Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
11/210: Anti-human CD4 FITC conjugated
NIBSC code: 11/210
Instructions for use
(Version 1.0, Dated 27/03/2020)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is intended for use as a flow cytometry reference reagent and may be used to measure the CD4 antigen on human leukocytes.

2. CAUTION

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

This material is prepared from a murine monoclonal antibody. 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

There is no unitage assigned to this product. It is not for use as a calibrator.

4. CONTENTS

Country of origin of biological material: United Kingdom.

The freeze dried stabilised standard in this vial, coded 11/210, has been made from 0.5 mL of a mouse anti-human CD4 monoclonal antibody, conjugated to FITC. It is of an IgG1 lambda isotype.
Each vial contains approximately 170µg of freeze-dried mouse anti-human CD4 labelled with approximately 3.6 FITC molecules per IgG.

5. STORAGE

Reference materials are manufactured and held at NIBSC within assured, temperature-controlled storage facilities. On receipt, Reference Materials should be stored below -18°C until use, or the expiry date of the material. Once reconstituted, this antibody should be protected from direct sunlight.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

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 0.5 mL of sterile distilled water at room temperature and allow to equilibrate for 10-30 minutes before use. It is suggested that 4µL of antibody per 10^6 leucocytes should be used, however the exact volume should be determined by the end user. At NIBSC the antibody has been found to provide suitable separation between CD4 positive and negative populations between 3 and 20µL of antibody per 10^6 leucocytes.
The material has been successfully used with multiple flow cytometry platforms. There is limited data on the use of this material in combination with other antibodies. Suitability should therefore be determined by the end user.

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.

Accelerated degradation studies have shown freeze-dried antibodies stored in unopened vials below -18°C to be extremely stable over a number of years. This material contains penicilin & streptomycin antibiotics, but no preservative. Once reconstituted, sodium azide or an alternative preservative should be added by the end user, if it is not kept in a sterile environment. An allowance for the extra volume should be made when determining the test volume. The reconstituted antibody should not be re-frozen, but can be stored at 2 - 8°C for 12 months, protected from sunlight.
The material may be used until the ratio between the MFI of the CD4 positive and negative populations falls below 10. (see Figure1).

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

N/A

10. ACKNOWLEDGEMENTS

We are extremely grateful to all participants of the collaborative study.

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 murine origin		
Toxicological properties			
Effects of inhalation:	Not established, avoid inhalation		

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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 ampoule 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.

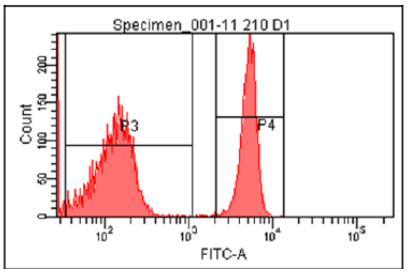
16. INFORMATION FOR CUSTOMS USE ONLY

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: 0.5 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

Figure 1

Representative binding activity of the material used with whole blood (4µL per 1mL whole blood).

If the ratio between the MFI of the CD4 positive cell population (P4) and the CD4 negative population (P3) falls below 10, the material should be discarded and a fresh vial obtained.



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