Download Instructions for Capillary Electrophoresis Dx Consumables Product Documents

Pub. No. MAN0026540 Rev. D.0

Download the instructions for use (IFU)

The IFU for this product is provided in a Thermo Fisher™ Connect Platform resource library.

1. Go to **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, then sign in to thermofisher.com.

   Note: If you do not have a thermofisher.com account, click **Create Account** in the sign in screen, then follow the instructions.

2. In the resource library, locate your product, then download and extract the ZIP folder containing the IFU.

3. Open the instructions for use with a PDF viewer such as Adobe Reader™ (**https://get.adobe.com/reader/**).

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Revision history: Pub. No. MAN0026540 D.0

Revision	Date	Description
D.0	7 March 2023	Translations were added.
C.0	6 January 2023	The manufacturing site was changed.
B.0	29 July 2022	Translations were added.
A.0	21 April 2022	New electronic documentation instructions for accessing instructions for use for capillary electrophoresis consumables.

Digitally signed by Ceaicovschi Tudor
Date: 2023.06.30 14:06:59 EEST
Reason: MoldSign Signature
Location: Moldova

CE IVD

For In Vitro Diagnostic Use.

7 March 2023

ThermoFisher SCIENTIFIC

Инструкции за изтегляне на продуктови документи за консумативи Dx за капилярна електрофореза

№ на публикацията MAN0026540 **Ред.** D.0

Изтеглете инструкциите за употреба

Инструкциите за употреба за този продукт са налични в библиотеката с ресурси на Thermo Fisher™ Connect Platform.

1. Отворете **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, след което влезте в thermofisher.com.

   Забележка: Ако нямате акаунт в thermofisher.com, щракнете върху **Create Account (Създаване на акаунт)** на екрана за вписване, след което следвайте инструкциите.

2. В библиотеката с ресурси открийте своя продукт, след това изтеглете и извлечете компресираната папка (ZIP), съдържаща инструкциите за употреба.

3. Отворете инструкциите за употреба с PDF визуализатор, например с Adobe Reader™ (**https://get.adobe.com/reader/**).

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Преведено от английски от номер на публикация MAN0026540 D.0.

История на редакциите: № на публикацията MAN0026540 D.0

Редакция	Дата	Описание
D.0	7 март 2023 г.	Добавени са преводи.
C.0	6 януари 2023 г.	Променен е производственият обект.
B.0	29 юли 2022 г.	Добавени са преводи.
A.0	21 април 2022 г.	Нови инструкции относно електронните документи за достъп до инструкции за употреба за консумативи за капилярна електрофореза.

CE IVD

За in vitro диагностична употреба.

7 март 2023 г.

ThermoFisher SCIENTIFIC

Pokyny ke stažení produktové dokumentace spotřebního materiálu pro kapilární elektroforézu Dx

Pub. č. MAN0026540 Rev. D.0

Stažení návodu k použití (IFU)

Návod k použití tohoto výrobku je k dispozici v knihovně zdrojů platformy Thermo Fisher™ Connect Platform.

1. Přejděte na stránku **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, poté se přihlaste na webu thermofisher.com.

   Poznámka: Pokud účet na webu thermofisher.com nemáte, klikněte na přihlašovací obrazovce na možnost **Create Account (Vytvořit účet)** a postupujte podle pokynů.

2. V knihovně zdrojů vyhledejte svůj výrobek a poté stáhněte a extrahujte složku ZIP obsahující návod k použití.

3. Otevřete návod k použití v aplikaci na prohlížení souborů PDF, jako je například Adobe Reader™ (**https://get.adobe.com/reader/**).

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Přeloženo z angličtiny dle publikace číslo MAN0026540 D.0.

Historie revizí: Pub. č. MAN0026540 D.0

Revize	Datum	Popis
D.0	7. března 2023	Byly přidány překlady.
C.0	6. ledna 2023	Byla změněna výrobní lokalita.
B.0	29. července 2022	Byly přidány překlady.
A.0	21. dubna 2022	Nové pokyny pro elektronickou dokumentaci pro přístup k návodům k použití spotřebního materiálu pro kapilární elektroforézu.

CE IVD

Pro diagnostické použití in vitro.

Download brugervejledningen med produktdokumentation om Dx-forbrugsvarer til kapillærelektroforese

Publ. nr. MAN0026540 Rev. D.0

Download brugsanvisningen

Brugsanvisningen til dette produkt er i et Thermo Fisher™ Connect Platform-ressourcebibliotek.

1. Gå til **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, og log derefter ind på thermofisher.com.

   Bemærk: Hvis du ikke har en konto på thermofisher.com, skal du klikke på **Create Account (Opret konto)** på loginskærmen og derefter følge instruktionerne.

2. I ressourcebiblioteket skal du finde dit produkt og downloade og udpakke ZIP-mappen med brugsanvisningen.

3. Åbn brugervejledningen med en PDF-fremviser som Adobe Reader™ (**https://get.adobe.com/reader/**).

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Oversat fra engelsk, fra publikationsnummer MAN0026540 D.0.

Revisionshistorik: Publ. nr. MAN0026540 D.0

Revision	Dato	Beskrivelse
D.0	7. marts 2023	Oversættelser er blevet tilføjet.
C.0	6. januar 2023	Produktionsfaciliteterne er blevet ændret.
B.0	29. juli 2022	Oversættelser er blevet tilføjet.
A.0	21. april 2022	Ny elektronisk dokumentationsvejledning, herunder brugervejledningen til forbrugsvarer til kapillærelektroforese.

CE IVD

Til *in vitro*-diagnostisk brug.

7. marts 2023

ThermoFisher SCIENTIFIC

Anweisungen zum Download der Produktdokumentation der Verbrauchsmaterialien für die Kapillarelektrophorese Dx

Pub.-Nr. MAN0026540 Vers. D.0

Gebrauchsanweisung herunterladen

Die Gebrauchsanweisung für dieses Produkt ist in einer Thermo Fisher™ Connect Platform Ressourcenbibliothek zu finden.

1. Gehen Sie zu **apps.thermofisher.com/apps/spa/#/publiclib/cedx** und melden Sie sich dann bei thermofisher.com an.

   Hinweis: Wenn Sie kein thermofisher.com-Konto haben, klicken Sie im Anmeldebildschirm auf **Create Account (Konto anlegen)** und befolgen Sie anschließend die Anweisungen.

2. Navigieren Sie in der Ressourcenbibliothek zu Ihrem Produkt, laden Sie den Zip-Ordner mit der Gebrauchsanweisung herunter und entpacken Sie ihn.

3. Öffnen Sie die Gebrauchsanweisung mit einem PDF Viewer, z. B. Adobe Reader™ (**https://get.adobe.com/reader/**).

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Übersetzung aus dem Englischen, Publikationsnummer MAN0026540 D.0.

Versionsverlauf: Pub.-Nr. MAN0026540 D.0

Version	Datum	Beschreibung
D.0	7. März 2023	Übersetzungen wurden hinzugefügt.
C.0	6. Januar 2023	Der Fertigungsstandort wurde geändert.
B.0	29. Juli 2022	Übersetzungen wurden hinzugefügt.
A.0	21. April 2022	Neue Anweisungen für den Zugriff auf die elektronische Dokumentation zu den Verbrauchsmaterialien für die Kapillarelektrophorese.

CE IVD

Für den Einsatz in der In-vitro-Diagnostik.

Οδηγίες λήψης για τα έγγραφα προϊόντος αναλωσίμων τριχοειδούς ηλεκτροφόρησης Dx

Αρ. δημ. MAN0026540 Αναθ. D.0

Λήψη των οδηγιών χρήσης (IFU)

Οι οδηγίες χρήσης (IFU) για αυτό το προϊόν παρέχονται σε μια βιβλιοθήκη πόρων της Thermo Fisher™ Connect Platform.

1. Μεταβείτε στη διεύθυνση **apps.thermofisher.com/apps/spa/#/publiclib/cedx** και, στη συνέχεια, συνδεθείτε στον ιστότοπο thermofisher.com.

   Σημείωση: Εάν δεν έχετε λογαριασμό στον ιστότοπο thermofisher.com, κάντε κλικ στην επιλογή **Create Account (Δημιουργία λογαριασμού)** στην οθόνη σύνδεσης και, στη συνέχεια, ακολουθήστε τις οδηγίες.

2. Στη βιβλιοθήκη πόρων, εντοπίστε το προϊόν σας και, στη συνέχεια, πραγματοποιήστε λήψη και εξαγωγή του φακέλου ZIP που περιέχει τις οδηγίες χρήσης (IFU).

3. Ανοίξτε τις οδηγίες χρήσης με ένα πρόγραμμα προβολής PDF, όπως το Adobe Reader™ (**https://get.adobe.com/reader/**).

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Μετάφραση από τα Αγγλικά, από τον Αριθμό δημοσίευσης MAN0026540 D.0.

Ιστορικό αναθεώρησης: Αρ. δημ. MAN0026540 D.0

Αναθεώρηση	Ημερομηνία	Περιγραφή
D.0	7 Μαρτίου 2023	Προστέθηκαν μεταφράσεις.
C.0	6 Ιανουαρίου 2023	Άλλαξε το κέντρο κατασκευής.
B.0	29 Ιουλίου 2022	Προστέθηκαν μεταφράσεις.
A.0	21 Απριλίου 2022	Νέες οδηγίες ηλεκτρονικής τεκμηρίωσης για την πρόσβαση στις οδηγίες χρήσης για τα αναλώσιμα τριχοειδούς ηλεκτροφόρησης.

CE IVD

Για in vitro διαγνωστική χρήση.

7 Μαρτίου 2023

ThermoFisher SCIENTIFIC

Instrucciones de descarga para los documentos de producto de los consumibles de electroforesis capilar Dx

N.º de pub. MAN0026540 Rev. D.0

Descargar las instrucciones de uso (IFU)

Las IFU de este producto están disponibles en la librería de recursos de Thermo Fisher™ Connect Platform.

1. Vaya a **apps.thermofisher.com/apps/spa/#/publiclib/cedx** e inicie sesión en thermofisher.com.

   Nota: Si no tiene una cuenta de thermofisher.com, haga clic en **Create Account (Crear cuenta)** en la pantalla de inicio de sesión y siga las instrucciones.

2. En la librería de recursos, localice su producto, luego descárguelo y extraiga la carpeta ZIP que contiene las IFU.

3. Abra las instrucciones con un visor de PDF como Adobe Reader™ (**https://get.adobe.com/reader/**).

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Traducido del inglés, del publicación N.º MAN0026540 D.0.

Historial de revisiones: N.º de pub. MAN0026540 D.0

Revisión	Fecha	Descripción
D.0	7 de marzo de 2023	Se han añadido traducciones.
C.0	6 de enero de 2023	Se ha modificado el centro de fabricación:
B.0	29 de julio de 2022	Se han añadido traducciones.
A.0	21 de abril de 2022	Nuevas instrucciones de documentación electrónica para acceder a las instrucciones de uso de consumibles para electroforesis capilar.

CE IVD

Para utilización en diagnóstico in vitro.

Latausohjeet Capillary Electrophoresis Dx -kulutustarvikkeiden tuoteasiakirjoille

Julk. nro MAN0026540 Ver. D.0

Lataa käyttöohjeet (IFU)

Tämän tuotteen käyttöohjeet ovat Thermo Fisher™ Connect Platform -resurssikirjastossa.

1. Mene osoitteeseen **apps.thermofisher.com/apps/spa/#/publiclib/cedx** ja kirjaudu sitten sisään osoitteeseen thermofisher.com.

   Huomautus: Jos sinulla ei ole thermofisher.com-tiliä, napsauta **Create Account (Luo tili)** -painiketta kirjautumisnäytössä ja noudata sitten ohjeita.

2. Etsi resurssikirjastosta haluamasi tuote ja lataa ja pura sitten käyttöohjeet sisältävä ZIP-kansio.

3. Avaa käyttöohjeet PDF-katseluohjelmalla, kuten Adobe Reader™ (**https://get.adobe.com/reader/**).

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Käännetty englannista, julkaisunumero MAN0026540 D.0.

Versiohistoria: Julk. nro MAN0026540 D.0

Versio	Päivämäärä	Kuvaus
D.0	7. maaliskuuta 2023	Käännöksiä on lisätty.
C.0	6. tammikuuta 2023	Valmistuspaikka on muuttunut.
B.0	29. heinäkuuta 2022	Käännöksiä on lisätty.
A.0	21. huhtikuuta 2022	Uudet sähköiset asiakirjaohjeet kapillaarielektroforeesin kulutustarvikkeiden käyttöohjeiden lukemiseen.

CE IVD

In vitro -diagnostiikkaan.

7. maaliskuuta 2023

ThermoFisher SCIENTIFIC

Instructions de téléchargement pour la documentation produit des consommables Dx d'électrophorèse capillaire

Pub. n° MAN0026540 Rév. D.0

Télécharger la notice d'utilisation (IFU)

La notice d'utilisation de ce produit est fournie dans une bibliothèque de ressources de Thermo Fisher™ Connect Platform.

1. Accédez à **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, puis identifiez-vous sur thermofisher.com.

   Remarque : Si vous n'avez pas de compte thermofisher.com, cliquez sur **Create Account (Créer un compte)** à l'écran de connexion, puis suivez les instructions.

