

# **NIAID RESEARCH RESOURCES FOR INTERFERON RESEARCH**

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# Interferon Reagents

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## **PART 1. General Information**

### **A. Background and Purpose**

The need for well-characterized reference reagents as an adjunct to research has long been recognized by the National Institute of Allergy and Infectious Diseases (NIAID). In 1969, NIAID accepted the responsibility for the preparation and evaluation of a panel of Interferon International Reference Reagents. These reference reagents, produced under NIAID contracts with industry, universities, and nonprofit research organizations, were selected in consultation with acknowledged authorities in the field. The potency of the reagents is based on the results of repetitive testing in a number of different laboratories having expertise in interferon assay procedures. Complete details concerning production and testing are provided with each ampoule shipped. The interferon standard preparations designated by the World Health Organization (WHO) as International Standards or International Reference Preparations are the sole reagents for the international standardization of interferons used for both clinical therapy and experimental research. Reference standards for human and murine interferons as well as antibodies to the interferons are distributed by the Repository. These materials are not intended for either diagnostic or therapeutic use.

### **B. Availability and Distribution of Reference Reagents**

NIAID interferon reagents are intended for use as laboratory reference standards only. One ampoule of a reagent is provided to an investigator per year. They are not intended for either diagnostic or therapeutic use. Each of the reagents has been defined as containing a certain amount of interferon per ampoule based on specific assay methods. If you have questions about a particular reagent, please contact the Repository at the number below.

Interferon reagent catalogs and order forms are available for downloading at the NIAID Repository website, [www.bratonbiotech.com](http://www.bratonbiotech.com). If you are unable to access the Internet, you may request the latest copy of the interferon catalog and order form by directly contacting the Repository using the fax or telephone numbers listed below. Reagent request forms must be completed by hand, they are not available for on-line completion or submission. Prior to submitting your completed and signed request form, please make a copy for your files. Then forward all completed and signed original documents to the Repository address listed below. To help expedite your order the Repository does accept the completed and signed forms by fax. Failure to submit all completed and signed original documents to the Repository will prevent us from considering any future reagent requests that are submitted by you or your organization. Please forward all correspondence to:

Dr. Sharan VedBrat  
KamTek, inc.  
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## **PART II.**

### **Interferon Reagents Currently Available for Distribution**

**A.**

**Interferon Reference Standards**

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Proper Name    | Human Interferon Alpha [HuIFN- $\alpha$ (Leukocyte)] |
| B. Catalog Number | Ga23-902-530   |
| C. Class          | WHO International Standard                           |
| D. Reference Note | # 29   |

**II. Method of Preparation**

- |                  |   |
|------------------|---|
| A. TC System     | Human leukocytes induced with Sendai virus  |
| B. Medium used   | Tricine-buffered MEM + 5% human serum   |
| C. Treatment     | Purified by Cantell's method of differential precipitation to obtain fraction PIF-A. Suspended in 0.1M sodium phosphate buffer, pH 7 supplemented with human serum albumin 5mg/ml |
| D. Freeze-drying | Residual moisture about 3%; backfilled with argon and heat-sealed at atmospheric pressure   |

**III. Potency**

- |                         |  |
|-------------------------|--|
| A. Titer                | 12,000 International Units/ampoule   |
| B. Molecular Weight     | 15,000 Daltons and 20,000 Daltons  |
| C. Isoelectric focusing | 2 approximately equal peaks of activity with isoelectric points of 5.6 and 6.1 |

**IV. Purity**

- |                                   |  |
|-----------------------------------|--|
| A. Activity on heterologous cells | $5.5 \times 10^4$ Laboratory Units (LU)/ml in human A549 cells,<br>$3.7 \times 10^4$ LU/ml in bovine ERTr cells,<br>$6.2 \times 10^4$ LU/ml in feline FEA cells and<br>420 LU/ml in murine L cells |
| B. Sterility                      | No evidence of mycoplasma, bacteria or fungal contamination  |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Human Interferon Alpha<br>(Leukocyte)   |
| B. Volume                        | 1 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over a 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C |

**VI. Producer**

The Medical College of Wisconsin\*  
N01-AI-02658

**VII. References**

13, 16, 17, 22, 23, 24, 30, 33, 35

\*Bulk purified material provided by Keri Cantell, National Public Health Inst., Helsinki.

