

FT3 and FT4 control sample

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: PI-B48021-01	Current version: IFU-B48021-01
—	IVDR requirements incorporated

REF B48021

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Control sample is intended for use as an assayed quality control to monitor the precision in determinations of Beckman Coulter RIA FT3 (IM1579, IM3320) and FT4 RIA KIT (IM1363, IM3321).

WARNING AND PRECAUTIONS

General remarks:

The vials with control sample should be opened as shortly as possible to avoid excessive evaporation.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

Materials of human origin

The materials of human origin, contained in this control sample, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this control sample with all necessary precautions.

The summary of safety and performance for this in vitro diagnostic medical device is available to the public in the European database on medical device (EUDAMED) when this database is available, and the information has been uploaded by the Notified Body. The web address of the EUDAMED public web site is: <https://ec.europa.eu/tools/eudamed>.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

GHS HAZARD CLASSIFICATION

Not classified as hazardous



Safety Data Sheet is available at beckmancoulter.com/techdocs

MATERIALS PROVIDED

Unopened reagents are stable until the expiration date indicated on the FT3 and FT4 control sample label, when stored at 2-8°C.

Storage conditions for reagents after reconstitution are indicated in paragraph Procedure.

Control samples: five vials (lyophilized)

The vial contains T3, T4 in human serum with sodium azide (<0.1%). The control sample is traceable to an internal reference standard.

PROCEDURE

Reconstitution of control sample

The content of the vial must be brought to room temperature before reconstitution with the volume of distilled water indicated on the vial label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing.

Store the reconstituted solution at 2-8°C for three weeks then aliquoted at < -18°C for up to three months. Freezing and thawing do not affect the determination, even if repeated ten times.

Assay procedure

Control sample should be assayed according to Direction for use for Beckman Coulter manual kits: RIA FT3 (IM1579, IM3320) and FT4 RIA KIT (IM1363, IM3321).

RESULTS

Results are obtained from the standard curve RIA FT3 (IM1579, IM3320) and FT4 RIA KIT (IM1363, IM3321) by interpolation. Declared ranges are specified in an attached Supplement.








LIMITATIONS

This product must be used exclusively with the Beckman Coulter RIA FT3 (IM1579, IM3320) and FT4 RIA KIT (IM1363, IM3321).

APPENDIX

Symbols Key

Symbols Key

- REF** Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κυδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Úrün Referansı / Ссылка на продукт / Референца за производ / 產品參考
- IVD** In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / In Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷
- CONTENTS** Contents / Contenu / Inhalt / Contenuto / Contenido / Περιεχόμενο / 組成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄
-  Manufactured by / Fabriqué par / Hergestellt von / Prodotto da / Fabricado por / Tillverkas av / Κατασκευαστής / 制造商 / Gamintojas / Gyártó: / Producent / Výrobce / Výrobca / 제조 / Üretici / Изготовлено / Произведено от / 製造商
-  Contains sufficient for <n> tests / Contenu suffisant pour "n" tests / Inhalt ausreichend für <n> Prüfungen / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos / Conteúdo suficiente para "n" ensaios / Räcker till "n" antal tester / Περιεχόμενο επαρκές για "n" εξετάσεις / 含量足够 <n> 次测试 / Turinio pakanka <n > tyrim / <n> teszthez elegendő mennyiséget tartalmaz / Zawartość wystarcza na <n> testów / Lze použít pro <n> testů / Obsah vystačí na <n > testov / <n> 테스트에 대해 충분한 양 포함 / <n> sayida test için yeterli / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 內容物足夠執行 <n> 次測試
- CE** CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / 标志 / CE ženklas / CE jelzés / Znak CE / Značka CE / Označenie CE / CE 표시 / CE İşareti / Маркировка CE / CE маркировка / CE 標識
- SDS** Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表
-  Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postępujcie podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanna Talimatna Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明
-  Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo(i) di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 温度范围 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sıcaklık aralıkları / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明
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-  Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum expirace / Dátum expirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日
- LOT** Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號
-  Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

CTRL Control / Contrôle / Kontrolle / Controllo / Control / Controllo / Kontrolle / Μάρτυρας / 质控品 / Kontrollinè / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品

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