2. Dans la bibliothèque de ressources, localisez votre produit, puis téléchargez et exportez le dossier ZIP contenant la notice d'utilisation.

3. Ouvrez les instructions pour les utiliser avec un lecteur de PDF tel que Adobe Reader™ (**https://get.adobe.com/reader/**).

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Traduit de l'anglais, depuis la publication numéro MAN0026540 D.0.

Historique des révisions : Pub. n° MAN0026540 D.0

Révision	Date	Description
D.0	7 mars 2023	Des traductions ont été ajoutées.
C.0	6 janvier 2023	Le site de fabrication a été modifié.
B.0	29 juillet 2022	Des traductions ont été ajoutées.
A.0	21 avril 2022	Nouvelles instructions relatives à la documentation électronique pour accéder aux modes d'emploi des consommables d'électrophorèse capillaire.

CE IVD

Pour usage diagnostique in vitro.

Kapilláriselektroforézis diagnosztika – fogyóeszközök termékdokumentumainak letöltésére vonatkozó utasítások

Kiadv.szám MAN0026540 D.0 átdolg.

A használati útmutató letöltése (IFU)

A termék használati útmutatója a Thermo Fisher™ Connect Platform forráskönyvtárban található.

1. Lépjen a **apps.thermofisher.com/apps/spa/#/publiclib/cedx** webhelyre, majd jelentkezzen be a thermofisher.com fiókba.

   Megjegyzés: Ha nem rendelkezik thermofisher.com fiókkal, kattintson a bejelentkező képernyőn a **Create Account (Fiók létrehozása)** lehetőségre, és kövesse az utasításokat.

2. A forráskönyvtárban keresse meg a terméket, majd töltse le és csomagolja ki a használati útmutatót tartalmazó ZIP-mappát.

3. Nyissa meg a használati útmutatót egy PDF-olvasóval, például az Adobe Reader™ (**https://get.adobe.com/reader/**) szoftverrel.

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Angolból fordítva, a következő kiadványszámú dokumentumból: MAN0026540 D.0.

Korábbi átdolgozások: Kiadv.szám MAN0026540 D.0

Átdolgozás	Dátum	Leírás
D.0	2023. 7 március	Fordítások hozzáadva.
C.0	2023. 6 január	A gyártás helyszíne megváltozott.
B.0	2022. 29 július	Fordítások hozzáadva.
A.0	2022. 21 április	Új elektronikus dokumentáció használatára vonatkozó utasítások a kapilláriselektroforézis-fogyóeszközök használati útmutatóinak eléréséhez.

CE IVD

In vitro diagnosztikai használatra.

Istruzioni per il download dei documenti del prodotto Parti consumabili Dx per elettroforesi capillare

N. di pub. MAN0026540 Rev. D.0

Scaricare le istruzioni per l'uso (IFU)

Le istruzioni per l'uso di questo prodotto sono fornite in una raccolta di risorse sulla Thermo Fisher™ Connect Platform.

1. Andare sul sito **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, quindi effettuare l'accesso a thermofisher.com.

   Nota: Se non si dispone di un account thermofisher.com, fare clic su **Create Account (Crea account)** nella schermata di accesso, quindi seguire le istruzioni.

2. Nella raccolta di risorse, individuare il prodotto interessato, quindi scaricare il file ZIP contenente le istruzioni per l'uso ed estrarlo.

3. Aprire le istruzioni per l'uso con un visualizzatore di PDF, come Adobe Reader™ (**https://get.adobe.com/reader/**).

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Life Technologies Holdings Pte Ltd | Block 33 | Marsiling Industrial Estate Road 3 | #07-06, Singapore 739256

Tradotto dall'inglese dalla pubblicazione numero MAN0026540 D.0.

Cronologia delle revisioni: N. di pub. MAN0026540 D.0

Revisione	Data	Descrizione
D.0	7 marzo 2023	Sono state aggiunte le traduzioni.
C.0	6 gennaio 2023	È cambiato il centro di produzione.
B.0	29 luglio 2022	Sono state aggiunte le traduzioni.
A.0	21 aprile 2022	Nuove indicazioni relative alla documentazione elettronica per accedere alle istruzioni per l'uso delle parti consumabili per elettroforesi capillare.

CE IVD

Per uso diagnostico in vitro.

7 marzo 2023

ThermoFisher SCIENTIFIC

Last ned instruksjoner for produktdokumenter for forbruksvarer for Capillary Electrophoresis Dx

Pub.nr. MAN0026540 Rev. D.0

Last ned bruksanvisningen (IFU)

Bruksanvisningen for dette produktet finnes i et ressursbibliotek på Thermo Fisher™ Connect Platform.

1. Gå til **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, og logg deretter på thermofisher.com.

   Merk: Hvis du ikke har en konto på thermofisher.com, klikker du på **Create Account (Opprett konto)** i påloggingsskjermbildet og følger instruksjonene.

2. Finn produktet ditt i ressursbiblioteket, last ned ZIP-mappen og pakk ut bruksanvisningen.

3. Åpne bruksanvisningen i et PDF-visningsprogram som Adobe Reader™ (**https://get.adobe.com/reader/**).

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Life Technologies Holdings Pte Ltd | Block 33 | Marsiling Industrial Estate Road 3 | #07-06, Singapore 739256

Oversatt fra engelsk, fra publikasjon nummer MAN0026540 D.0.

Revisjonshistorikk: Pub.nr. MAN0026540 D.0

Revisjon	Dato	Beskrivelse
D.0	7. mars 2023	Oversettelser er lagt til.
C.0	6. januar 2023	Produksjonsstedet er endret.
B.0	29. juli 2022	Oversettelser er lagt til.
A.0	21. april 2022	Nye instruksjoner for elektronisk dokumentasjon for å få tilgang til bruksanvisningen for forbruksvarer for kapillær elektroforese.

CE IVD

For in vitro-diagnostisk bruk.

7. mars 2023

ThermoFisher SCIENTIFIC

Download instructies voor Capillary Electrophoresis Dx verbruiksproducten productdocumenten

Pub.nr. MAN0026540 Rev. D.0

Download de gebruiksaanwijzing (IFU)

De gebruiksaanwijzing van dit product wordt aangeboden in een resource library van het Thermo Fisher™ Connect Platform.

1. Ga naar **apps.thermofisher.com/apps/spa/#/publiclib/cedx** en meld u aan bij thermofisher.com.

   Opmerking: Als u geen thermofisher.com-account hebt, klik dan op **Create Account (Account aanmaken)** op het aanmeldingsscherm en volg de aanwijzingen.

2. Zoek naar uw product in de resource library en download en pak de gecomprimeerde map die de gebruiksaanwijzing bevat, uit.

3. Open de gebruiksaanwijzing met een pdf-lezer zoals Adobe Reader™ (**https://get.adobe.com/reader/**).

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Vertaald uit het Engels, van publicatienummer MAN0026540 D.0.

Revisiegeschiedenis: Pub.nr. MAN0026540 D.0

Revisie	Datum	Beschrijving
D.0	7 maart 2023	Vertalingen zijn toegevoegd.
C.0	6 januari 2023	De productielocatie is veranderd
B.0	29 juli 2022	Vertalingen zijn toegevoegd.
A.0	21 april 2022	Nieuwe instructies voor elektronische documentatie voor toegang tot de gebruiksaanwijzingen van verbruiksproducten voor capillaire elektroforese.

CE IVD

Voor in-vitrodiagnostisch gebruik.

Pobierz instrukcje dotyczące dokumentacji produktu dotyczącej materiałów eksploatacyjnych do elektroforezy kapilarnej Dx

Nr publ. MAN0026540 Wer. D.0

Pobieranie instrukcji użytkowania (IFU)

Instrukcja użytkowania produktu znajduje się w bibliotece zasobów platformy Thermo Fisher™ Connect Platform.

1. Przejść do **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, a następnie zalogować się na konto thermofisher.com.

   Uwaga: W przypadku braku konta thermofisher.com kliknąć opcję **Create Account (Utwórz konto)** na ekranie logowania, a następnie postępować zgodnie z instrukcjami.

2. W bibliotece zasobów zlokalizować swój produkt, a następnie pobrać i wyodrębnić folder ZIP zawierający instrukcję użytkowania.

3. Otworzyć instrukcję obsługi z przeglądarką PDF, taką jak Adobe Reader™ (**https://get.adobe.com/reader/**).

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Tłumaczenie z dokumentu w języku angielskim o numerze publikacji MAN0026540 D.0.

Historia wersji: Nr publ. MAN0026540 D.0

Wersja	Data	Opis
D.0	7 marca 2023 r.	Dodano tłumaczenia.
C.0	6 stycznia 2023 r.	Zmieniono zakład produkcyjny.
B.0	29 lipca 2022 r.	Dodano tłumaczenia.
A.0	21 kwietnia 2022 r.	Nowe instrukcje dotyczące dokumentacji elektronicznej umożliwiającej dostęp do instrukcji użytkowania materiałów eksploatacyjnych do elektroforezy kapilarnej.

CE IVD

Do diagnostyki in vitro.

7 marca 2023 r.

ThermoFisher SCIENTIFIC

Instruções de transferência para documentos de produtos consumíveis Dx para eletroforese capilar

N.º de pub. MAN0026540 Rev. D.0

Transferir as instruções de utilização (IFU)

As IFU deste produto são fornecidas numa biblioteca de recursos da Thermo Fisher™ Connect Platform.

1. Aceda a **apps.thermofisher.com/apps/spa/#/publiclib/cedx** e, em seguida, inicie sessão em thermofisher.com.

   Nota: Caso não tenha uma conta thermofisher.com, clique em **Create Account (Criar conta)** no ecrã de início de sessão e, em seguida, siga as instruções.

2. Na biblioteca de recursos, localize o seu produto e, em seguida, transfira e extraia a pasta ZIP que contém as IFU.

3. Abra as instruções de utilização com um visualizador de PDF, tal como Adobe Reader™ (**https://get.adobe.com/reader/**).

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thermofisher.com/support | thermofisher.com/askaquestion

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Traduzido do inglês a partir do Número de publicação MAN0026540 D.0.

Histórico de revisões: N.º de pub. MAN0026540 D.0

Revisão	Data	Descrição
D.0	7 de março de 2023	Adição de traduções.
C.0	6 de janeiro de 2023	Alteração do local de fabrico.
B.0	29 de julho de 2022	Adição de traduções.
A.0	21 de abril de 2022	Novas instruções da documentação eletrónica para aceder a instruções de utilização de consumíveis para eletroforese capilar.

CE IVD

Para uso em diagnóstico in vitro.

Instrucțiuni privind descărcarea Documentației produsului pentru Consumabilele destinate electroforezei capilare

Nr. pub. MAN0026540 Rev. D.0

Descărcați instrucțiunile de utilizare (IFU)

IFU pentru acest produs sunt furnizate într-o bibliotecă de resurse Thermo Fisher™ Connect Platform.

1. Accesați **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, apoi conectați-vă la thermofisher.com.

   Notă: Dacă nu aveți cont pe thermofisher.com, faceți clic pe **Create Account (Creare cont)** în ecranul de conectare, apoi urmați instrucțiunile.

2. În biblioteca de resurse, localizați produsul, apoi descărcați și extrageți folderul ZIP care conține IFU.

3. Deschideți instrucțiunile de utilizare cu un vizualizator PDF, precum Adobe Reader™ (**https://get.adobe.com/reader/**).

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Life Technologies Holdings Pte Ltd | Block 33 | Marsiling Industrial Estate Road 3 | #07-06, Singapore 739256

Tradus din limba engleză, de la publicația numărul MAN0026540 D.0.

Istoric revizuiri: Nr. pub. MAN0026540 D.0

Revizuire	Dată	Descriere
D.0	7 martie 2023	Au fost adăugate traduceri.
C.0	6 ianuarie 2023	A fost schimbat centrul de producție.
B.0	29 iulie 2022	Au fost adăugate traduceri.
A.0	21 aprilie 2022	Instrucțiuni noi privind documentația electronică pentru accesarea instrucțiunilor de utilizare a consumabilelor destinate electroforezei capilare.

CE IVD

A se utiliza pentru diagnosticarea in vitro.

7 martie 2023

ThermoFisher SCIENTIFIC

Инструкция по загрузке документации по продукции для расходных материалов для диагностики методом капиллярного электрофореза

№ публ. MAN0026540 Ред. D.0

Загрузить инструкцию по применению (IFU)

IFU для данного изделия приведена в библиотеке ресурсов Thermo Fisher™ Connect Platform.

1. Перейдите к **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, затем выполните вход в thermofisher.com.

   Примечание: При отсутствии учетной записи thermofisher.com нажмите **Create Account (Создать учетную запись)** на экране входа в систему и следуйте инструкциям.

2. В библиотеке ресурсов найдите нужное изделие, затем загрузите и распакуйте папку ZIP, содержащую IFU.

3. Откройте инструкцию по применению с помощью средства просмотра PDF, например Adobe Reader™ (**https://get.adobe.com/reader/**).

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Переведено с английского языка на основании публикации № MAN0026540 D.0.

История редакций: № публ. MAN0026540 D.0

Редакция	Дата	Описание
D.0	7 марта 2023 г.	Добавлены переводы.
C.0	6 января 2023 г.	Изменена производственная площадка.
B.0	29 июля 2022 г.	Добавлены переводы.
A.0	21 апреля 2022 г.	Новая инструкция, касающаяся электронной документации, с указаниями относительно доступа к инструкции по применению расходных материалов для капиллярного электрофореза.