**I. Reagent**

- A. Proper Name Human Interferon Alpha [(Hu)IFN- $\alpha$  (Lymphoblastoid)]
- B. Catalog Number Ga23-901-532
- C. Class WHO International Standard
- D. Reference Note # 30

**II. Method of Preparation**

- A. TC System Human lymphoblastoid Namalwa cell lines induced with Sendai virus
- B. Medium used
- C. Treatment Purified by serial chromatography at Wellcome Research Laboratories. Suspended in 0.1 M sodium phosphate buffer, pH 7 supplemented with 5 mg/ml human serum albumin
- D. Freeze-drying Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure

**III. Potency**

- A. Titer 25,000 International Units/ampoule
- B. Molecular Weight 15,500 Daltons
- C. Isoelectric focusing One major peak of activity at isoelectric point 5.8, with a shoulder at 6.2

**IV. Purity**

- A. Activity on heterologous 1.2 x 10<sup>5</sup> Laboratory Units (LU)/ml in human A549 cells, 1.9 x 10<sup>5</sup> LU/ml in bovine EBTr cells, 7 x 10<sup>4</sup> LU/ml in feline FEA cells and 320 LU/ml in murine cells
- B. Sterility No evidence of mycoplasma, bacteria or fungal contamination

**V. Ampouled Preparation**

- A. Contents Human Interferon Alpha (Lymphoblastoid)
- B. Volume 1 ml before freeze-drying
- C. Storage temperature -70°C recommended
- D. Stability after freeze-drying 70% of activity was lost during heating to 80°C; 81% as temperature reached 90°C. Product is estimated to have unlimited stability at -20° and -70°C

**VI. Producer**

The Medical College of Wisconsin\*  
N01 AI-02658

**VII. References**

12, 16, 17, 23, 24, 29, 30, 33, 35

\*Bulk purified material provided by Norman Finter, Wellcome Research Laboratories

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Proper Name    | Human Recombinant Alpha 2a (Alpha A) Interferon (rHuIFN- $\alpha$ 2a) |
| B. Catalog Number | Gxa01-901-535   |
| C. Class          | WHO International Standard  |
| D. Reference Note | # 31  |

**II. Method of Preparation**

- |                    |   |
|--------------------|---|
| A. Producer System | <u>E. coli</u> cells transformed with a plasmid derived from pLeIFA25   |
| B. Medium used     | Nutrient medium   |
| C. Treatment       | Purified by serial chromatography. Suspended in sodium chloride (9 mg/ml) with human serum albumin (5 mg/ml) pH 6.9 |
| D. Freeze-drying   | Lyophilized and sealed under nitrogen   |

**III. Potency**

- |                     |                                  |
|---------------------|----------------------------------|
| A. Titer            | 9000 International Units/ampoule |
| B. Molecular Weight | 18,500 Daltons                   |

**IV. Purity**

- |                                   |  |
|-----------------------------------|--|
| A. Activity on heterologous cells | As % of activity observed in human WISH cells: monkey, Vero (9%); bovine, MDBK (150%); guinea pig transformed (30%); feline, Felung (130%). Negligible activity (<1%) was observed on cell lines of the following species: mouse, rat, rabbit, hamster and horse |
| B. Sterility                      | No evidence of microbial growth  |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Human Recombinant Alpha 2a (Alpha A)  |
| B. Volume                        | 1.0 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over a 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C |

**VI. Producer**

Hoffman LaRoche, Inc.  
Nutley, New Jersey

**VII. References**

16, 17, 19, 21, 23, 27, 28, 30, 33, 35

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Proper Name    | Human Interferon Beta (HuIFN- $\beta$ ) |
| B. Catalog Number | Gb23-902-531                            |
| C. Class          | WHO International Standard              |
| D. Reference Note | # 35                                    |

**II. Method of Preparation**

- |                  |   |
|------------------|---|
| A. TC System     | Produced in FS-4 human foreskin fibroblast cultures by super-induction with poly(I)·poly(C)   |
| B. Medium used   |   |
| C. Treatment     | Chromatography on controlled pore glass at Dr. Rentschler Arzneimittel GmbH Co. Suspended in 0.1 M sodium phosphate, pH 7 supplemented with human serum albumin 1 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying | Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure  |

**III. Potency**

- |                         |   |
|-------------------------|---|
| A. Titer                | 15,000 International Units (IU)/ampoule           |
| B. Molecular Weight     | 22,000 Daltons                                    |
| C. Isoelectric focusing | A major peak of activity at isoelectric point 5.5 |

**IV. Purity**

- |                                   |   |
|-----------------------------------|---|
| A. Activity on heterologous cells | 2.2X10 <sup>4</sup> Laboratory Units (LU)/ml in human A549 cells,<br>1.8X10 <sup>2</sup> LU/ml in murine L cells and<br>8.25X10 <sup>2</sup> LU/ml in RK-13 cells |
| B. Sterility                      | No evidence of bacterial or fungal contamination  |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Human Interferon Beta   |
| B. Volume                        | 1.0 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28 hour period. Product is estimated to have unlimited stability at -20°C and -70°C |

