

Certificate of analysis of sample IL-4 10/01

lot G017/LC1/030526

04-GMPHuIL4-50 µg

GMP-IL-4, 50 µg

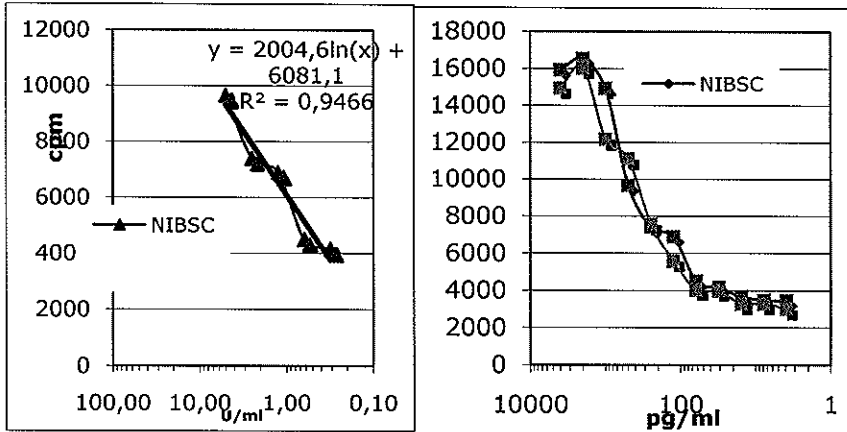


pg/ml	cpm	$y=a\ln(x)+b$	$\ln(x)=(y-b)/a$	U/cup	U/ng
4000,0	14946	a	2004	4,42	83,4
2000,0	16026	b	6081	4,96	143,0
1000,0	12174			3,04	20,9
500,0	11121			2,51	12,4
250,0	7564			0,74	2,1
125,0	5584			-0,25	0,8
62,5	4018			-1,03	0,4
31,3	3972			-1,05	0,3
15,6	3278			-1,40	0,2
7,8	3293			-1,39	0,2
3,9	3003			-1,54	0,2

NIBSC standard TF1 cells

Average **6,8**
S.D. **1,4**

6,8 10**6 U/mg



Brussels 1090, 20 august 2010
Lieven GEVAERT, bio-engineer



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lot G017/LC1/030526

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GMP-IL-4, 50 µg

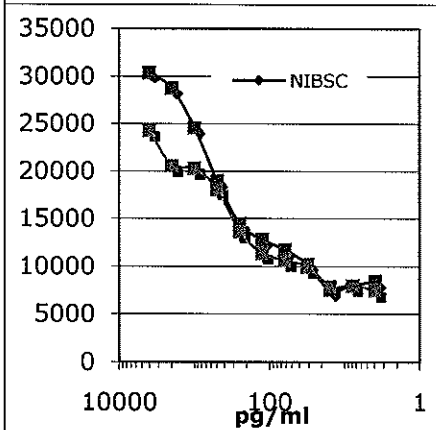
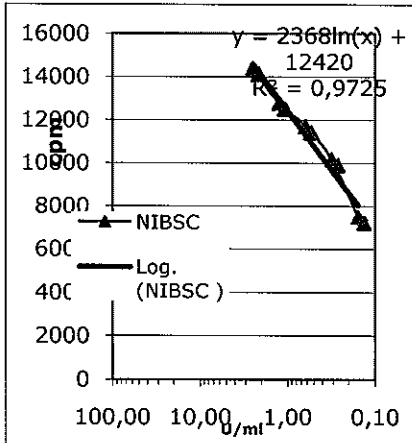


pg/ml	cpm	$y = a \ln(x) + b$		$\ln(x) = (y-b)/a$	U/cup	U/ng
4000,0	24270	a	2368	5,00	149,0	37
2000,0	20545	b	12420	3,43	30,9	15
1000,0	20283			3,32	27,7	28
500,0	18018			2,36	10,6	21
250,0	13590			0,49	1,6	6,6
125,0	11325			-0,46	0,6	5,0
62,5	10585			-0,77	0,5	7,4
31,3	9904			-1,06	0,3	11
15,6	7844			-1,93	0,1	9
7,8	7935			-1,89	0,2	19
3,9	7413			-2,11	0,1	31

NIBSC standard TF1 cells

Average **6,3**
S.D. **1,2**

6,3 10**6U/mg



Brussels 1090, 8 september 2010

Lieven GEVAERT, bio-engineer



HIL4 (RECOMBINANT HUMAN INTERLEUKIN4)
STABILITY TESTING (on final container lot G017/LC1/030526/FP) NB: Time 0 = Final Container
a) After 7 days at 37°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	10.9 10 ⁶ U/mg	PASS
Abnormal toxicity / General safety	on mice	No weight loss, no abnormal reaction	Absence of symptoms	PASS
	on guinea-pigs	No weight loss, no abnormal reaction	Absence of symptoms	PASS
Sterility test	FTM (30-35°C)	Absence of growth	Absence of growth	PASS
	TSB (20-25°C)	Absence of growth	Absence of growth	PASS

b) After 3 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	11.8 10 ⁶ U/mg	PASS

c) After 6 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	20.7 10 ⁶ U/mg	PASS

d) After 9 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	12.0 10 ⁶ U/mg	PASS

e) After 12 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	13.8 10 ⁶ U/mg	PASS





HIL4 (RECOMBINANT HUMAN INTERLEUKIN4)

STABILITY TESTING (on final container lot G017/LC1/030526/FP) NB: Time 0 = Final Container

f) After 18 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Activity	Bioassay	> 5 10 ⁶ U/mg	13.2 10 ⁶ U/mg	PASS

g) After 24 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Abnormal toxicity / General safety	on mice	No weight loss, no abnormal reaction	Absence	PASS
	on guinea-pigs	No weight loss, no abnormal reaction	Absence	PASS
Sterility test	FTM (30-35°C)	Absence of growth	Absence of growth	PASS
	TSB (20-25°C)	Absence of growth	Absence of growth	PASS

h) After 36 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS

i) After 48 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS

j) After 60 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS





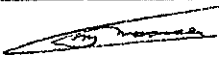
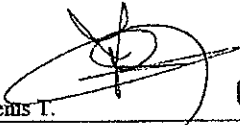
HIL4 (RECOMBINANT HUMAN INTERLEUKIN4)

STABILITY TESTING (on final container lot G017/LC1/030526/FP) NB: Time 0 = Final Container

k) After 72 months at -20°C

TESTS		SPECIFICATION	RESULT	CONCLUSION
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band at about 15kDa	PASS

Comment: No significant changes in Coomassie blue stained SDS-PAGE or in Western Blot were observed on the product after 72 months storage at $\leq -20^{\circ}\text{C}$.

Quality Control Director	QA Director - Qualified Person
Signature : 	Signature : 
Date : 05 OCT. 2009	Date : 06 OCT. 2009
Name : Massacr M.	Name : Braems T.