CE IVD

Для диагностики in vitro.

7 марта 2023 г.

ThermoFisher SCIENTIFIC

Prevezmite si pokyny pre spotrebné materiály na kapilárnu elektroforézu Dx – Dokumentácia k produktom

Č. pub. MAN0026540 Rev. D.0

Prevziať návod na použitie

Návod na použitie tohto výrobku je k dispozícii v knižnici zdrojov Thermo Fisher™ Connect Platform.

1. Prejdite na **apps.thermofisher.com/apps/spa/#/publiclib/cedx** a prihláste sa na stránku thermofisher.com.

   Poznámka: Ak nemáte účet thermofisher.com, kliknite na možnosť **Create Account (Vytvoriť účet)** na prihlasovacej obrazovke a potom postupujte podľa pokynov.

2. V knižnici zdrojov vyhľadajte svoj výrobok, potom si prevezmite a rozbaľte priečinok ZIP, ktorý obsahuje návod na použitie.

3. Otvorte návod na použitie použitím prehliadača PDF, ako je napríklad Adobe Reader™ (**https://get.adobe.com/reader/**).

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Preložené z angličtiny, z čísla publikácie MAN0026540 D.0.

História revízie: Č. pub. MAN0026540 D.0

Revízia	Dátum	Popis
D.0	7. marca 2023	Boli pridané preklady.
C.0	6. januára 2023	Zmenilo sa miesto výroby.
B.0	29. júla 2022	Boli pridané preklady.
A.0	21. apríla 2022	Nové pokyny k elektronickej dokumentácii na získanie prístupu k návodom na použitie pre spotrebné materiály na kapilárnu elektroforézu.

CE IVD

Na diagnostické použitie In Vitro.

7. marca 2023

ThermoFisher SCIENTIFIC

Hämta anvisningar för förbrukningsartikel Capillary Electrophoresis Dx Produktdokumentation

Utg.nr MAN0026540 Rev. D.0

Ladda ner bruksanvisningen (IFU)

Bruksanvisningen för denna produkt finns i ett Thermo Fisher™ Connect Platform-resursbibliotek.

1. Gå till **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, och logga sedan in på thermofisher.com.

   Obs: Om du inte har ett konto på thermofisher.com klickar du på **Create Account (Skapa konto)** på inloggningsskärmbilden, och följer instruktionerna.

2. Leta upp din produkt i resursbiblioteket, ladda sedan ned och extrahera ZIP-mappen som innehåller bruksanvisningen.

3. Öppna bruksanvisningen med en PDF-läsare såsom Adobe Reader™ (**https://get.adobe.com/reader/**).

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Översatt från engelska, från utgivningsnummer MAN0026540 D.0.

Revisionshistorik: Utg.nr MAN0026540 D.0

Revision	Datum	Beskrivning
D.0	7 mars 2023	Översättningar lades till.
C.0	6 januari 2023	Tillverkningsanläggningen ändrades.
B.0	29 juli 2022	Översättningar lades till.
A.0	21 april 2022	Nya elektroniska anvisningar avseende åtkomstinstruktioner för förbrukningsartiklar för kapillärelektrofores.

CE IVD

För *in vitro*-diagnostik.

7 mars 2023

ThermoFisher SCIENTIFIC

Завантаження документів з інструкціями для витратних матеріалів до діагностичної системи капілярного електрофорезу

Публ. № MAN0026540 Ред. D.0

Завантаження інструкцій із використання

Інструкції з використання цього продукту наведено в бібліотеці ресурсів Thermo Fisher™ Connect Platform.

1. Перейдіть за посиланням **apps.thermofisher.com/apps/spa/#/publiclib/cedx**, потім увійдіть у систему на сайті thermofisher.com.

   Примітка: Якщо у вас немає облікового запису thermofisher.com, на екрані входу натисніть **Create Account (Створити обліковий запис)** і дотримуйтесь інструкцій.

2. Знайдіть свій продукт у бібліотеці ресурсів, потім завантажте й витягніть папку з архіву ZIP, у якій містяться інструкції з використання.

3. Відкрийте інструкції з використання за допомогою програми перегляду файлів PDF, як-от Adobe Reader™ (**https://get.adobe.com/reader/**).

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Перекладено з англійської мови, з публікації під номером MAN0026540 D.0.

Історія редакцій: Публ. № MAN0026540 D.0

Редакція	Дата	Опис
D.0	7 березня 2023 р.	Додано переклад.
C.0	6 січня 2023 р.	Змінено адресу заводу-виробника.
B.0	29 липня 2022 р.	Додано переклад.
A.0	21 квітня 2022 р.	Нова електронна документація з указівками щодо отримання доступу до інструкцій із використання витратних матеріалів до системи капілярного електрофорезу.

CE IVD

Для діагностики in vitro.

7 березня 2023 р.

ThermoFisher SCIENTIFIC

毛细管电泳 Dx 耗材产品文档下载说明

出版编号 MAN0026540 **修订版** D.0

下载使用说明 (IFU)

在 Thermo Fisher™ Connect Platform 资源库中提供了本产品的 IFU。

1. 打开 apps.thermofisher.com/apps/spa/#/publiclib/cedx，然后登录 thermofisher.com。
   注释: 如果您没有 thermofisher.com 帐户，请在登录屏幕单击 **Create Account（创建帐户）**，然后按照说明操作。
2. 在资源库中，找到您的产品，然后下载并提取包含 IFU 的 ZIP 文件夹。
3. 使用 PDF 文件阅读器例如 Adobe Reader™ (https://get.adobe.com/reader/) 打开使用说明。

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译自出版物编号 MAN0026540 D.0 的英文版。

修订历史: 出版物编号 出版编号 MAN0026540 D.0

版本	日期	说明
D.0	2023 年 3 月 7 日	增加了翻译版。
C.0	2023 年 1 月 6 日	变更了制造场地。
B.0	2022 年 7 月 29 日	增加了翻译版。
A.0	2022 年 4 月 21 日	有关访问毛细管电泳耗材使用说明的新电子文档说明。

CE IVD

用于体外诊断。

2023 年 3 月 7 日

ThermoFisher SCIENTIFIC

applied biosystems by life technologies

Certificate of Analysis

Capillary Array 50cm
3500 Dx

REF	4404684
SN	L512JA309
	2013-10-05

TEST	SPECIFICATION	RESULT
Capillary Leak Test Each array is tested to assure absence of leaks.		
Leak Test	No Leaks	PASS
Capillary Plug Test Each array is tested to assure absence of plugged capillaries.		
Plug Test	No Plugged Capillaries	PASS
Fluorescence Background Test Each array is tested to assure background fluorescence is within specification.		
Fluorescence Background Test	Conforms to Specification	PASS
Capillary Mapping Test Each array is tested to verify that capillary inlet and outlet spatial positioning correspond.		
Mapping Test	Conforms to Specification	PASS

When used with the 3500 Dx series systems, this device meets the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and complies with QSR 21CFR820.

ISO13485:2003 REGISTERED

Singapore

IVD

Quality Assurance Manager

Life Technologies Holdings Pte Ltd, Block 33, Marsiling Industrial Estate Road 3, #07-06, Singapore 739256 Tel: (65) 6362 9300
For more information go to www.lifetechnologies.com or email us at cofarequest@lifetech.com.

Doc P/N 4442857 Rev B

LABSYSTEMS DIAGNOSTICS
speaking your language

NeoNat SCID SMA

REAL TIME PCR KIT

The NeoNat SCID SMA is a Real-Time PCR assay for screening Severe Combined Immunodeficiency (SCID) Syndrome and Spinal Muscular Atrophy (SMA) in newborns DNA from Dried Blood Spot (DBS) samples.

- Greater flexibility with separate multiplexing of SCID and SMA from one kit
- Kit contains all the reagents and components to perform DNA extraction from DBS
- Ready to use reaction mix and calibrators preloaded plates enable convenience for users
- Four levels of DBS controls with defined target gene copies per µL
- Compatible with multiple qPCR instruments
- Short turnaround time of ~120 mins from DNA extraction to result analysis

CE IVD RUO Research Use Only

Assay Description

- NeoNat SCID SMA Real time PCR kit is based on 5' nuclease technique
- Screens T-cell receptor excision circle (TREC) / Kappa deleting recombination excision circle (KREC) for SCID and Survival Motor Neuron 1 (SMN1) & Survival Motor Neuron 2 (SMN2) for SMA. The β-globin gene serves as an internal control

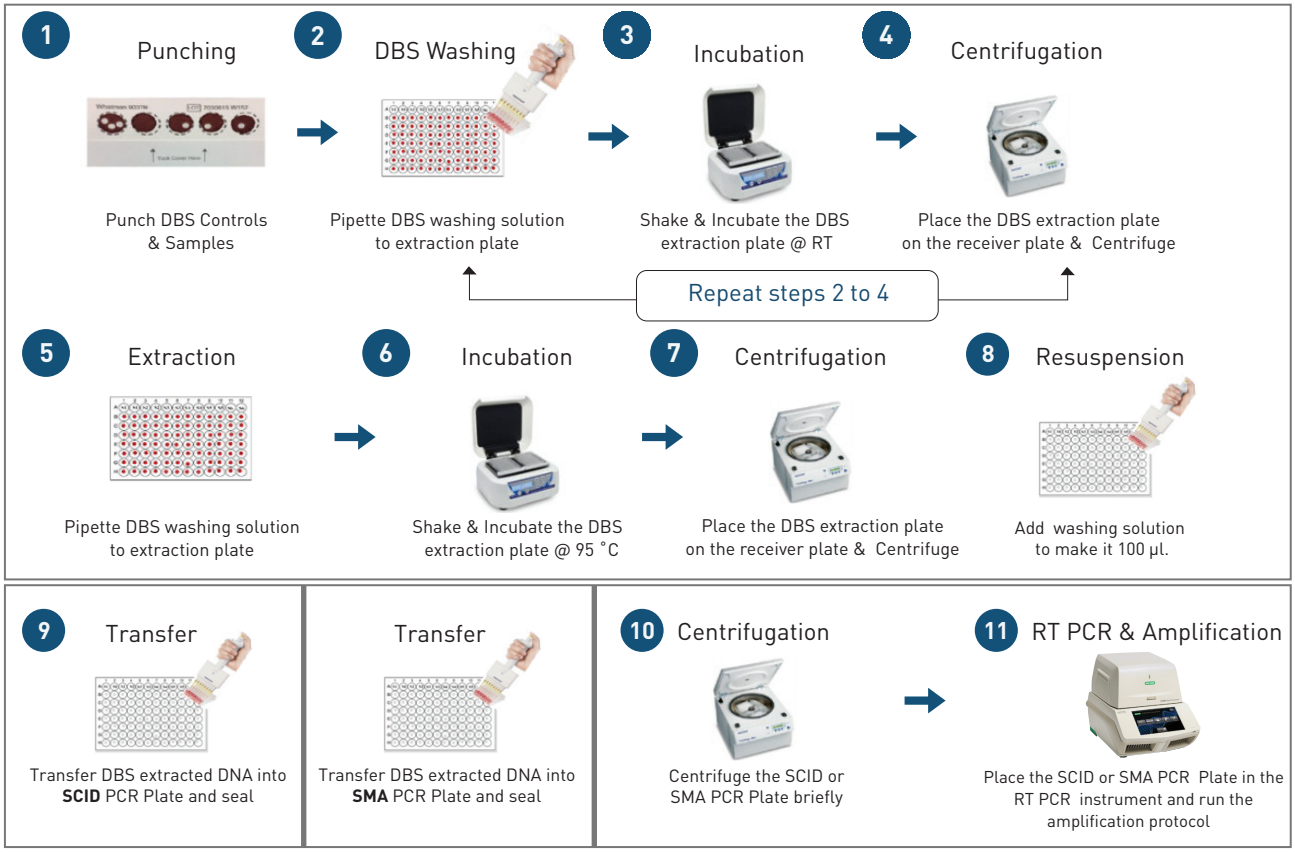
Performance

- The assay demonstrates excellent performance with 100% sensitivity and specificity for all the samples tested
- The analytical sensitivity shows a limit of detection of <5.0 copies/µL for TREC & KREC and <2.5 copies/µL for SMN1 & SMN2

Compatibility

- Kit compatible with most real-time PCR instruments in the market with at least three measurement channels (FAM, VIC/or HEX, & CY5)
- Developed and validated with Biorad CFX 96 and Thermofisher Quantstudio 5 & 6.

DNA EXTRACTION FROM DBS & PCR REACTION



Ordering Information

96 Reactions	8100481
192 Reactions*	8100482
480 Reactions*	8100483

*Please check the availability

For more information please order your IFU from
Labsystems Diagnostics Oy
Tiilitie 3, FI-01720 VANTAA, Finland Tel: +358 (0) 20 155 7530
sales@labsystemsdx.com | www.labsystemsdx.com

applied biosystems
by Thermo Fisher Scientific

Certificate of Analysis

Real-Time PCR Systems Spectral Calibration Kit I, 96-Well

Product No. **4349180**
Lot No. **2305202**

TEST	SPECIFICATION	RESULT

Material Test

Applied Biosystems performs spectrofluorimetric analysis using a calibrated PerkinElmer LS55 Fluorescence Spectrometer to test fluorescence emission wavelength maximum in each lot of component bulk material used in the Spectral Calibration Kit. The PerkinElmer LS55 is calibrated using a mercury arc lamp which verifies the emission monochrometer wavelength accuracy and then the excitation wavelength accuracy is verified against the emission wavelength as a reference.