**VI. Producer**

Dr. Rentschler Arzneimittel GmbH Co. and The Medical College of Wisconsin

**VII. References**

4, 15, 16, 23, 24, 30, 33, 35, 40, 41, 45, 46

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Proper Name    | Human Recombinant Beta <sub>ser17</sub> Interferon (rHuIFN-β <sub>ser</sub> ) |
| B. Catalog Number | Gxb02-901-535   |
| C. Class          | WHO International Standard  |
| D. Reference Note | # 37  |

**II. Method of Preparation**

- |                    |   |
|--------------------|---|
| A. Producer System | Plasmid-transformed <u>E. coli</u>  |
| B. Medium used     |   |
| C. Treatment       | Purified by precipitation, chromatography and diafiltration at Cetus Corp. Suspended in 0.1 M sodium phosphate, pH 7 with human serum albumin 1 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying   | Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure  |

**III. Potency**

- |                     |  |
|---------------------|--|
| A. Titer            | 6,000 International Units (IU)/ampoule |
| B. Molecular Weight | 19,000 Daltons                         |

**IV. Purity**

- |                                   |  |
|-----------------------------------|--|
| A. Activity on heterologous cells | About 150 Laboratory Units/ml in mouse L cells   |
| B. Sterility                      | No evidence of bacterial or fungal contamination |

**V. Ampouled Preparation**

- |                                  |  |
|----------------------------------|--|
| A. Contents                      | Human Recombinant Interferon Beta <sub>ser17</sub>   |
| B. Volume                        | 1.0 ml before freeze-drying  |
| C. Storage temperature           | -70°C recommended  |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C. |

**VI. Producer**

Triton, Cetus and the Medical College of Wisconsin

**VII. References**

15, 16, 23, 24, 30, 33, 35, 39, 40, 41, 42, 43, 44, 45

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Proper Name    | Human Recombinant Gamma Interferon (rHuIFN- $\gamma$ ) |
| B. Catalog Number | Gxg01-902-535  |
| C. Class          | WHO International Standard                             |
| D. Reference Note | # 43   |

**II. Method of Preparation**

- |                    |   |
|--------------------|---|
| A. Producer System | Extracted from plasmid-transformed <u>E. coli</u> cultures  |
| B. Medium used     |   |
| C. Treatment       | Purified by chromatography at Genetech. Suspended in sodium acetate 20 mM, pH 5.2 with human serum albumin 20 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying   | Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure  |

**III. Potency**

- |                     |   |
|---------------------|---|
| A. Titer            | 80,000 International Units (IU)/ampoule |
| B. Molecular Weight |   |

**IV. Purity**

- |                                   |  |
|-----------------------------------|--|
| A. Activity on heterologous cells | None   |
| B. Sterility                      | No evidence of bacterial or fungal contamination |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Human Recombinant Interferon Gamma  |
| B. Volume                        | 1.0 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at -70°C |

**VI. Producer**

Medical College of Wisconsin\*

**VII. References**

15, 16, 23, 24, 30, 33, 35, 39, 40, 41

\*Bulk purified material supplied by Genetech

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Proper Name    | Murine Interferon Alpha (MuIFN- $\alpha$ ) |
| B. Catalog Number | Ga02-901-511                               |
| C. Class          | WHO International Standard                 |
| D. Reference Note | # 40                                       |

**II. Method of Preparation**

- |                  |  |
|------------------|--|
| A. TC System     | Induced in L cells by Newcastle Disease Virus (NDV)  |
| B. Medium used   | Protein-free nutrient medium   |
| C. Treatment     | MuIFN- $\alpha$ separated from MuIFN- $\beta$ by chromatography on controlled pore glass. Suspended in sodium phosphate 0.1 M, pH 7 with human serum albumin 1 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying | Residual moisture about 3%; backfilled with argon and heat-sealed at atmospheric pressure  |

**III. Potency**

- |                         |  |
|-------------------------|--|
| A. Titer                | 16,000 International Units (IU)/ampoule  |
| B. Molecular Weight     | 28,000 Daltons - primary component (99.5%)<br>36,000 Daltons - minor component |
| C. Isoelectric focusing | A major peak of activity at isoelectric point 7.4                              |

**IV. Purity**

- |                                   |   |
|-----------------------------------|---|
| A. Activity on heterologous cells | 200 Laboratory Units (LU)/ml in human A549 cells and 53 LU/ml in rabbit RK-13 cells |
| B. Sterility                      | No evidence of bacterial or fungal contamination                                    |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Murine Interferon Alpha   |
| B. Volume                        | 1.0 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C |

**VI. Producer**

Medical College of Wisconsin\*

**VII. References**

15, 16, 23, 24, 30, 33, 35, 41, 45

\*Bulk material supplied by LEE Biomolecular Research Labs

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Proper Name    | Murine Interferon Alpha/Beta (MuIFN- $\alpha/\beta$ ) |
| B. Catalog Number | Gu02-901-511  |
| C. Class          | WHO International Standard                            |
| D. Reference Note | # 39  |

