CONTRACT FOR THE PROVISION OF „AUTHORITY´S TEST REPORT“

The Federal Republic of Germany

represented by the President of the **Paul-Ehrlich-Institut**,
Prof. Dr. Klaus Cichutek,
Paul-Ehrlich-Str. 51-59, 63225 Langen

(hereinafter referred to as PEI)

and

STATE INSTITUTE FOR DRUG CONTROL,

represented by
PharmDr. Zdeněk Blahuta

Šrobárova 48, 100 41 Prague 10, Czech Republic

(hereinafter referred to as client)

enter into the following contract for the preparation of „Authority´s Test Reports”:

Preamble

(1) The Paul-Ehrlich-Institut (PEI), the Federal Agency for Sera and Vaccines, is the competent German authority for the marketing authorisation of bacterial and viral

vaccines and acts as Official Medicines Control Laboratory (OMCL) for batch release. The PEI has long experience in the experimental testing of medicinal products.

(2) The client - the **State Institute for Drug Control** - intends to contract out to the PEI the testing for anti A and anti B Haemagglutins in human normal immunoglobulins, for anti D purity in human normal immunoglobulins and for anti-D potency in human anti-D immunoglobulins.

Section 1

Subject matter of the contract

(1) The subject of this contract is the performance of experimental tests in medicinal products. For this purpose, the client intends to receive „Authority´s Test Reports" from the PEI as evidence for the quality of the respective blood product batches.

(2) The PEI undertakes to carry out the tests of this contract on the samples received from the client. The PEI shall issue to the client an „Authority´s Test Report" containing the results of the test. The actual design of „Authority´s Test Report" shall be based on the example report shown in Annex 1.

(3) The client undertakes to provide the PEI with test samples in sufficient quantity for each test order. Relevant technical information shall accompany each batch. Transportation shall be organised by the client, care being taken that the required storage and transport conditions. Shipping costs and risks shall be borne by the client..

(4) The client shall pay the PEI for the tests charges in the amount laid down in Annex 2.

Section 2

Test performance

(1) The PEI shall perform the test and prepare the „Authority´s Test Report" within not more than 14 days and in case of an out of specification result within not more than 28 days .after receipt of the appropriate samples from the client.

(2) The PEI shall perform the test agreed upon in accordance with the state of scientific knowledge and with the same care required for the official batch testing of products authorised in Germany.

(3) The test and other services, if required, are performed in consideration of the requirements and rules of the quality assurance system at the PEI. For a major part of the test methods established at the PEI. Reference is made to the accredited test methods on the PEI website under this link:

http://www.pei.de/DE/institut/qualitaetsmanagement-pei/akkreditierungen/akkreditierungen-node.html

Section 3

Terms and Conditions of Payment

(1) The PEI shall charge the **State Institute for Drug Control** separately for each „Authority´s Test Report. Invoicing is carried out immediately after the performance of the test. If possible, the invoice is transmitted together with the „Authority´s Test Report" by regular mail. Each invoice from the PEI shall include the necessary details for the respective bank transfer (e.g. invoice number, transaction number, and bank details). The invoice shall be paid by the client within 41 days from invoice date. A bank transfer is the preferred method of payment. If, in exceptional cases, payments are carried out by check, the respective payment is considered as carried out only when the check has been paid into the account. The amount shall be paid without deductions. Any fees, banking charges, etc. shall be borne by the client.

(2) The fees laid down in Annex 2 refer to the delivery of „Authority´s Test Reports" by regular mail. Additional fees are charged for special forms of delivery (e.g.

certified or express mail) or other additional services (e.g. certification by embassies or issuing of copies) on request of the client.

(3) The PEI may charge for late payment default interest.

Section 4
Use of the „Authority´s Test Reports“

The State Institute for Drug Control may use the „Authority´s Test Reports" only in compliance with the contractual purpose laid down in the preamble to this contract. Any other uses require prior written consent by the PEI.