Component	Part Number	Lot Number			
SYBR® GREEN Dye	4349763	2305278	522 ± 5 nm	**520 nm**	**Pass**
ROX™ Dye	4349411	2305328	601 ± 5 nm	**603 nm**	**Pass**
TAMRA™ Dye	4349410	2305326	578 ± 4 nm	**578 nm**	**Pass**
NED™ Dye	4349408	2305336	573 ± 4nm	**572 nm**	**Pass**
JOE™ Dye	4349409	2305329	548 ± 4 nm	**550 nm**	**Pass**
VIC® Dye	4349764	2305313	548 ± 4 nm	**548 nm**	**Pass**
FAM™ Dye	4349762	2305307	518 ± 4 nm	**519 nm**	**Pass**
ROI™ Dye	4349415	2305397	Visual Inspection	**Pass**	
Background	4330124	2305417	Visual Inspection	**Pass**	

For Research Use Only. Not for use in diagnostic procedures.

ISO13485 REGISTERED FACILITY

Singapore

Tan Chuen Fang 13 JUN 2023

Quality Assurance
(Name, Signature & Date)

Life Technologies Holdings Pte Ltd, Block 33, Marsiling Industrial Estate Road 3, #07-06, Singapore 739256 Tel: (65) 6362 9300
To obtain a Certificate of Analysis on-line go to www.thermofisher.com or email us at QA-SG_COA_Request@lifetech.com

Doc p/n: 100030347 Rev C

7500 Real-Time PCR Systems Spectral Calibration Kit I

Catalog Number 4349180

Pub. No. 4350071 **Rev.** D

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Contents and storage

Contents	Amount	Storage
Background Plate sealed with an optical cover	1	–25°C to –15°C
Spectral Calibration Plates sealed with optical covers	7	
Region of Interest (ROI) Calibration Plate sealed with an optical cover	1	

Related Documentation

For detailed information on instrument setup and the calibration process, refer to the *Applied Biosystems™ 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide* (Pub. no. 4347828).

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale found on Life Technologies' website at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.

For support visit **thermofisher.com/support** or email **techsupport@lifetech.com**

1 December 2015

ThermoFisher SCIENTIFIC

Thermo Fisher Scientific Baltics UAB
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Company code 122351387, VAT code LT223513811

ThermoFisher SCIENTIFIC
The world leader in serving science

CERTIFICATE OF ANALYSIS

A46109 **PowerTrack™ SYBR™ Green Master Mix**

Packaging Lot: **2746887**
Expiry Date: 30.04.2025 (DD.MM.YYYY)
Storage: at -20±5°C in the dark
Note: **For Research Use Only. Not for use in diagnostic procedures.**

Filling lots for components in package:

Lot	Quantity	Description
2728794	5 mL	PowerTrack™ SYBR™ Green Master Mix
2737196	1.25 mL	40X Yellow Sample Buffer

QUALITY CONTROL

Parameter	Method	Requirement	Result
Functional Test	The product is functionally tested by qPCR analysis. It must demonstrate functional performance using a target concentration of plasmid DNA.	Average Ct for the target concentration is between 20 and 23	Pass
dNTP Concentrations	Determined by analytical method.	Within range of target concentration	Pass
Mg^{2+} Concentration	Determined by analytical method.	Within range of target concentration	Pass
K^{+} Concentration	Determined by analytical method.	Within range of target concentration	Pass
RNase Activity	Determined by analytical method.	No detectable activity level	Pass
DNase Activity	Determined by analytical method.	No detectable activity level	Pass
E. coli DNA Level	Determined by analytical method.	No detectable level	Pass

ISO CERTIFICATION
Manufactured by Thermo Fisher Scientific Baltics UAB, in compliance with ISO 9001 and ISO 13485 certified quality management system.

Quality authorized by QC: J. Žilinskienė

applied biosystems

PowerTrack™ SYBR™ Green Master Mix

USER GUIDE

Master mix with a two-dye tracking system for real-time PCR workflows

Catalog Numbers A46012, A46109, A46110, A46111, A46112, A46113

Publication Number MAN0018825

Revision B.0

ThermoFisher SCIENTIFIC

Thermo Fisher Scientific Baltics UAB | V.A. Graiciuno 8, LT-02241 | Vilnius, Lithuania
For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

The information in this guide is subject to change without notice.

Revision history: Pub. No. MAN0018825

Revision	Date	Description
B.0	29 July 2022	The volumes for preparing the PCR reactions were corrected (Table 2 on page 12 and Table 3 on page 13).
A.0	30 January 2020	New document.

Contents

1 Product information

IMPORTANT! Before using this product, read and understand the information in the "Safety" appendix in this document.

Product description

The Applied Biosystems™ PowerTrack™ SYBR™ Green Master Mix is a two-dye tracking system for real-time PCR.

It contains a visual dye-based indicator that allows the user to confirm that the sample was added to the master mix.

The master mix contains an inert blue dye. The optional Yellow Sample Buffer is added to the sample to track the sample through the PCR. The reaction mix turns green due to the inert blue dye and the Yellow Sample Buffer.

The SYBR™ Green dye binds to double-stranded DNA formed during real-time PCR. For more information, see "Overview of the chemistry" on page 22.

The master mix provides flexibility for varying primer melting temperatures (Tm). The Tm can be between 55°C and 65°C. For recommended primer concentrations for different Tm, see "Guidelines" on page 10.

The master mix contains the following components:

- SYBR™ Green dye
- DNA polymerase, with an antibody-mediated hot start
- Heat-labile Uracil-DNA Glycosylase (UDG)
- ROX™ dye (passive reference dye)
- dNTP blend containing dUTP/dTTP
- Inert blue dye
- Optimized buffer components

For more information about each component, see "Master mix components" on page 21.

The user provides primers, template, and water.

Contents and storage

Table 1 PowerTrack™ SYBR™ Green Master Mix

Cat. No.[1]	Amount	Storage
A46012	• 1 mL of master mix • 1.25 mL of Yellow Sample Buffer	Store master mix and Yellow Sample Buffer at –25°C to –15°C. Yellow Sample Buffer can be stored at 2–8°C for up to 1 year.
A46109	• 5 mL of master mix • 1.25 mL of Yellow Sample Buffer	
A46110 [2]	• 2 x 5 mL of master mix • 2 x 1.25 mL of Yellow Sample Buffer	
A46111 [2]	• 5 x 5 mL of master mix • 5 x 1.25 mL of Yellow Sample Buffer	
A46112 [2]	• 10 x 5 mL of master mix • 10 x 1.25 mL of Yellow Sample Buffer	
A46113	• 50 mL of master mix • 4 x 1.25 mL of Yellow Sample Buffer	

[1] Catalog numbers that appear as links open the web pages for those products.
[2] Products with multiples of the 5-mL size are shipped as multiple kits with the single 5-mL size.

Required materials

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Catalog numbers that appear as links open the web pages for those products.

IMPORTANT! Do not use plastics made of polyethylene terephthalate co-polyester, glycol modified (PTEG) for storage of the master mix or the reaction mixes. SYBR™ Green dye is not compatible with this type of plastic material. Polypropylene, high density polyethylene (HDPE), and polystyrene are recommended for storage.

Item	Source
One of the following Applied Biosystems™ instruments:	
• QuantStudio™ 6 Pro Real-Time PCR System or QuantStudio™ 7 Pro Real-Time PCR System • QuantStudio™ 3 or 5 Real-Time PCR System • QuantStudio™ 6 / QuantStudio™ 7 Flex Real-Time PCR System • QuantStudio™ 12K Flex Real–Time PCR System • ViiA™ 7 Real-Time PCR System • StepOnePlus™ Real-Time PCR System • StepOne™ Real-Time PCR System • 7500 Fast Real-Time PCR System • 7500 Real-Time PCR Instrument Or use a compatible real-time PCR instrument from another supplier.	Contact your local sales office.
Equipment	
Centrifuge with adapter for 96- or 384-well plates	MLS
Laboratory mixer (Vortex or equivalent)	MLS
Microcentrifuge	MLS
Pipettors	MLS
Plastics and other consumables	
Plates and seals for your instrument	**thermofisher.com/plastics**
Disposable gloves	MLS
Pipette tips with filters	MLS
Polypropylene tubes	MLS

Item	Source
Reagents and kits	
One of the following reverse transcription kits, if performing gene expression analysis:	
SuperScript™ IV VILO™ Master Mix	11756050
SuperScript™ IV VILO™ Master Mix with ezDNase™ Enzyme	11766050
High-Capacity cDNA Reverse Transcription Kit	4368814
High-Capacity cDNA Reverse Transcription Kit with RNase Inhibitor	4374967
High-Capacity RNA-to-cDNA™ Kit	4387406
Other reagents	
Nuclease-Free Water (not DEPC-Treated)	AM9930
TE, pH 8.0, RNase-free	AM9858

Workflow

PowerTrack™ SYBR™ Green Master Mix

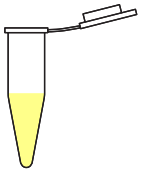
Start with cDNA or gDNA

See "Requirements for input DNA" on page 10.

Set up the plate document or plate file

(Optional) Add the Yellow Sample Buffer to the DNA

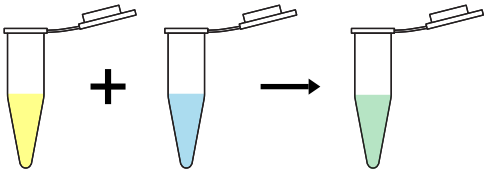
See "Prepare the PCR reactions" on page 11.



Combine the components for PCR.

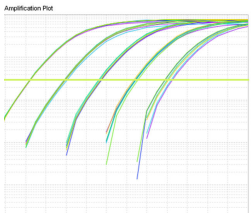
See "Prepare the PCR reactions" on page 11.

The reaction will turn green due to the Yellow Sample Buffer that was added to the DNA and the inert blue dye in the master mix.



Set up and run the real-time PCR instrument

Analyze the results



2 Methods

Guidelines

Requirements for input DNA

Use 1–10 ng of cDNA or 10–100 ng of gDNA per reaction.

For more information, see “RNA guidelines” on page 26 and “Template storage” on page 27.

Guidelines for PCR reactions

- Four replicates of each reaction are recommended.
- Reaction mixes can be prepared depending upon experimental requirements. Scale the components according to the number of reactions and include 10% overage.
- If using smaller reaction volumes, scale all components proportionally. Reaction volumes <10 µL are not recommended.
- The recommended final primer concentration for primers with a Tm of 55°C is 400 nM.

Guidelines for no-template control reactions

No-template control (NTC) reactions can be used to identify PCR contamination. NTC reactions contain all of the reaction components except for the sample.

Before you begin

Set up the plate document or plate file

Configure the plate document or plate file.

See the appropriate instrument user guide for detailed instructions.

Prepare the reagents

- Thaw the master mix.
- Once the master mix is thawed, swirl it to mix thoroughly.
- Thaw the DNA samples and primers on ice, vortex to mix, then centrifuge briefly.
- Vortex the Yellow Sample Buffer prior to use.

Prepare the PCR reactions

Note: The Yellow Sample Buffer is optional for the real-time PCR.

The Yellow Sample Buffer is supplied at a 40X concentration. It is added to the DNA template. The concentration of Yellow Sample Buffer in the final PCR must be 1X. It is recommended that the DNA template is 10–20% of the volume of the final PCR.

1. *(Optional)* Add the Yellow Sample Buffer (40X) to the amount of DNA that is used in the PCR.

Final reaction volume	Amount of Yellow Sample Buffer
20 µL	0.5 µL
10 µL	0.25 µL

   The Yellow Sample Buffer is diluted to 1X in the final reaction. See the following tables.

2. *(Optional)* Vortex, then centrifuge the DNA and Yellow Sample Buffer.
3. Combine the master mix, the primers, and nuclease-free water according to the following tables.

4. Combine the master mix, the primers, and nuclease-free water with the DNA and Yellow Sample Buffer according to the following tables.

Note: If the Yellow Sample Buffer is not used, add nuclease-free water to achieve the total PCR volume.

Table 2 20–µL reaction

Component	Stock concentration	Final concentration	Volume for 1 reaction (20–µL reaction)	Volume for 4 reactions with 10% overage (20–µL reaction)[1]
Yellow Sample Buffer and DNA (step 1)				
DNA[2]	5 ng/µL	0.5 ng/µL	2 µL[3]	8.8 µL
Yellow Sample Buffer	40X	1X	0.5 µL	2.2 µL
Master mix, primers, and nuclease-free water (step 3)				
PowerTrack™ SYBR™ Green Master Mix	2X	1X	10 µL	44.0 µL
Forward and reverse primers[4]	8,000 nM	400 nM	1 µL	4.4 µL
Nuclease-free water	—	—	6.5 µL	28.6 µL
Total PCR volume	**—**	**—**	**20 µL**	**88 µL**

[1] 10% overage is recommended for pipetting variations.
[2] Use 1–10ng of cDNA.
[3] Does not exceed 8.5 µL.
[4] The final primer concentration can vary from 300–800 nM. A final concentration of 400 nM is recommended for primers with a Tm of 55°C.