**II. Method of Preparation**

- |                  |  |
|------------------|--|
| A. TC System     | Induced in L cells by Newcastle Disease Virus (NDV)  |
| B. Medium used   | Protein-free nutrient medium   |
| C. Treatment     | NDV inactivated at pH 3 for 2 weeks at +4°C followed by dialysis. Suspended in sodium phosphate 0.1 M, pH 7 with human serum albumin 1 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying | Residual moisture about 3%; backfilled with argon and heat sealed at atmospheric pressure  |

**III. Potency**

- |                         |  |
|-------------------------|--|
| A. Titer                | 10,000 International Units (IU)/ampoule  |
| B. Molecular Weight     | 36,000 Daltons - major component (90%)<br>28,000 Daltons - minor component (10%) |
| C. Isoelectric focusing | A major peak of activity at isoelectric point 7.4                                |

**IV. Purity**

- |                                   |   |
|-----------------------------------|---|
| A. Activity on heterologous cells | None on human lung A549 cell line and rabbit kidney RK-13 cell line |
| B. Sterility                      | No evidence of bacterial or fungal contamination                    |

**V. Ampouled Preparation**

- |                                  |  |
|----------------------------------|--|
| A. Contents                      | Murine Interferon Alpha/Beta   |
| B. Volume                        | 1.0 ml before freeze-drying  |
| C. Storage temperature           | -70°C recommended  |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C. |

**VI. Producer**

Medical College of Wisconsin\*

**VII. References**

15, 16, 23, 24, 30, 33, 35, 41, 43

\*Bulk material supplied by LEE Biomolecular Research Labs

**I. Reagent**

A. Proper Name	Murine Interferon Beta (MuIFN- $\beta$ )
B. Catalog Number	Gb02-902-511
C. Class	WHO International Standard
D. Reference Note	# 41

**II. Method of Preparation**

A. TC System	Induced in L cells by Newcastle Disease Virus (NDV)
B. Medium used	Protein-free nutrient medium
C. Treatment	Purified by chromatography on controlled pore glass. Suspended in 0.1 M sodium phosphate, pH 7 with human serum albumin 1 mg/ml and gelatin 5 mg/ml
D. Freeze-drying	Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure.

**III. Potency**

A. Titer	15,000 International Units (IU)/ampoule
B. Molecular Weight	36,000 Daltons
C. Isoelectric focusing	A major peak of activity at isoelectric point 7.2

**IV. Purity**

A. Activity on heterologous cells	None on human lung A549 cell line and rabbit kidney RK-13 cell line
B. Sterility	No evidence of bacterial or fungal contamination

**V. Ampouled Preparation**

A. Contents	Murine Interferon Beta
B. Volume	1.0 ml before freeze-drying
C. Storage temperature	-70°C recommended
D. Stability after freeze-drying	No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at -20°C and -70°C.

**VI. Producer**

Medical College of Wisconsin\*

**VII. References**

15, 16, 23, 24, 30, 33, 35, 41, 45

\*Bulk material supplied by LEE Biomolecular Research Labs

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Proper Name    | Murine Interferon Gamma (MuIFN- $\gamma$ ) |
| B. Catalog Number | Gg02-901-533                               |
| C. Class          | WHO International Standard                 |
| D. Reference Note | # 42                                       |

**II. Method of Preparation**

- |                  |   |
|------------------|---|
| A. TC System     | Mouse splenocytes stimulated by Concanavalin A and pretreated with mezerein prior to induction with lentil lectin                                 |
| B. Medium used   | RPMI-1640 with 2.5% fetal bovine serum and 0.05 M 2-mercaptoethanol   |
| C. Treatment     | Purified by chromatography on yeast RNA Sepharose. Suspended in 0.1 M sodium phosphate, pH 7 with human serum albumin 1 mg/ml and gelatin 5 mg/ml |
| D. Freeze-drying | Residual moisture about 3%; backfilled with argon, and heat-sealed at atmospheric pressure  |

**III. Potency**

- |                         |   |
|-------------------------|---|
| A. Titer                | 1,000 International Units (IU)/ampoule  |
| B. Molecular Weight     | 20,000 and 40,000 Daltons   |
| C. Isoelectric focusing | A heterogeneous peak of activity within an isoelectric point range of 5.5 - 6.5 |

**IV. Purity**

- |                                   |   |
|-----------------------------------|---|
| A. Activity on heterologous cells | None on human lung A549 cells or on rabbit kidney RK-13 cells |
| B. Sterility                      | No evidence of bacterial or fungal contamination              |

