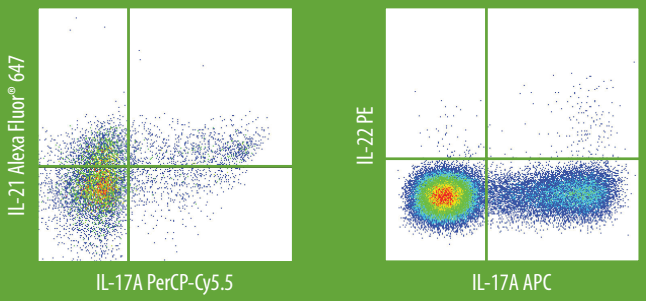
The Complete SOLUTION for Th17 Analysis

Induce, differentiate and analyze your mouse and human Th17 cells with novel reagents that are:

- *Well-characterized in relevant models*
- *Both specific and sensitive*

Flow Cytometry Antibodies:

- Act1
- CD161
- CD196
- IL-1RA
- IL-6
- IL-6Rα
- IL-17A
- IL-17F
- IL-17RA
- IL-21
- IL-22
- IL-23/12 p40
- RORγ(t)



Staining of IL-17A and either IL-21 (left) or IL-22 (right) in Mouse Th17-polarized Splenocytes.

ELISA Kits:

- IL-6
- IL-17A
- IL-17F
- IL-17AF
- IL-21
- IL-22
- IL-23
- TGFβ
- TNFα

Recombinant Proteins:

- IL-6
- IL-17A
- IL-17F
- IL-17AF
- IL-21
- IL-22
- IL-23
- TGFβ
- TNFα

IL-6 induction in RAW264.7 cells after treatment with recombinant mouse IL-17A, IL-17F or IL-17AF.

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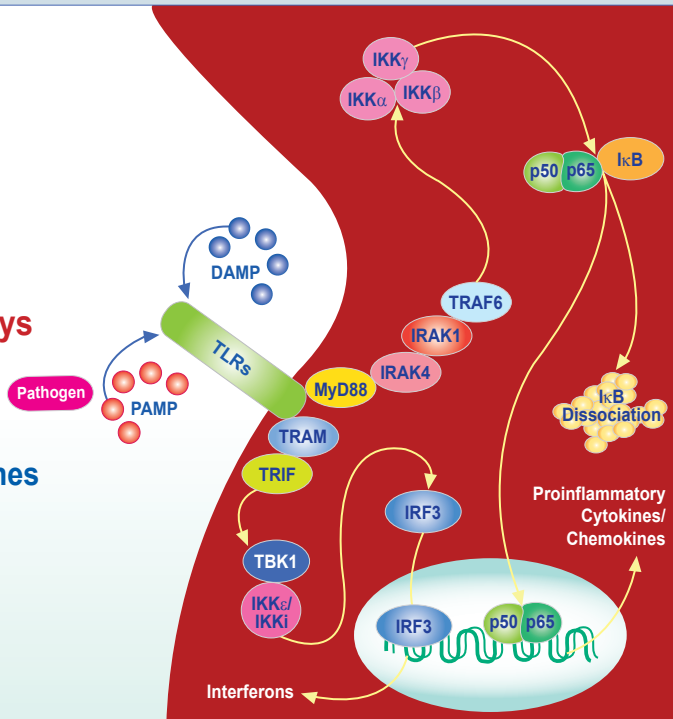
eBioscience®

IMGENEX

TLRSystem™

Leading edge antibodies, kits and reagents for Innate Immunity and Immune Signaling Pathways and now introducing the Reporter Cell Lines



New! **TLR/HEK 293 Stable Cell Lines & TLR/NF-κB/SEAPorter™ HEK 293 Stable Cell Lines**

Complete extensively validated sets of stably transfected or co-transfected cell lines to study TLR Expression and Functional Analysis or TLR-induced NF-κB activation pathways for screening TLR agonists and antagonists.

TLR/HEK 293 Stable Cell Lines

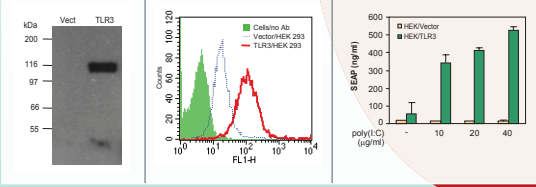
HEK 293 cells stably transfected with unique and original plasmids for human TLR1, TLR2, TLR3, TLR4, TLR5, TLR6, TLR7, TLR8 and TLR9.