Section 5
Confidentiality

(1) The parties shall treat all information on internal relationships and processes of the other party received in connection with this contract as confidential.

(2) The obligation to treat information as confidential does not apply if the respective party provides proof that the respective information

- was already known to the party,
- was lawfully acquired by third parties
- was already publicly known,
- became publicly known through no fault of the receiving party,
- was independently developed outside the collaboration agreed upon in this contract, or
- should be disclosed based on legal obligations, or judicial or official order.

(3) PEI commits not to disclose to third parties the results of assays and information in the context of this agreement and terms of reference.

Section 6
Liability

(1) Liability of the PEI shall be restricted to gross negligence and wilful misconduct.

Section 7
Term of contract

(1) This contract shall come into effect with the date of the last signature.

(2) The term of contract is 1 year from the date of its coming into effect. The contract shall end automatically after the end of this term, unless an extension of the contract is mutually agreed upon in writing. In case of an extension, especially the amount of the fees shall be revised and adapted.

The proposal for a revision shall be sent to the client for approval at the latest two months before the date of the possible renewal and will be validated by the signature of the client. The client reserves the right to cancel in case of an excessive increased cost.

The present agreement can be cancelled by each party at any time by sending of a recorded delivery letter with acknowledgement of receipt with a 6 months notice.

(3) The termination of the contract is possible only on solid ground. Solid ground for the client applies especially if the PEI repeatedly does not observe the scientific care agreed upon, or if it repeatedly does not deliver the „Authority´s Test Reports" within the periods agreed upon, or contravenes its obligations laid down in Section 5 of this contract. Solid ground for the PEI applies if the client repeatedly does not meet his payment obligations or contravenes its obligations laid down in Sections 4 and/or 5 of this contract.

(4) The regulations laid down in Section 4, 5 and 6 shall survive termination of this contract.

Section 8

Disagreement and disputes

(1) If disagreements or lawsuits appear between the State Institute for Drug Ccontrol and PEI relating to the execution of this present agreement, the two establishments commit to reach an amicable agreement.

Section 9

Final Clause

(1) If individual provisions of this contract should become null and void or ineffective, this shall not affect the validity of the other provisions laid down in this contract. In this case, the parties oblige to replace or amend such provisions by legally valid regulations which best fulfil the original intention of the parties to the contract.

(2) Any modifications of or amendment to this contract shall be drawn up in writing.

(3) This contract shall be subject to the laws of the Federal Republic of Germany. Langen in the *land* (federal state) of Hessen shall be the area of jurisdiction.

(4) The following annexes shall form part of this contract:

Annex 1: „Authority´s Test Report“
Annex 2: Fees
Annex 3: Reference to Guidelines and standards

Signatures

For the PEI:

Langen, Germany 02.09.15
(Place, date)

Prof. Dr. K. Cichutek
President of the Paul-Ehrlich-Institut

(Name of signatory)

(Signature)

For the State Institute for drug and control :

Praque, Czech Republic 10.8.2015
(Place, date)

PharmDr. Zdeněk Blahuta ,
State Institute for Drug Control

(Name of signatory)

(Signature)

Státní ústav pro kontrolu
Šrobárova 48
100 41 Praha 10
(100)

Annex 1: „Authority´s Test Report“

DAkkS Deutsche Akkreditierungsstelle D-PL-13072-01-00	**PAUL-EHRLICH-INSTITUT** **Federal Institute for Vaccines and Biomedicines** **63225 Langen, Germany**	

Section: Monoclonal and Polyclonal antibodies

Contracting party:	State Institute for Drug Control Section: Biological methods Srobarova 48 100 41 Prague 10, Czech Republic
Manufacturer:	Grifols
Product name:	Flebogamma DIF 50mg/ml
Kind of product:	human normal Immunoglobulin
Licence number:	
Batch number:	
Expiry date:	