**V. Ampouled Preparation**

- |                                  |   |
|----------------------------------|---|
| A. Contents                      | Murine Interferon Gamma   |
| B. Volume                        | 1.0 ml before freeze-drying   |
| C. Storage temperature           | -70°C recommended   |
| D. Stability after freeze-drying | No loss of activity during heating from 50°C to 90°C over 28-hour period. Product is estimated to have unlimited stability at +4°C, -20°C and -70°C |

**VI. Producer**

Medical College of Wisconsin

**VII. References**

15, 16, 23, 24, 30, 33, 35, 41, 45, 47

**I. Reagent**

- |                   |                            |
|-------------------|----------------------------|
| A. Proper Name    | Rabbit Interferon          |
| B. Catalog Number | G019-902-528               |
| C. Class          | WHO International Standard |
| D. Reference Note | # 10A                      |

**II. Method of Preparation**

- |                  |  |
|------------------|--|
| A. TC System     | Rabbit kidney cells [primary and secondary (through 3 <sup>rd</sup> passage)]<br>infected with bluetongue virus (strain BT-8)  |
| B. Medium used   | MEM + 2% fetal bovine serum  |
| C. Treatment     | Partially purified on zeolite, pH 3.5 for 48 hrs. Suspended in 0.1 M<br>sodium phosphate, pH 7 with 0.5% bovine plasma albumin |
| D. Freeze-drying | Residual moisture 3%; back-filled with argon and heat-sealed   |

**III. Potency**

- |                                      |                                    |
|--------------------------------------|------------------------------------|
| A. Titer                             | 10,000 International Units/ampoule |
| B. Molecular Weight (G-200 Sephadex) | 45,000 Daltons                     |
| C. Ultracentrifugation               | No loss in activity                |

**IV. Purity**

- |                                   |  |
|-----------------------------------|--|
| A. Activity on heterologous cells | None (<10) on mouse L cells by GDVII HA-yield reduction test;<br>20 Laboratory Units/ml on human BUD-8 cell strain |
| B. Sterility                      | No evidence of bacterial, mycoplasma, viral or fungal<br>contamination   |

**V. Ampouled Preparation**

- |                                  |  |
|----------------------------------|--|
| A. Contents                      | Rabbit Interferon                              |
| B. Volume                        | 1 ml before freeze-drying                      |
| C. Storage temperature           | -70°C recommended                              |
| D. Stability after freeze-drying | 50% of activity remaining after 18 hrs at 90°C |

**VI. Producer**

The Medical College of Wisconsin

**VII. References**

10, 11

**B.**

**Interferon Control Sera and Antisera**

**I. Reagent**

- A. Name Antiserum to human leukocyte interferon
- B. Type Specific anti-globulin to HuIFN- $\alpha$
- C. Catalog Number G026-501-568
- D. Class Research Reference Reagent
- E. Reference Note # 22R

**II. Production Data**

- A. Animal Suffolk-Hampshire female yearling sheep
- B. Immunizing material Partially-purified Sendai virus-induced human leukocyte IFN
- C. Adjuvant used Freund's complete in booster inoculations

**III. Potency**

- A. Neutralizing titer 1:700,000 against 10 Laboratory Units of human leukocyte IFN- $\alpha$   
(Cat # Ga23-902-530)

**IV. Purity**

- A. Antibody cross-reactivity < 1:100 against HuIFN- $\beta$
- B. Sterility Filter-sterilized

**V. Ampouled Preparation**

- A. Contents Absorbed, ammonium sulfate-precipitated sheep immune globulin
- B. Volume 0.5 ml before freeze-drying
- C. Reconstitution 0.5 ml of sterile physiologic saline solution or an appropriate medium
- D. Storage temperature 4°C

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 2, 3, 4, 6, 7, 8

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Name           | Control for antiserum to human leukocyte interferon                            |
| B. Type           | Control serum globulin for anti-HuIFN- $\alpha$ antiserum (Cat # G026-501-568) |
| C. Catalog Number | G027-501-568   |
| D. Class          | Research Reference Reagent   |
| E. Reference Note | # 23   |

**II. Production Data**

- |                        |   |
|------------------------|---|
| A. Animal              | Suffolk Hampshire female yearling sheep   |
| B. Immunizing material | Void volume of affinity chromatography of crude human leukocyte IFN preparations that did not bind to adsorbed anti-IFN globulin bound to Sepharose 4B. |
| C. Adjuvant used       | Freund's complete adjuvant in initial and booster inoculations  |

**III. Potency**

- |                       |   |
|-----------------------|---|
| A. Neutralizing titer | <50 against 8-10 Laboratory Units human IFN |
|-----------------------|---|

**IV. Purity**

- |              |  |
|--------------|--|
| A. Sterility | No evidence of bacterial or fungal contamination |
|--------------|--|

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized sheep immune globulin                                      |
| B. Volume              | 0.5 ml before freeze-drying  |
| C. Reconstitution      | 0.5 ml of sterile physiologic saline solution or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 2, 3, 4, 5, 7