Table 3 10–µL reaction

Component	Stock concentration	Final concentration	Volume for 1 reaction (10–µL reaction)	Volume for 4 reactions with 10% overage (10–µL reaction)[1]
Yellow Sample Buffer and DNA (step 1)				
DNA[2]	5 ng/µL	0.5 ng/µL	1 µL[3]	4.4 µL
Yellow Sample Buffer	40X	1X	0.25 µL	1.1 µL
Master mix, primers, and nuclease-free water (step 3)				
PowerTrack™ SYBR™ Green Master Mix	2X	1X	5 µL	22.0 µL
Forward and reverse primers[4]	8,000 nM	400 nM	0.5 µL	2.2 µL
Nuclease-free water	—	—	3.25 µL	14.3 µL
Total PCR volume	**—**	**—**	**10 µL**	**44 µL**

[1] 10% overage is recommended for pipetting variations.
[2] Use 1–10ng of cDNA.
[3] Does not exceed 4.25 µL.
[4] The final primer concentration can vary from 300–800 nM. A final concentration of 400 nM is recommended for primers with a Tm of 55°C.

IMPORTANT! The reaction turns green due to the Yellow Sample Buffer added to the DNA and the inert blue dye in the master mix.

5. Mix the components thoroughly, then centrifuge briefly to collect the contents at the bottom of the tube.
6. Transfer the appropriate volume of each reaction to each well of an optical plate.
7. Seal the plate with an optical adhesive cover, then centrifuge briefly to collect the contents at the bottom of each well and eliminate any air bubbles.

PCR can be performed on the reaction plate up to 8 hours after completing the set-up, when stored at room temperature protected from light.

Set up and run the real-time PCR instrument

1. Set up the thermal protocol according to one of the following tables.

Note: Standard cycling conditions are recommended for genomic DNA templates or long amplicons.

Table 4 Fast cycling mode

Step	Temperature	Duration	Cycles
Enzyme activation	95°C	2 minutes	1
Denature	95°C	5 seconds	40
Anneal/extend	60°C	30 seconds	

Table 5 Standard cycling mode

Step	Temperature	Duration	Cycles
Enzyme activation	95°C	2 minutes	1
Denature	95°C	15 seconds	40
Anneal/extend	60°C	60 seconds	

2. Set the instrument to perform a default dissociation step, according to one of the following tables.

Table 6 Fast cycling mode

Step	Ramp rate[1]	Temperature	Time
1	1.99°C/second	95°C	15 seconds
2	1.77°C/second	60°C	1 minute
3 (Dissociation)	0.075°C/second	95°C	15 seconds

[1] Use the default ramp rate for the StepOnePlus™ Instrument.

Table 7 Standard cycling mode

Step	Ramp rate[1]	Temperature	Time
1	1.6°C/second	95°C	15 seconds
2	1.6°C/second	60°C	1 minute
3 (Dissociation)	0.075°C/second	95°C	15 seconds

[1] Use the default ramp rate for the StepOnePlus™ Instrument.

Note: A dissociation step must be performed immediately after the real-time PCR run with PowerTrack™ SYBR™ Green Master Mix.

3. Set up the options.
   - Experiment type: Standard curve
   - Reagent: SYBR™ Green reagents
   - Reporter: SYBR™ Green
   - Quencher: None
   - Passive reference dye: ROX™ dye
   - Ramp speed: Standard or fast
   - Melt curve ramp increment (all instruments, except StepOnePlus™ instrument): Continuous
     (StepOnePlus™ only): Step and hold
4. Set the reaction volume appropriate for the reaction plate.
5. Load the reaction plate into the real-time PCR instrument.
6. Start the run.

Analyze the results

1. View the amplification plots.

   For more information, see “A typical amplification plot” on page 24.
2. Determine the baseline and threshold cycles (C_q) for the amplification curves using the instrument software.

   For more information, see the following sections:
   - “Baseline and threshold values” on page 24
   - “Troubleshooting baseline settings” on page 18
   - “Troubleshooting threshold settings” on page 19
3. Check for nonspecific amplification using melt curves.

   It is important to check for nonspecific amplification because SYBR™ Green dye detects any double-stranded DNA.

   For more information, see “Melt curves” on page 25.
4. Perform relative or absolute quantitation.

Option	Description
Relative quantitation	The target is compared to an internal standard, using either the standard curve or comparative C_q method.
Absolute quantitation	The C_q of the unknown samples is compared against a standard curve with known copy numbers.

A

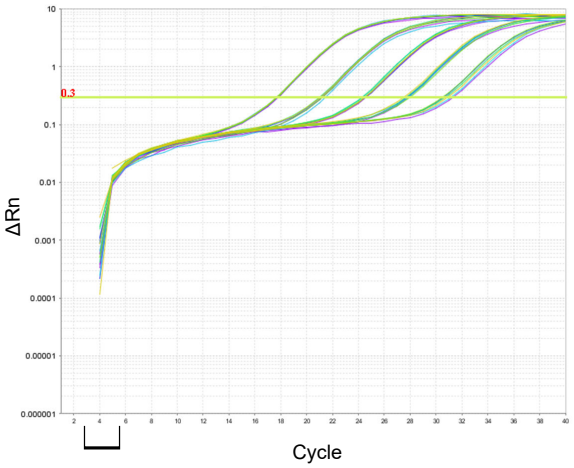
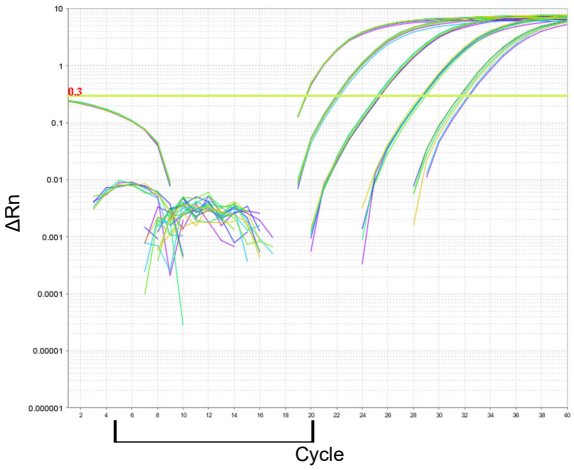
Troubleshooting

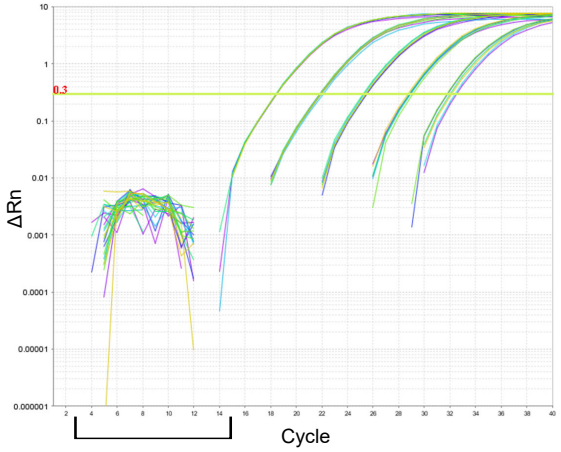
General troubleshooting

Observation	Possible cause	Recommended action
The C_q values are high, there is poor precision, or the PCR reactions failed	There is insufficient DNA template.	Use up to 100 ng of DNA template per reaction. Typically, 1–10 ng cDNA or 10–100 ng genomic DNA per reaction is sufficient.
	The quality of the DNA template is poor.	Quantify the amount of DNA template and ensure the recommended amount is used (see "Template quantitation using O.D. 260" on page 27).
		Test the DNA template for the presence of PCR inhibitors. Repeat the PCR reaction with a DNA template free of PCR inhibitors, if necessary.
	The sample has degraded.	Prepare fresh cDNA or gDNA, then repeat the experiment.
	Incorrect volumes of components were pipetted for the PCR reactions.	Prepare the PCR reactions as described in "Prepare the PCR reactions" on page 11.
	Too few PCR cycles were used.	Increase the number of PCR cycles to the default setting of 40 (see "Set up and run the real-time PCR instrument" on page 14) .
	There was primer-dimer formation and residual polymerase activity.	• Optimize the thermal cycling temperatures. • Reduce the primer concentration. • Redesign the primers.
Low ΔR_n or R_n values are obtained	The extension time was too short.	Use the recommended standard cycling thermal profile settings (see "Set up and run the real-time PCR instrument" on page 14).

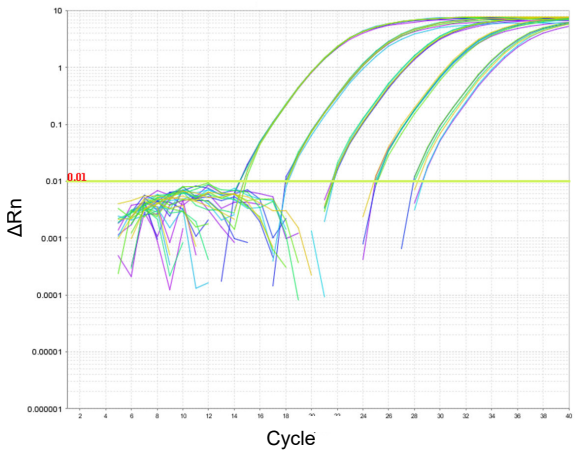
Observation	Possible cause	Recommended action
Low ΔR_n or R_n values are obtained *(continued)*	There was primer-dimer formation and residual polymerase activity.	Optimize the thermal cycling temperatures.
		Reduce the primer concentration.
		Redesign the primers.
The R_n vs. cycle plot is not displayed	ROX™ dye was not selected as the passive reference when the plate document was set up.	Select ROX™ dye as the passive reference when setting up the plate document.
		Select ROX™ dye as the passive reference, then reanalyze the data. The run does not need to be repeated.
The ΔR_n or R_n values are extremely high	ROX™ dye was not selected as the passive reference when the plate document was set up.	Select ROX™ dye as the passive reference when setting up the plate document.
		Select ROX™ dye as the passive reference, then reanalyze the data. The run does not need to be repeated.
	There was evaporation from the reaction plate.	Ensure that the reaction plate is sealed completely, especially around the edges.
The R_n values obtained in early cycles are low	The C_q value is less than 15.	Adjust the upper baseline range to a value less than 15.
There is high variability across the reaction plate	ROX™ dye was not selected as the passive reference when the plate document was set up.	Select ROX™ dye as the passive reference when setting up the plate document.
	There was evaporation from the reaction plate.	Ensure that the reaction plate is sealed completely, especially around the edges.
There is high variability between replicates	The reaction plate was not mixed well.	Mix the reaction mix gently by inversion, then centrifuge briefly before aliquoting to the reaction plate.
The **BADROX** flag is displayed	The were droplets on the sides of the wells of the reaction plate.	Set up and repeat the run. Centrifuge the plate to collect the contents at the bottom of the well.
	There was evaporation of the reagents.	Set up and repeat the run. Ensure that the plate is sealed properly.
	The incorrect concentration of passive reference dye was used.	Ensure that the correct concentration of the master mix is added to the reaction. See “Prepare the PCR reactions” on page 11.
The amplification plot is sup-optimal for primers with a Tm of 55°C	The run protocol is not optimal.	Change the annealing temperature to 55°C.
		Design the primers with a Tm of 60°C.

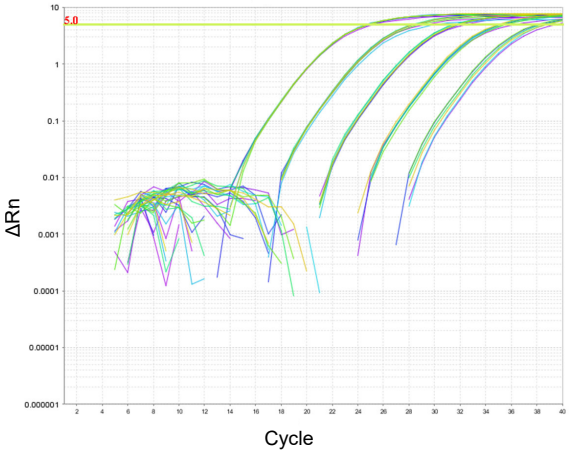
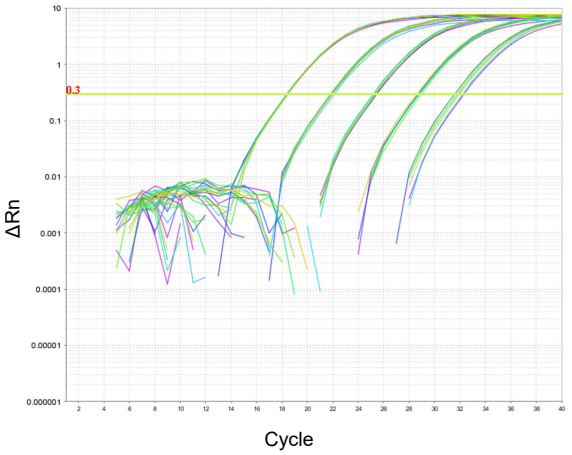
Troubleshooting baseline settings

Observation	Possible cause	Recommended action
The baseline is set too low  **Figure 1**	The baseline is set too low (cycles 3–5).	Manually adjust the baseline to a higher range of cycles (see Figure 3 on page 19).
The baseline is set too high  **Figure 2**	The baseline is set too high (cycles 5–20).	Manually adjust the baseline to a lower range of cycles (see Figure 3 on page 19).

