

FT3 and FT4 control sample

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

REVISION HISTORY

Previous version: IFU-B48021-01	Current version: IFU-B48021-02
—	Addition of Biohazard to the symbolkey table.

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 / Кодικός 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

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