**I. Reagent**

- A. Name Antiserum to human lymphoblastoid interferon (anti-HuIFN- $\alpha$ )
- B. Type Specific anti-globulin to HuIFN- $\alpha$
- C. Catalog Number G030-501-553
- D. Class Research Reference Reagent

**II. Production Data**

- A. Animal Calf
- B. Immunizing material Partially purified Sendai virus-induced lymphoblastoid (Namalwa) interferon
- C. Purification Repeated passage through a "scrubber" column consisting of Sepharose-4B linked with proteins from allantoic fluid, Sendai virus, and Namalwa cells

**III. Potency**

- A. Neutralizing titer # of interferon units neutralized by the contents of one vial  
Namalwa 40,000  
Primary leukocyte 40,000  
Fibroblast 10,000

**IV. Ampouled Preparation**

- A. Contents Freeze-dried material from 1 ml purified globulin in 0.15M NaCl
- B. Reconstitution 2 ml water containing 0.1% SDS
- C. Storage temperature 4°C or lower

**V. Producer**

Wellcome Research Laboratories

**I. Reagent**

- A. Name Control for antiserum to human lymphoblastoid interferon
- B. Type Control serum globulin for anti-HuIFN- $\alpha$  antiserum (Cat # G030-501-553)
- C. Catalog Number G031-501-553
- D. Class Research Reference Reagent

**II. Production Data**

- A. Animal Calf
- B. Immunizing material None
- C. Purification Passed through a "scrubber" column consisting of Sepharose linked with proteins from allantoic fluid, Sendai virus, and Namalwa cells

**III. Potency**

- A. Neutralizing titer # of interferon units neutralized by the contents of one vial
- |            |      |
|------------|------|
| Namalwa    | < 25 |
| Leukocyte  | < 25 |
| Fibroblast | < 25 |

**IV. Ampouled Preparation**

- A. Contents Freeze-dried material from 1 ml purified bovine globulin in 0.15M NaCl
- B. Reconstitution 2 ml water containing 0.1% SDS
- C. Storage temperature 4°C or lower

**V. Producer**

Wellcome Research Laboratories

**I. Reagent**

- A. Name Antiserum to human alpha-2b (HuIFN- $\alpha$ b)
- B. Type Antiserum
- C. Catalog Number G037-501-572
- D. Class WHO International Reference Reagent
- E. Reference Note # 44

**II. Production Data**

- A. Species Human
- B. Immunizing antigen Recombinant interferon Alpha-2b
- C. Adjuvant used None. Antibodies to interferon occurred during HuIFN- $\alpha$ 2 treatment

**III. Potency**

- A. Neutralizing titer 1:9500 against 10 Laboratory Units of HuIFN- $\alpha$ 2

**IV. Purity**

- A. Sterility No bacteria or fungi were cultured from the preparation before or after freeze-drying
- B. Antibody cross-reactivity No detectable activity against natural HuIFN- $\beta$  or recombinant HuIFN- $\beta_{\text{ser17}}$

**V. Ampouled Preparation**

- A. Contents Lyophilized human serum globulin
- B. Volume 1.0 ml before freeze-drying
- C. Reconstitution 1.0 ml of sterile distilled water or an appropriate medium
- D. Storage temperature 4°C or lower

**VI. Producer & Contract**

Bulk serum provided by Dr. Wieland Wolf of Bioferon, Laupheim, Germany. Characterization and freeze-drying by The Medical College of Wisconsin

**VII. References**

16, 33, 41, 48, 49

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Name           | Antiserum to human fibroblast interferon |
| B. Type           | Specific anti-globulin to HuIFN- $\beta$ |
| C. Catalog Number | G028-501-568                             |
| D. Class          | Research Reference Reagent               |
| E. Reference Note | # 24                                     |

**II. Production Data**

- |                        |   |
|------------------------|---|
| A. Animal              | Suffolk-Hampshire female yearling sheep   |
| B. Immunizing material | Human fibroblast interferon prepared in diploid cell strains induced with poly (I) poly (C) and purified to a specific activity of $1 \times 10^6$ units per mg protein |
| C. Adjuvant used       | Freund's complete in booster inoculations   |

**III. Potency**

- |                       |   |
|-----------------------|---|
| A. Neutralizing titer | 1:12,000 against 8-10 units of HuIFN- $\beta$ |
|-----------------------|---|

**IV. Purity**

- |              |  |
|--------------|--|
| A. Sterility | No evidence of bacterial or fungal contamination |
|--------------|--|

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized sheep immune globulin                                      |
| B. Volume              | 0.5 ml   |
| C. Reconstitution      | 0.5 ml of sterile physiologic saline solution or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 3, 4, 8, 9, 14