Observation	Possible cause	Recommended action
The baseline is set correctly  **Figure 3**	The baseline is set correctly (cycles 3–15).	No action is required.

Troubleshooting threshold settings

Observation	Possible cause	Recommended action
The threshold is set too low  **Figure 4**	The threshold is set too low.	Manually adjust the threshold to a higher ΔR_n (see Figure 6 on page 20).

Observation	Possible cause	Recommended action
The threshold is set too high  **Figure 5**	The threshold is set too high.	Manually adjust the threshold to a lower ΔR_n (see Figure 6 on page 20).
The threshold is set correctly  **Figure 6**	The threshold is set correctly.	No action is required.

B

Background information

Master mix components

Table 8 Function of the components of the master mix

Component	Function
Antibody-mediated hot start polymerase	• Provides tight control over *Taq* activation, preventing undesirable early activity of the polymerase at low temperatures that can lead to nonspecific amplification. • Allows flexibility in reaction set-up, including pre-mixing of PCR reagents and storage at room temperature for up to 8 hours prior to cycling. • Allows activation of polymerase after only 2 minutes at 95°C.
Heat-labile uracil-DNA glycosylase (UDG)	• A 26 kDa recombinant enzyme derived from the thermolabile UDG gene isolated from marine bacteria, and expressed in *E. coli*. • Prevents reamplification of carryover PCR products by removing any uracil incorporated into single- or double-stranded amplicons. • Acts on single- and double-stranded dU-containing DNA by hydrolyzing uracil-glycosidic bonds at dU-containing DNA site, creating an alkali-sensitive apyrimidic site in the DNA. • Prevents reamplification of carryover PCR products in an assay if all previous PCR for the assay was performed using a dUTP-containing master mix. • Allows stability of PCR products for 72 hours post-amplification. • Has no activity on RNA or dT-containing DNA.
dUTP/dTTP	• Enables UDG activity and maintains optimal PCR results.
SYBR™ Green dye	• Detects PCR products by fluorescing upon binding to double-stranded DNA formed during PCR (see “Overview of the chemistry” on page 22).
ROX™ passive reference	• Provides an internal reference to which the reporter-dye signal can be normalized during data analysis. • Normalization is necessary to correct for fluorescence fluctuations due to changes in volume.

Overview of the chemistry

The SYBR™ Green dye is used to detect PCR products by binding to double-stranded DNA formed during PCR.

1. When the master mix is added to a sample, the SYBR™ Green dye immediately binds to all double-stranded DNA (dsDNA) present in the sample.
   The SYBR™ Green dye is only fluorescent when bound to dsDNA.
2. During PCR, DNA polymerase amplifies the target sequence which creates the PCR products.
3. The SYBR™ Green dye then binds to each new copy of double-stranded DNA, generating a fluorescent signal.
4. As the PCR progresses, more PCR product is created.
   The SYBR™ Green dye binds to all double-stranded DNA, so the result is an increase in fluorescence intensity proportional to the amount of PCR product produced.

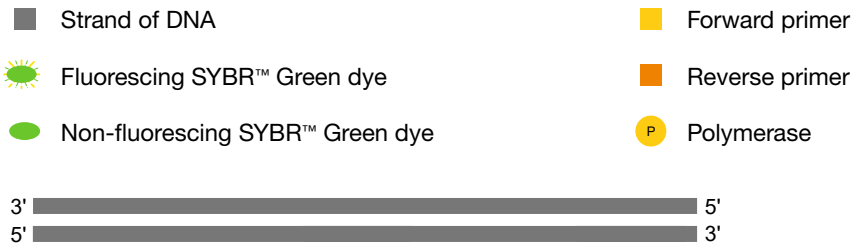


Figure 7 DNA template

Figure 8 SYBR™ Green dye binds to all double-stranded DNA

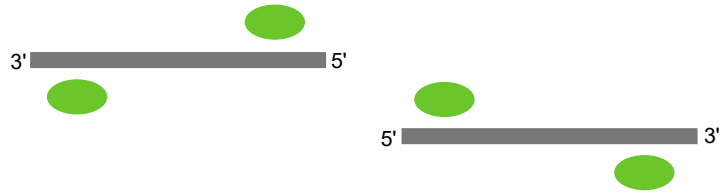


Figure 9 Denaturation

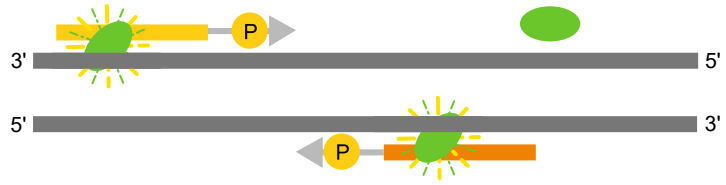


Figure 10 Polymerization

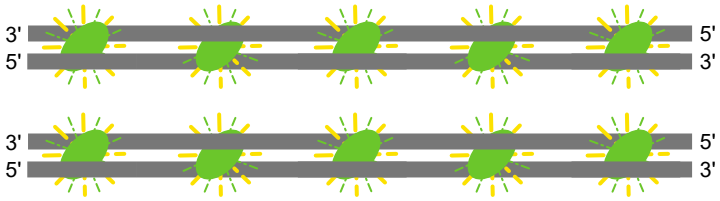


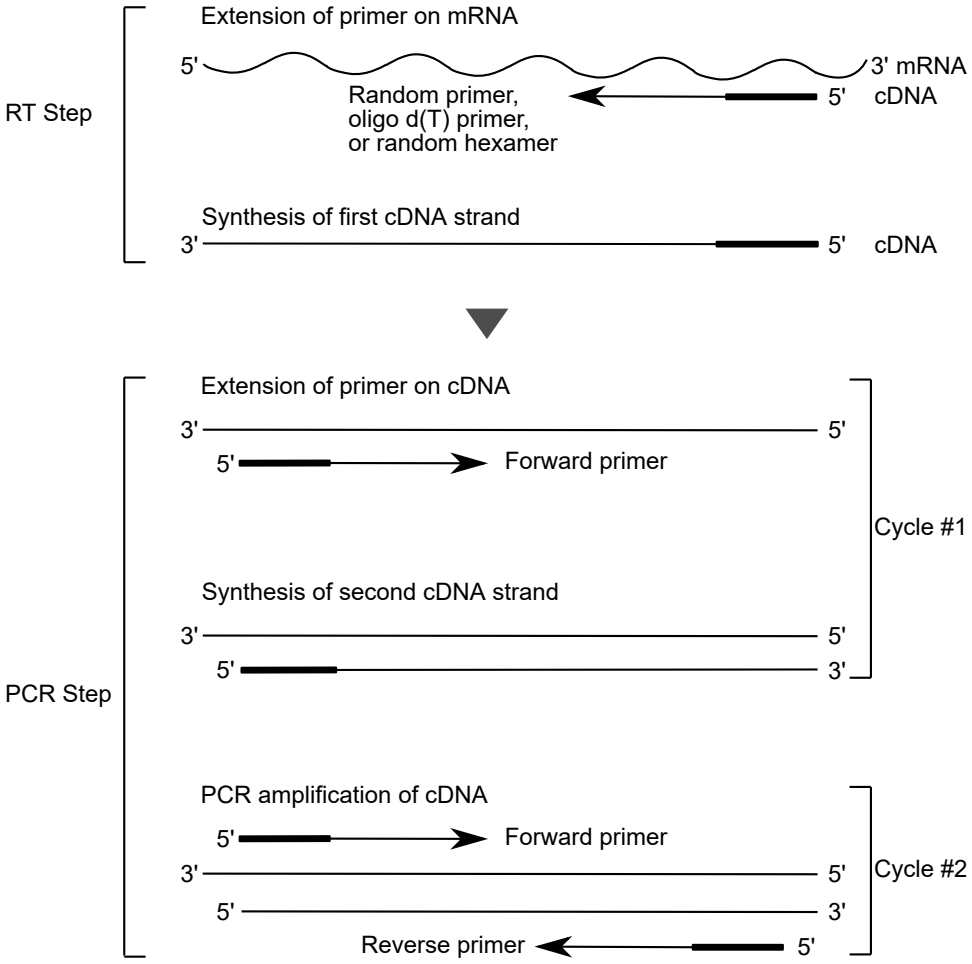
Figure 11 Completion

Two-step RT-PCR

For more information, go to **thermofisher.com/qpcreducation**.

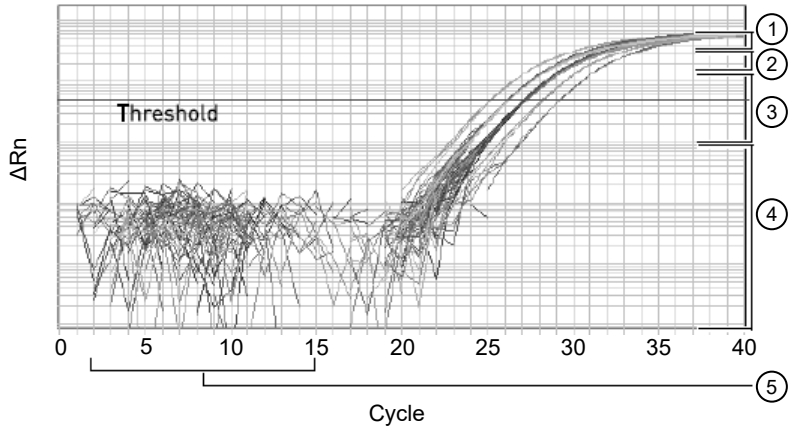
When performing a two-step RT-PCR reaction, total RNA or mRNA must first be reverse transcribed into cDNA.

1. In the reverse transcription (RT) step, cDNA is reverse transcribed from total RNA samples using random primers from the reverse transcription kit.
2. In the PCR step, PCR products are synthesized from cDNA samples using the master mix.



A typical amplification plot

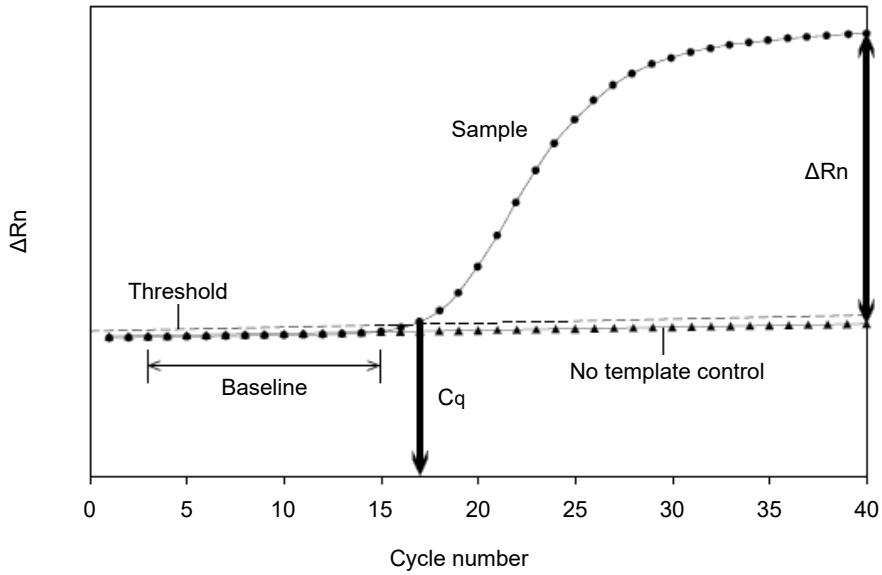
A typical amplification plot is shown below.



① Plateau phase
② Linear phase
③ Exponential phase (geometric phase)
④ Background
⑤ Baseline

Baseline and threshold values

- **Baseline**—the initial cycles of PCR in which there is little change in fluorescence signal.
- **C_q**—the intersection of the threshold with the amplification plot.
- **Threshold**—set above the background and within the exponential growth phase of the amplification curve.



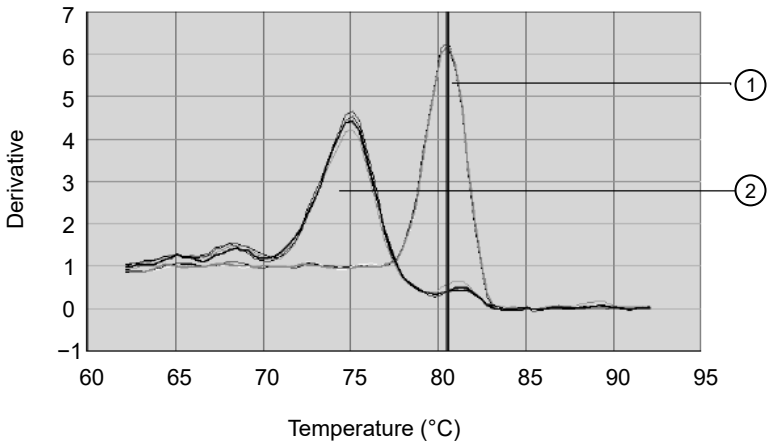
Automatic calculation of the baseline and threshold can be conducted using the software on your instrument. Alternatively, baseline and threshold can be set manually.

