11). In a study by Grimsey et al. (10) 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 (12).

EXPECTED VALUES

CanAg NSE EIA was used to measure NSE antigen levels in specimens from 495 apparently healthy blood donors. In this study 97.5 % of the subjects had a NSE concentration at or below 10.5 µg/L and 95 % of the subjects had a NSE concentration at or below 9.9 µg /L. Median serum level was 6.5 µg/L.

It is recommended that each laboratory establish its own reference range with the population of interest and sample collection procedures used within the laboratory.

PERFORMANCE CHARACTERISTICS

Precision

Total precision was determined according to NCCLS guideline EP5-A (8) using four levels of frozen pooled human serum containing added NSE. Each sample was randomly pipetted in duplicates and analysed twice each day over 20 days. The analyses were undertaken during a period of 40 months, by ≥ three different technicians and using 20 different CanAg NSE EIA kit batches.

Sample	Replicates	Mean µg/L	Within-run SD (µg/L)	Within-run CV %	Between-day SD (µg/L)	Between-day CV %
NSE 1	80	10.3	0.24	2.3	0.57	5.5
NSE 2	80	23.7	0.82	3.5	0.97	4.1
NSE 3	80	48.2	1.02	2.1	1.93	4.0
NSE 4	80	92.7	1.60	1.7	3.44	3.7

Detection limit

The detection limit of the CanAg NSE EIA assay is < 1 µg/L defined as the concentration corresponding to the mean of the absorbance values for the NSE Calibrator A plus 2 standard deviations according to the formula:

$$\frac{2 \times SD\ CAL\ A}{OD\ CAL\ B - OD\ CAL\ A} \times [CAL\ B]\ \mu g/L$$

Hook effect

No hook effect has been noticed for NSE concentrations up to 200 000 µg/L.

Linearity

Patient samples were diluted with normal serum and analysed. The obtained values were in the range 93–101 % of the expected values.

Specificity

The monoclonal antibodies used are specific for the γ-subunit of enolase. No measurable cross-reactions with other enolase have been observed.
The NCCLS guideline EP7-P (9) 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 (± 10 %) interference
Lipemia (Intralipid®)	10 mg/mL
Bilirubin, unconjugated	0.6 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 600 ng/mL. The mean NSE concentration was determined for each sample and the percent recovery for each biotin concentration was calculated using the formula: Recovery (%) = 100x (Mean NSE concentration w. biotin added/Mean NSE concentration w. diluent only added).

NSE analyte level	Biotin test conc. (ng/mL)	Expected NSE conc. (µg/L)	Observed NSE conc. (µg/L)	Recovery (%)
Low	15	13,3	13,1	98
High 1	15	75,7	74,3	98
High 2	15	59,5	58,8	99
Low	30	13,3	13,1	98
High 1	30	75,5	73,3	97
High 2	30	59,7	57,1	96
Low	60	13,2	12,5	95
High 1	60	75,7	68,0	90
High 2	60	60,5	58,4	97
Low	600	13,3	1,75	13
High 1	600	74,8	10,3	14
High 2	600	62,8	4,97	8

Based on linear regression analysis, the lowest concentration of biotin found to influence test results (≥10%) was 78 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 distposal:	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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