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Name           | Control antiserum to human fibroblast interferon                      |
| B. Type           | Control serum globulin for G028-501-568 anti-HuIFN- $\beta$ antiserum |
| C. Catalog Number | G029-501-568  |
| D. Class          | Research Reference Reagent  |
| E. Reference Note | # 25  |

**II. Production Data**

- |                        |   |
|------------------------|---|
| A. Animal              | Suffolk-Hampshire female yearling sheep   |
| B. Immunizing material | Void volume from chromatography of crude human diploid fibroblast interferon preparations that did not bind to a controlled pore glass column |
| C. Adjuvant used       | Freund's complete in initial and booster inoculations   |

**III. Potency**

- |                       |  |
|-----------------------|--|
| A. Neutralizing titer | <50 against 8-10 units of HuIFN- $\beta$ |
|-----------------------|--|

**IV. Purity**

- |              |  |
|--------------|--|
| A. Sterility | No evidence of bacterial or fungal contamination |
|--------------|--|

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized sheep immune globulin                                      |
| B. Volume              | 0.5 ml before freeze-drying  |
| C. Reconstitution      | 0.5 ml of sterile physiologic saline solution or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 3, 4, 5, 9, 14

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Name           | Antiserum to human beta (HuIFN- $\beta$ ) |
| B. Type           | Antiserum                                 |
| C. Catalog Number | G038-501-572                              |
| D. Class          | WHO International Reference Reagent       |
| E. Reference Note | # 45                                      |

**II. Production Data**

- |                       |   |
|-----------------------|---|
| A. Species            | Human   |
| B. Immunizing antigen | Interferon $\beta$ (natural human fibroblast)                           |
| C. Adjuvant used      | None. Antibodies to interferon occurred during HuIFN- $\beta$ treatment |

**III. Potency**

- |                       |  |
|-----------------------|--|
| A. Neutralizing titer | 1:1700 against 10 Laboratory Units of HuIFN- $\beta$ |
|-----------------------|--|

**IV. Purity**

- |                              |   |
|------------------------------|---|
| A. Sterility                 | No bacteria or fungi were cultured from the preparation before or after freeze drying |
| B. Antibody cross-reactivity | No detectable neutralizing antibody was detected against HuIFN- $\alpha$ or $\gamma$  |

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized human globulin                                 |
| B. Volume              | 1.0 ml before freeze-drying                                |
| C. Reconstitution      | 1.0 ml of sterile distilled water or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

Bulk serum provided by Dr. Peter von Wussow of the Medizinische Hochschule, Hannover, Germany. Characterization and freeze-drying by The Medical College of Wisconsin

**VII. References**

16, 33, 41, 48, 49

**I. Reagent**

- A. Name Antiserum to human interferon-gamma
- B. Type Specific anti-globulin to HuIFN- $\gamma$
- C. Catalog Number G034-501-565
- D. Class Research Reference Reagent
- E. Reference Note # 34

**II. Production Data**

- A. Animal Rabbit
- B. Immunizing material HuIFN- $\gamma$  produced by human peripheral blood leukocytes stimulated with staphylococcal enterotoxin A and partially purified by control pore glass bead absorption and gel filtration
- C. Adjuvant used Equal volumes of Freund's complete and 30% Arlacel A in initial inoculations and Freund's incomplete in booster inoculations

**III. Potency**

- A. Neutralizing titer 1:1300 against 10 units of HuIFN- $\gamma$  in Sindbis virus/human WISH cell microtiter assay

**IV. Purity**

- A. Cross-reactivity No cross-reactivity against human IFN- $\alpha$  or IFN- $\beta$

**V. Ampouled Preparation**

- A. Contents Lyophilized rabbit immune globulin
- B. Volume 1.0 ml before freeze-drying
- C. Reconstitution 1.0 ml of sterile distilled water or an appropriate medium
- D. Storage temperature 4°C or lower

**VI. Producer & Contract**

University of Texas Medical Branch, Galveston  
Contract N01-AI-02659

**VII. References**

17, 18, 26, 31, 32, 38

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Name           | Antiserum to murine interferon-gamma           |
| B. Type           | Specific anti-globulin to murine IFN- $\gamma$ |
| C. Catalog Number | G032-501-565                                   |
| D. Class          | Research Reference Reagent                     |
| E. Reference Note | # 32   |

**II. Production Data**

- |                       |   |
|-----------------------|---|
| A. Animal             | Rabbit  |
| B. Immunizing antigen | Mouse IFN- $\gamma$ produced by stimulating murine spleen cells with staphylococcal enterotoxin A and partially purified by control pore glass bead absorption and gel filtration |
| C. Adjuvant used      | Freund's complete plus 30% Arlacel A in initial inoculation and Freund's incomplete in booster inoculations   |