For examples of amplification plots where the baseline values and the threshold values are set too high or too low, see “Troubleshooting baseline settings” on page 18 and “Troubleshooting threshold settings” on page 19.

Melt curves

A melt curve is a graph that displays dissociation data from the amplicons of quantitative PCR runs. Change in fluorescence, due to a dye interacting with double-stranded DNA, is plotted against temperature. A single peak indicates specific amplification, whereas multiple peaks or shoulders indicate nonspecific amplification or primer-dimer formation.

Primer-dimers are most prevalent in NTC wells and sample wells containing a low concentration of template.



This melt curve shows typical primer-dimer formation. The specific product is shown with a melting temperature (T_m) of 80.5°C, but the primer-dimer has a characteristically lower T_m of 75°C.

① Melt curve of a specific product
② Melt curve of a primer-dimer

C Template quality and quantity

Go to **thermofisher.com/qpcreducation** for more information about DNA template quality, RNA guidelines, template quantitation, and template storage.

DNA template quality

Both agarose gel electrophoresis and spectrophotometry are used to examine DNA quality.

- **Agarose gel electrophoresis** – Purified DNA should run as a single band on an agarose gel. Agarose gels reveal contaminating DNAs and RNAs, but not proteins.
- **Spectrophotometry** – The A_{260}/A_{280} ratio should be 1.8 to 2.0. Smaller ratios usually indicate contamination by protein or organic chemicals. Spectrophotometry can reveal protein contamination, but not DNA or RNA contamination.

RNA guidelines

RNA should be reverse transcribed into cDNA prior to use in a PowerTrack™ SYBR™ Green Master Mix reaction. For recommended reverse transcription kits, see “Required materials” on page 7.

For optimal performance prior to reverse transcription, total RNA or mRNA should be:

- Between 0.002 µg/µL and 0.2 µg/µL
- Less than 0.005% of genomic DNA by weight
- Free of inhibitors of reverse transcription and PCR
- Dissolved in PCR-compatible buffer
- Free of RNase activity

  IMPORTANT! If you suspect that the RNA contains RNase activity, add RNase inhibitor to the reverse transcription reaction at a final concentration of 1.0 U/µL.

- Nondenatured

  IMPORTANT! It is not necessary to denature the RNA. Denaturation of the RNA may reduce the yield of cDNA for some gene targets.

Template quantitation using O.D. 260

Template quantitation is critical for successful PCR reactions. The most common way to determine DNA quantity is to measure the absorbance (optical density or O.D.) of a sample at 260 nm in a spectrophotometer.

One O.D. unit is the amount of substance dissolved in 1.0 mL that gives an absorbance reading of 1.00 in a spectrophotometer with a 1-cm path length. The wavelength is assumed to be 260 nm unless state otherwise. A_{260} values can be converted into µg/µL using Beer's Law:

Absorbance (260 nm) = sum of extinction coefficient contributions × cuvette pathlength × concentration

The following formulas are derived from Beer's Law:

- Concentration of single-stranded DNA = A_{260} × 33 µg/µL
- Concentration of double-stranded DNA = A_{260} × 50 µg/µL
- Concentration of single-stranded RNA = A_{260} × 40 µg/µL

Note: Absorbance measurements of highly concentrated (O.D. >1.0) or very dilute (O.D. <0.05) DNA or RNA samples can be inaccurate. Dilute or concentrate the DNA/RNA to obtain a reading within the acceptable range.

Template storage

- Store purified RNA templates at –20°C or –70°C in Nuclease-Free Water.
- Store purified DNA templates at –20°C or –70°C in TE, pH 8.0.

D Primer design, target sequences, and optimizing primer concentration

Primer design guidelines

Primers should be designed using Primer Express™ Software or similar software. See the *Primer Express™ Software Version 3.0 Getting Started Guide* (Pub. No. 4362460).

- Keep the GC content in the 30–70% range.
- The optimal primer length is 20 bases.
- Avoid runs of identical nucleotides. If repeats are present, there must be fewer than four consecutive G residues.
- Make sure the last five nucleotides at the 3' end contain no more than two G and/or C bases.

Template	Design guideline
DNA	Design the primers as described above.
Plasmid DNA	
Genomic DNA	
cDNA	Design the primers as described above and see “Selecting an amplicon site for cDNA” on page 29.
RNA	Design the primers as described above.

Avoiding primer-dimers

Use primers that contain dA nucleotides near the 3' ends so that any primer-dimer generated is efficiently degraded by UDG at least as well as any dU-containing PCR products. The farther a dA nucleotide from the 3' end, the more likely partially degraded primer-dimer molecules can serve as a template for a subsequent PCR amplification.

Production of primer-dimers could lower the amplification yield of the desired target region. If primers cannot be selected with dA nucleotides near the ends, consider using primers with 3' terminal dU-nucleotides. Single-stranded DNA with terminal dU nucleotides are not substrates for UDG , and therefore the primers are not degraded. Biotin-dUMP derivatives are not substrates for UDG.

For more information about designing primers, see “Primer design guidelines” on page 28.

Do not use UDG in subsequent amplifications of dU-containing PCR template, such as in nested PCR protocols. The UNG degrades the dU-containing PCR products, preventing further amplification.

Identifying target sequence and amplicon size

A target template is a DNA sequence, including cDNA, genomic DNA, or plasmid nucleotide sequence that you want to amplify.

Primers are designed to amplify amplicons (segments of DNA) within the target sequence using Primer Express™ Software. Shorter amplicons work best. Consistent results are obtained for amplicon size ranges from 50–150 bp.

Selecting an amplicon site for cDNA

Selecting a good amplicon site ensures amplification of the target cDNA without co-amplifying the genomic sequence, pseudogenes, and related genes.

- The amplicon should span one or more introns to avoid amplification of the target gene in genomic DNA.
- The primer pair must be specific to the target gene; the primer pair does not amplify pseudogenes or other related genes.
- Primers should be designed according to the guidelines in the Primer Express™ Software.
- Amplicons should be tested and those with the highest signal-to-noise ratio should be selected (low C_q with cDNA and no amplification with no template control or genomic DNA).
- The sequence may need to be examined and the amplicon redesigned if no good sequence is found. Alternatively, more sites may need to be screened.

If the gene of interest does not have introns, then an amplicon cannot be designed that amplifies the mRNA sequence without amplifying the genomic sequence. RT–minus controls may need to be run.

Optimize primer concentrations for PCR

Overview

By independently varying the forward and reverse primer concentrations, you can identify the primer concentrations that provide optimal assay performance. The primer concentrations you select should provide a low C_q and a high ΔR_n when run against the target template, but should not produce nonspecific product formation with NTCs.

Quantitate primers

1. Measure the absorbance (at 260 nm of a 1:100 dilution) of each primer oligonucleotide in TE buffer.
2. Calculate the sum of extinction coefficient contributions for each primer:
   - Extinction coefficient contribution = Σ (extinction coefficient × number of bases in oligonucleotide sequence)
3. Calculate the oligonucleotide concentration in µM for each primer:
   - Absorbance at 260 nm = sum of extinction coefficient contribution × cuvette pathlength × concentration / 100
   - Rearrange to solve for concentration:
     - Concentration = 100 [absorbance at 260 nm / (sum of extinction coefficient contribution × cuvette pathlength)]

Example calculation of primer concentration

In this example, the concentration of a primer (in TE buffer, diluted 1:100), with the sequence `5′-CGTACTCGTTCGTGCTGC-3′` is calculated using the following values:

Chromophore	Extinction coefficient	Number of specific chromophores in example sequence	Extinction coefficient contribution
A	15,200	1	15,200
C	7050	6	42,300
G	12,010	5	60,050
T	8400	6	50,400
Total	—	—	167,950

- Measured absorbance at 260 nm = 0.13
- Sum of extinction coefficient = 167,950 $M^{-1}cm^{-1}$ contributions for probe
- Cuvette pathlength = 0.3 cm
- Absorbance (260 nm) = sum of extinction coefficient contributions × cuvette pathlength × oligonucleotide concentration / 100

- 0.31 = 167,950 $M^{-1}cm^{-1}$ × 0.3 cm × C / 100
- C = 258 µM

Determine the optimal primer concentration for PCR

Calibrate your instrument for SYBR™ Green dye, if necessary. See the instrument user guide for calibration instructions. It is recommended to calibrate your instrument every six months.

1. Prepare a 96-well reaction plate.

   Use 10–100 ng of gDNA or 1–10 ng of cDNA template. The final concentration of the master mix is 1X.

   Note: The plate configuration accounts for four replicates of each of the following nine variations of primer concentration applied to both template and NTC wells:

Reverse primer (nM)	Forward primer (nM)		
	300	500	800
300	300 / 300	500 / 300	800 / 300
500	300 / 500	500 / 500	800 / 500
800	300 / 800	500 / 800	800 / 800

2. Set up the thermal protocol (see “Set up and run the real-time PCR instrument” on page 14).
3. Load the plate into the real-time PCR instrument.
4. Start the run.
5. Compile the results for ΔR_n and C_q, then select the minimum forward and reverse primer concentrations that yield the maximum ΔR_n values and low C_q values.

Confirm the absence of nonspecific amplification

Melt curves help you select the optimal primer concentrations for your quantification assays with SYBR™ Green dye.

1. Review the linear view of the amplification plot in your NTC wells.

   Note: In Figure 12 on page 32, the strong amplification of the NTC wells indicates that significant nonspecific amplification is occurring.

2. Generate a melt curve with your real-time PCR system.

   Note: In the example shown in Figure 13 on page 32, the melting temperature of the product generated in the absence of template is lower than the melting temperature of the specific product generated with template. This variation is typical of primer-dimer formation, and it indicates that lower primer concentration may provide optimal results.

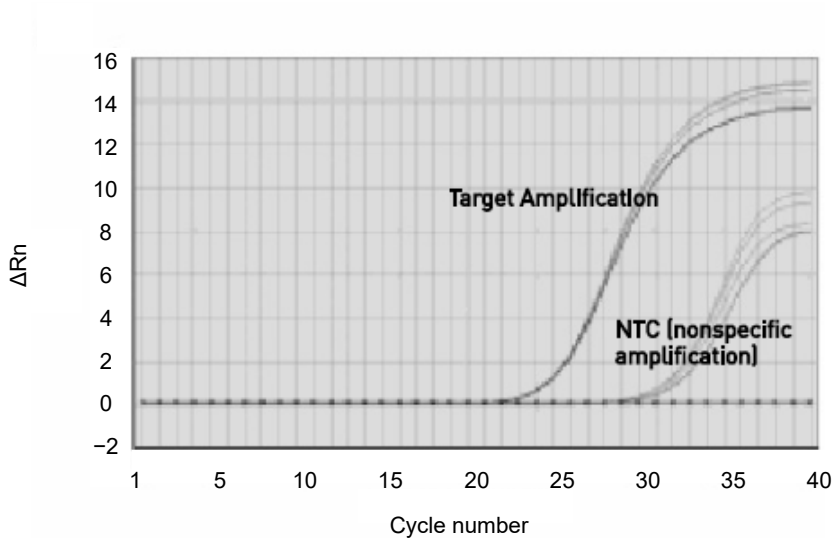


Figure 12 Amplification plot (linear view) demonstrating suspected nonspecific amplification in NTC wells

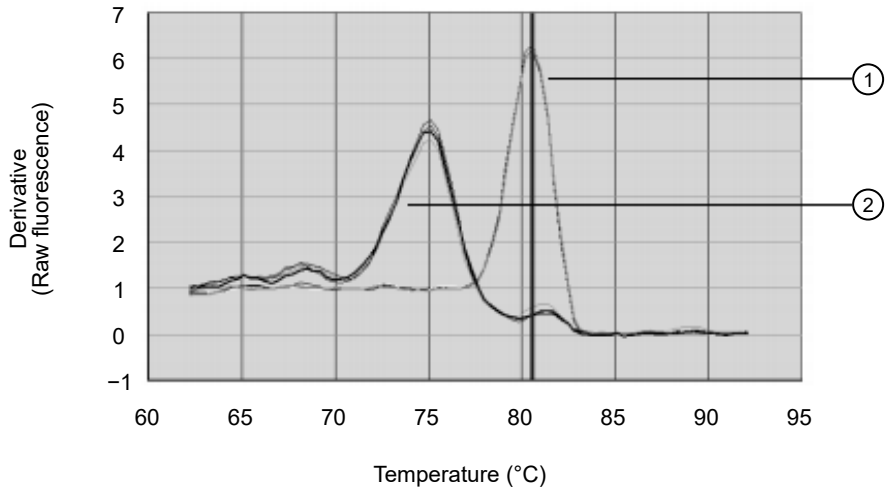


Figure 13 Melt curve analysis confirming that product in NTC wells has a melting temperature different from the specific product

① Target amplification
② NTC (nonspecific amplification)

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

AVERTISSEMENT ! PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES. Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

WARNING! **HAZARDOUS WASTE (from instruments).** Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.

WARNING! **4L Reagent and Waste Bottle Safety.** Four-liter reagent and waste bottles can crack and leak. Each 4-liter bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position.