Method:	**Anti-A and Anti-B Haemagglutinins**
Operating Procedure:	according to monograph 2.6.20 “Anti-A and Anti-B Haemagglutinins” method B: direct method

Reference preparation:	Immunoglobulin for anti-A/ Anti B antibodies test negative control WHO 7/308 Immunoglobulin for anti-A/ Anti B antibodies test positive control WHO 07/306

	Test result in titre steps
Product specifications	Anti-A: ≤ 1:64 Anti-B: ≤ 1:64
manufacturer´s result	
PEI´s result	

Result Sample	**Negative control**	**Positive control**

Remarks:

This batch has been examined using testing procedures for which the Paul-Ehrlich-Institute has been accredited.

Date: _____ **Responsible person:** _____

Annex 1: „Authority´s Test Report“

DAkkS Deutsche Akkreditierungsstelle D-PL-13072-01-00	**PAUL-EHRLICH-INSTITUT** **Federal Institute for Vaccines and Biomedicines** **63225 Langen, Germany**	

Section: Monoclonal and Polyclonal antibodies

Contracting party:	State Institute for Drug Control Section: Biological methods Srobarova 48 100 41 Prague 10, Czech Republic
Manufacturer:	Grifols
Product name:	Flebogamma DIF 50mg/ml
Kind of product:	human normal Immunoglobulin
Licence number:	
Batch number:	
Expiry date:	

Method:	**Anti-D purity**
Operating Procedure:	according to monograph 2.6.26 “Test for anti-D antibodies in human immunoglobulin”

Reference preparation:	Immunoglobulin WHO anti-D antibodies test negative control 04/140 Immunoglobulin WHO anti-D antibodies test positive control 04/132

	Test result in titre steps
Product specifications	negative (titre product ≤ titre positive control)
manufacturer´s result	
PEI´s result	

Result Sample	**Negative control**	**Positive control**

Remarks:

This batch has been examined using testing procedures for which the Paul-Ehrlich-Institute has been accredited.

Date: _____ **Responsible person:** _____

Annex 1: „Authority´s Test Report“

DAkkS Deutsche Akkreditierungsstelle D-PL-13072-01-00	**PAUL-EHRLICH-INSTITUT** **Federal Institute for Vaccines and Biomedicines** **63225 Langen, Germany**	

Section: Monoclonal and Polyclonal antibodies

Contracting party:	State Institute for Drug Control Section: Biological methods Srobarova 48 100 41 Prague 10, Czech Republic
Manufacturer:	Grifols
Product name:	Igamad 1500 IU
Kind of product:	human anti-D Immunoglobulin
Licence number:	
Batch number:	
Expiry date:	

Method:	**Anti-D potency**
Operating Procedure:	according to monograph 2.7.13 “Assay of human anti-D immunoglobulin” method C (flow cytometry)

Reference preparation:	2nd WHO International Standard 01/572, Anti-D-Ig human, 285 IU/ Ampule

	Test result in IU / ml
Product specifications	
manufacturer´s result	
PEI´s result	

Remarks:

This batch has been examined using testing procedures for which the Paul-Ehrlich-Institute has been accredited.

Date: _____ **Responsible person:** _____

Annex 2: Fees

The following fees apply for the performance and the preparation and delivery of the appropriate „Authority´s Test Report“:

1.	For anti A and anti B Haemagglutinins in human normal immunoglobulin	200.00 Euro
2.	For anti D purity in human normal immunoglobulin	200.00 Euro
3.	For anti-D potency in human anti-D immunoglobulin	600.00 Euro
4.	Other services in addition to the scope agreed upon (e.g. certified or express mail; or other additional services such as certification by embassies or issuing of copies on request of the client) shall be invoiced separately, depending on the workload.	

Annex 3: OMCL Guidelines and standards

The following guidelines and standards in force are taken into account in preparing the tests agreed upon:

- Ph. Eur. monograph 2.6.20
- Ph. Eur. monograph 2.6.26
- Ph. Eur. monograph 2.7.13