**III. Potency**

- |                       |  |
|-----------------------|--|
| A. Neutralizing titer | 1:800 against 10 Laboratory Units of MuIFN- $\gamma$ |
|-----------------------|--|

**IV. Purity**

- |                              |  |
|------------------------------|--|
| A. Antibody cross-reactivity | No cross neutralization against other murine interferons |
|------------------------------|--|

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized rabbit immune globulin                         |
| B. Volume              | 1.0 ml before freeze-drying                                |
| C. Reconstitution      | 1.0 ml of sterile distilled water or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

University of Texas Medical Branch, Galveston  
N01-AI-02659

**VII. References**

17, 18, 20, 32, 34, 36, 37, 38

**I. Reagent**

- |                   |   |
|-------------------|---|
| A. Name           | Control for antiserum to murine interferon-gamma  |
| B. Type           | Control serum globulin for G032-501-565 antiserum |
| C. Catalog Number | G033-501-565                                      |
| D. Class          | Research Reference Reagent                        |
| E. Reference Note | # 33  |

**II. Production Data**

- |                        |  |
|------------------------|--|
| A. Animal              | Rabbit   |
| B. Immunizing material | Culture supernatant fluids of unstimulated mouse spleen cells, partially purified by control pore glass bead absorption and gel filtration |
| C. Adjuvant used       | Freund's complete plus 30% Arlacel A   |

**III. Potency**

- |                       |  |
|-----------------------|--|
| A. Neutralizing titer | No neutralizing activity against mouse IFN $\gamma$ was observed |
|-----------------------|--|

**IV. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized rabbit serum globulin                          |
| B. Volume              | 1.0 ml before freeze-drying                                |
| C. Reconstitution      | 1.0 ml of sterile distilled water or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**V. Producer & Contract**

University of Texas Medical Branch, Galveston  
N01-AI-02659

**VI. References**

17, 18, 20

**I. Reagent**

- |                   |  |
|-------------------|--|
| A. Name           | Antiserum to murine L-cell (MuIFN L-Cell)            |
| B. Type           | Specific anti-globulin to murine IFN- $\alpha/\beta$ |
| C. Catalog Number | G024-501-568   |
| D. Class          | Research Reference Reagent                           |
| E. Reference Note | # 19   |

**II. Production Data**

- |                        |  |
|------------------------|--|
| A. Animal              | Suffolk-Hampshire female yearling sheep  |
| B. Immunizing material | Mouse interferon prepared in L-929 cells induced by live Newcastle disease virus. IFN contained approximately 20% MuIFN- $\alpha$ and 80% MuIFN- $\beta$ . Booster inoculation was with L-cell IFN purified by affinity chromatography |
| C. Adjuvant used       | Freund's complete in booster inoculations  |

**III. Potency**

- |                       |   |
|-----------------------|---|
| A. Neutralizing titer | 1:300,000 against 8-10 reference units mouse IFN ( $\alpha$ and $\beta$ ) |
|-----------------------|---|

**IV. Purity**

- |                     |  |
|---------------------|--|
| A. Sterility        | No evidence of bacterial or fungal contamination     |
| B. Cross reactivity | Low levels of antibody to human leukocyte interferon |

**V. Ampouled Preparation**

- |                        |  |
|------------------------|--|
| A. Contents            | Lyophilized sheep serum globulin                                       |
| B. Volume              | 0.5 ml before freeze-drying  |
| C. Reconstitution      | 0.5 ml of sterile physiologic saline solution or an appropriate medium |
| D. Storage temperature | 4°C or lower   |

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 3, 4, 5, 8

**I. Reagent**

A. Name	Control for antiserum to murine IFN- $\alpha/\beta$
B. Type	Control serum globulin for G024-501-568
C. Catalog Number	G025-501-568
D. Class	Research Reference Reagent
E. Reference Note	# 20

**II. Production Data**

A. Animal	Suffolk-Hampshire female yearling sheep
B. Immunizing antigen	Void volume from affinity chromatography of crude mouse L-929 cell interferon preparations that did not bind to absorbed anti-interferon globulin or bovine plasma albumin bound to Sepharose 4B
C. Adjuvant used	Freund's complete in initial and booster inoculations

**III. Potency**

A. Neutralizing titer	< 50 against 8-10 units of mouse IFN ( $\alpha$ and $\beta$ )
-----------------------	---

**IV. Purity**

A. Sterility	No evidence of bacterial or fungal contamination
--------------	--

**V. Ampouled Preparation**

A. Contents	Lyophilized sheep serum globulin
B. Volume	0.5 ml before freeze-drying
C. Reconstitution	0.5 ml of sterile physiologic saline solution or an appropriate medium
D. Storage temperature	4°C or lower

**VI. Producer & Contract**

Medical College of Pennsylvania  
N01-AI-82568

**VII. References**

1, 3, 4, 5

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