Biological hazard safety

WARNING! **BIOHAZARD.** Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  www.who.int/publications/i/item/9789240011311

Documentation and support

Related documentation

Document	Pub. No.
PowerTrack™ SYBR™ Green Master Mix Quick Reference	MAN0018826

Customer and technical support

Visit **thermofisher.com/support** for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
  - Product FAQs
  - Software, patches, and updates
  - Training for many applications and instruments
- Order and web support
- Product documentation
  - User guides, manuals, and protocols
  - Certificates of Analysis
  - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

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Quality Management System

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Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

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2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
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Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

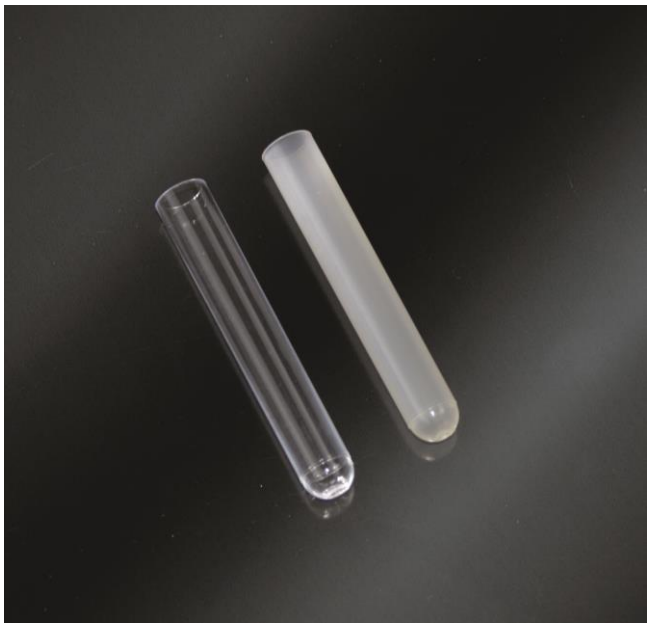
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
19.10.2020

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **1075/MO**

DESCRIZIONE / *DESCRIPTION*



PROVETTE CILINDRICHE DA 5ML
Provette cilindriche da 5ml fondo ad "U" tipo SORVALL CW1, non graduate, senza bordo.
Prodotte in polipropilene medicale (PP), traslucido ed infrangibile. Autoclavabili a + 121°C
Dispositivo Latex free

5ML CYLINDRICAL TEST TUBES
5ML CYLINDRICAL TEST TUBES WITH "U" BOTTOM SORVALL CW1 TYPE, NOT GRADUATED, WITHOUT RIM.
MANUFACTURED IN MEDICAL POLYPROPYLENE (PP), TRANSLUCENT AND UNBREAKABLE. AUTOCLAVABLE UP TO +121 °C
LATEX FREE DEVICE

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000
CE *Marked product* - *manufactured in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000*

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbilogical status*
Materiale impiegato	POLIPROPILENE / *POLYPROPYLENE*	*Raw material*
Temperature tollerate provetta	MIN -10°C MAX +121°C	*Temperature range - test tube*
Dimensioni (mm)	Ø 12 x 75	*Dimensions (mm)*
Volume (ml)	5,0	*Volume (ml)*
Spessore (mm)	1,0	*Thickness (mm)*
Peso (gr.)	2,1	*Weight (gr.)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (per esempio urina, sangue, sperma, saliva, espettorato, pus, etc) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale Dispositivi Medici (CND) > W050301020102 (Provette senza additivi in materiale plastico per analisi)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1896512/R
Classificazione EDMA > 51091001 - Other containers for samples of human origin

Intended purpose is "IN VITRO MEDICAL DEVICE" adapted to contain a human biological sample (for example urine, blood, semen, saliva, sputum, pus, etc) in order to perform diagnostic analysis laboratory. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *W050301020102 (Samples analyses, plastic tubes without additives).*
EDMA code > *51091001 - Other containers for samples of human origin*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

L'uso in centrifuga non deve superare la velocità massima di 5.000 r.p.m. per un massimo di 20 min.
For a maximum centrifuge speed of 5,000 r.p.m to be kept for 20" max

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	4.000	Confezione interna (pz): *Internal packing (pcs):*	1.000	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	52,5 x 37,5 x 35	Peso (Kg): *Weight (Kg):*	9,83	Volume (m^3): *Volume (m^3):*	0,069

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Gilson Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

Gilson Pipette Tips

Gilson Pipette Tips

Designed for use in a wide variety of pipetting applications, compatibility with Gilson Pipettors.
PP material.
Size:10ul,200ul,1000ul,5000ul
Various color optional easy to identify
Non sterile.

Cat No.	Description	Qty/Case(bags)
640101	Gilson pipette tips,10ul, clear, 1000tips/bag	100
640102	Gilson pipette tips,200ul, yellow, 1000tips/bag	50
640103	Gilson pipette tips,1000ul, blue, 500tips/bag	50
640104	Gilson pipette tips,5000ul, clear, 300tips/bag	30

This is a translation of the certificate ES16/20725.01

DELTALAB, S.L.

Pol.Ind. La Llana, Plaza de la Verneda, 1, 08191 Rubí, Barcelona

Has been assessed under the management system of the certified organisation defined in the main certificate ES16/20725 as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products and cosmetics.

This certificate is valid from 11 October 2022 until 11 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 2.
The validity of this certificate depends on the validity of the main certificate.

SGS International Certification Services Iberica, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España
t +34 91 313 8115 - www.sgs.com

This is a translation of the certificate ES19/86440.01

DELTALAB, S.L.

Pol.Ind. La Llana, Plaza de la Verneda, 1, 08191 Rubí, Barcelona

Has been assessed under the management system of the certified organisation defined in the main certificate ES19/86440 as meeting the requirements of

ISO 14001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products and cosmetics.

This certificate is valid from 31 August 2022 until 29 August 2025 and remains valid subject to satisfactory surveillance audits.

Issue 2.
The validity of this certificate depends on the validity of the main certificate.

SGS International Certification Services Iberica, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España
t +34 91 313 8115 - www.sgs.com

Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza de la Verneda 1, 08191 Rubi, Barcelona, Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and sale of sterile and non-sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.
Distribution of non-active medical devices and in vitro diagnostic medical devices.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.
Distribución de productos sanitarios no activos y productos sanitarios para diagnóstico in vitro.

Disseny, fabricació i comercialització de productes sanitaris estèrils i no estèrils per a la presa, transport i conservació de mostres biològiques per a anàlisis clíniques i de IVD.
Distribució de productes sanitaris no actius i productes sanitaris per a diagnòstic in vitro.

This certificate is valid from 12 October 2022 until 11 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 10. Certified since 12 October 2010.

Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

UKAS MANAGEMENT SYSTEMS 0005

INTEGRATED MANAGEMENT POLICY

Deltalab, S.L. defines and makes public its commitment with the Standard ISO 9001:2015 Quality Management Systems, ISO 14001:2015 Environmental Management Systems and ISO 13485:2016 Medical devices – Quality Management Systems, with the aim to create value and satisfy all its interested parties:

- Shareholders
- Members of the organisation
- Customers and suppliers
- All members of the surrounding community

The development of this Integrated Management System Policy is carried out with the philosophy of Continuous Improvement and with the support of all the processes described in our Integrated Management System, in order to achieve the following objectives:

1. Become leaders in the design and manufacture of single use products for the laboratory.
2. Bring solutions to cover the current and future customer needs, related to:

    - Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiology, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis.
    - Design, manufacture and sale of sterile and non-sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.
    - Commercialization of diagnosis reagents, equipment and instrumentation for laboratory and equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
    - Commercialization of personal care, cosmetics and dietetic products

3. Maintain a constant growth, both in local and international markets, by means of mergers, acquisitions and by launching new products.
4. Achieve the full satisfaction of our customers, by means of a strict compliance to the agreements and expectations agreed with them, as well as the excellence in the service.
5. Reach a high level of innovation of our products and processes, in cooperation with universities, research centers, key opinion leaders and experts, both local and international.
6. Fulfil the legislation and regulatory requirements applicable to the activities carried out by the company, including those applicable to the quality of products and the environmental management.
7. Commit ourselves with the environmental protection, including the prevention of pollution.
8. Achieve and keep a high motivation and involvement of all members of the organisation, suppliers, distributors and customers, by fulfilling the highest Quality and environmental protection standards.
9. Improve the working conditions of all employees and ensure the technical capacity of the personnel by giving them the adequate training with the aim to achieve the required competence.
10. Establish a close relationship with the suppliers and guarantee the maximum quality of materials supplied by means of quality agreements.

The Integrated Management System is periodically reviewed to define the required actions to ensure that:

- ✓ The System is efficient, so that it is a tool for the routine of all the members of the organisation.
- ✓ The customer needs and requirements are duly identified, and their expectations are always met.
- ✓ All members of the organisation are familiar with and know the objectives and policy of the Integrated Management System, and that adequate training plans are defined to achieve them.
- ✓ Encourage the Continuous Improvement Philosophy, both related to Quality and Environmental Management.

This Policy is made available for the public and all interested parties.

JOSEP SAEZ
Managing Director
January 2019

Adhesive sealing film

Code: 900300, Deltalab, Spain

Code: 900300

Sealing film for use with microplates, multiwell plates and microtiter plates.

Advantages:

1. Minimises the risk of contamination or reagent spillage during ELISA or PCR processes.

2. Minimises the risk of contamination from tube to tube and from plate to plate.

3. Prevents sample evaporation.

A 5 mm wide strip (opaque white) at the lateral edges of the film helps pull the film from its protective paper and prevents it sticking onto fingers. The film is thermostable and

functional from –70 ºC to 95 ºC at 75% humidity.

RNAse, DNAse, DNA and PCR inhibidors free. DMSO resistant.

We recomend to use the “roller” 900330 to ensure a perfect seal.

QPCR adhesive film

Code: 900301, Deltalab, Spain

Code: 900301

Sealing film for use with microplates, multiwell plates and microtiter plates.

Advantages:

1. Minimises the risk of contamination or reagent spillage during ELISA or PCR processes.

2. Minimises the risk of contamination from tube to tube and from plate to plate.

3. Prevents sample evaporation.

A 5 mm wide strip (opaque white) at the lateral edges of the film helps pull the film from its protective paper and prevents it sticking onto fingers. The film is thermostable and

functional from –70 ºC to 95 ºC at 75% humidity.

RNAse, DNAse, DNA and PCR inhibidors free. DMSO resistant.

We recomend to use the “roller” 900330 to ensure a perfect seal.

EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products indicated on pages 2–3 are in conformity with relevant provisions of EC Council Directive 98/79/EC on *in vitro* diagnostic medical devices and fulfill the essential requirements of that directive.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 383 332 81 34.

European authorized representative:

BIORON GmbH
Address: In den Rauhweiden 20, 67354 Roemerberg, Germany, tel.: +49 (0) 6232 298 450.

Date: 2022/05/24
Place: Novosibirsk

Murat Khusainov
General Director
AO Vector-Best

Valid until: 2027/05/26

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to hepatitis A virus	D-0362
2.	VectoTBEV-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to tick-borne encephalitis virus	D-1156
3.	VectoMeasles-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to measles virus in blood serum (plasma)	D-1356
4.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
5.	LymeBest-IgG	Enzyme immunoassay kit for the detection of IgG to *Borrelia burgdorferi sensu lato* complex	D-1452
6.	LymeBest-IgM	Enzyme immunoassay kit for the detection of IgM to *Borrelia burgdorferi sensu lato* complex	D-1454
7.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
8.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
9.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus nuclear antigen in blood serum (plasma)	D-2170
10.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus early antigens in blood serum (plasma)	D-2172
11.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
12.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
13.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to *Toxocara* antigens in blood serum (plasma)	D-2752
14.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to *Trichinella* antigens in blood serum (plasma)	D-3152

15.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
16.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
17.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
18.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to *Echinococcus granulosus* antigens in blood serum (plasma)	D-3356
19.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to *Ascaris lumbricoides* antigens in blood serum (plasma)	D-3452
20.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgA to tissue transglutaminase in blood serum (plasma)	D-3758
21.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
22.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 1 in blood serum	D-3762
23.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 2 in blood serum	D-3764
24.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile virus in blood serum (plasma)	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile virus in blood serum (plasma)	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of the avidity index of IgG to West Nile virus in blood serum (plasma)	D-5154
27.	Interleukin-6-EIA-BEST	Enzyme immunoassay kit for the quantification of interleukin-6 in blood serum and urine	A-8768

Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату

применительно к областям

проектирование и разработка, производство и реализация медицинских изделий in-vitro диагностики (ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала, что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества – Регулирующие системные требования

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи	2020-07-04
Срок действия до	2023-07-03
Регистрационный №	D1213100019
Отчет №	P20-00568-173687
Штутгарт, Германия	2020-06-02

Руководитель сертификационного органа

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Приложение к Сертификату

№ D1213100019 от 2020-06-02 Стр. 1 из 1

Месторасположение	**Область действия**
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

Руководитель сертификационного органа

medical device certification mdc

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Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

VECTOR BEST

AO Vector-Best
Research and Production Area
Building 36,Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

with the locations listed in the attachment

for the scope

Design and development, production and distribution of medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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Attachment of the certificate

No. D1213100019 date 2020-06-02 Page 1 of 1

Location	Scope
AO Vector-Best Arbuzova str. 1/1, 630117 Novosibirsk Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best Pasechnaya str, 3, 630117 Novosibirsk Russian Federation	design and development, production of medical devices for in vitro diagnostics

medical device certification mdc

Head of Certification Body

mdc medical device certification GmbH
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