Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
FITC-CD4 Positive Control Cells
NIBSC code: SS-319/20
Instructions for use
(Version 4.0, Dated 05/03/2019)

This material is a self certified IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC".

1. INTENDED USE

This product is CE marked for use as an IVD within the EU member states and EEA countries. In all other territories this product can be used for research purposes only.

This material is intended for use as a positive control for CD4+ T cell enumeration by flow cytometry. It can be used to verify flow cytometry settings and analysis, for inter- and intra-laboratory performance monitoring, and for training and qualifying new users. Each vial contains human PBMC pre-labelled with a FITC conjugated anti-CD4 antibody.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

Each unit contains approximately 325.1 CD4+ T cells per microliter upon reconstitution. The expected range is 212.1 to 438.1 CD4+ T cells per microliter. This range reflects independent evaluation by 9 diagnostic laboratories. Each laboratory should establish its own acceptable range. This material is not for use as a calibrator.

4. CONTENTS

Country of origin of biological material: United Kingdom.
This material contains CD4-FITC labelled human peripheral blood mononuclear cells (PBMC) prepared from pooled donations from the National Blood Service.

5. STORAGE

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. On receipt, reference materials should be stored at -20°C until use.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

To reconstitute this material, dissolve the entire contents of the vial in 1.5ml of sterile distilled water at room temperature and allow it to equilibrate for 10-30 minutes before use. Transfer 50 microliters of reconstituted cells to a 12x75 mm tube containing lyophilised counting beads. Dilute with 950 microliters of PBS and analyse by flow cytometry. The expected range has been assigned in this way. The extent to which further dilutions allow for in-range values has not been assessed and is the responsibility of the user. The material has been tested for single-use only and as such its quality and performance as an IVD can only be assured on day of opening. Store in the dark.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

The expiry date shown on the label is valid for products stored at -20°C upon receipt. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC via the email address in section 11.

9. REFERENCES

Stebbings R, et al. Quantification of cells with specific phenotypes I: Determination of CD4+ cell count per microliter in reconstituted lyophilized human PBMC prelabeled with anti-CD4 FITC antibody. Cytometry A. 2015 Mar;87(3):244-53. doi:10.1002/cyto.a.22614. Epub 2015 Feb 5.

10. ACKNOWLEDGEMENTS

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: Freeze-dried powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains material of human origin		

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE

Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.
Action on Spillage and Method of Disposal	
Spillage of vial contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 1.0g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No