TLR/NF-κB/SEAPorter™ HEK 293 Cell Lines

HEK 293 cells stably co-transfected with human Toll-like Receptor (TLR) and NF-κB reporter genes. Available are TLR2, TLR3, TLR4, TLR5, TLR7, TLR8 and TLR9/NF-κB co-transfected cell lines.

TLR3/HEK Cell Line (IML-203)

WB	FACS	FA
Anti-HA	IMG-315C	SEAPorter™



Representative validation data for TLR3/HEK 293 Stable Reporter Cell Line (IML-203) illustrates detection of expression by Western Blotting, by Flow Cytometry (FACS) analysis and Functional Assay (FA) by SEAPorter™ Assay through activation by Poly(I).Poly(C) ligand for TLR3. All IMGENEX TLR and TLR/NF-κB Stable Reporter Cell Lines undergo similar extensive validation.

TLR Overview & Handbook

IMGENEX & Innate Immunity: The Story Toll'd

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Fluorochrome Conjugates for TLR Phenotyping of DCs & T Cell Subsets by Flow Cytometry

Additional Applications: Immunohistochemistry • Western Blotting • ELISA

TLRs & Associated Proteins

- TLRs 1-13
- Phospho TLRs
- TRIF
- TIRAP/Mal
- TBK1
- MD-2
- NALPs 1-14
- Caspase-1
- IKKα
- IκBα
- p65
- MyD88
- NOD1
- NOD2

Dendritic Cells

- pDC/iDC
- CD207
- BDCA-2/CD303
- DC-SIGN/CD209
- CD11b
- CD11c
- CD14
- CD40
- CD80
- CD83
- CD86
- CD123

T Cells

- CD3
- CD4
- CD8
- CD25
- CD40L
- CD127/IL7R
- GITR
- GITRL
- iNKT
- FOXP3
- FOXP3Δ2
- GPR83

NF-κB Pathways

- NF-κB Peptide Inhibitors
- Phospho-IκBα ActivELISA™ Kit
- NF-κB/p65 ActivELISA™ Kit
- NF-κB SEAPorter™ Assay Kit

TLR Ligands/Agonists

- Pam_3CSK_4
- Poly(I).Poly(C)
- LPS
- Flagellin
- MALP-2
- Imiquimod
- R-848
- CpG ODN

ActivELISA™ Kits for Cytokines, Chemokines + Inflammatory Mediators

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- IL-1α
- IL-1β
- PGE_2

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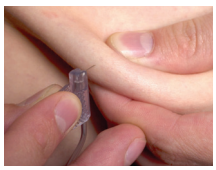

- Vivaglobin Sub-Q treatment is injected into the thigh, upper arm, stomach or hips on a weekly basis
- Injection-site reactions are typically mild to moderate and decrease substantially over time

Vivaglobin®

Immune Globulin Subcutaneous (Human)

Important Safety Information

Immune Globulin Subcutaneous (Human), Vivaglobin, is indicated for the treatment of patients with primary immunodeficiency (PI).

As with all immune globulin products, Vivaglobin is contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations and in persons with selective immunoglobulin A deficiency who have known antibody against IgA. If anaphylactic or anaphylactoid reactions are suspected, discontinue administration immediately and treat as medically appropriate.

Vivaglobin is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

In clinical trials, the most frequent adverse event was injection-site reaction, consisting of mild or moderate swelling, redness, and itching. No serious local site reactions were observed, and reactions tended to decrease substantially after repeated use. Other adverse events irrespective of causality included headache, gastrointestinal disorder, fever, nausea, sore throat, and rash.

As with all immune globulin (Ig) products, patients receiving Ig therapy for the first time, receiving a new product, or not having received Ig therapy within the preceding eight weeks may be at risk for developing reactions including fever, chills, nausea, and vomiting. On rare occasions, these reactions may lead to shock. Such patients should be monitored in a clinical setting during the initial administration.

Ig administration can transiently impair the efficacy of live attenuated virus vaccines, such as measles, mumps and rubella.

In clinical studies, administration of Vivaglobin has been shown to be safe and well tolerated in both adult and pediatric subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. Safety and efficacy were not studied in pediatric subjects under two years of age.

Please see brief summary of Prescribing Information on adjacent page.

Manufacturing and Distribution:
Vivaglobin is manufactured by CSL Behring AG and distributed by CSL Behring LLC.

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King of Prussia, PA 19406-0901 • USA
IO#9B046 12/2008

www.vivaglobin.com

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Vivaglobin®
Immune Globulin Subcutaneous (Human)

Manufactured by:
CSL Behring GmbH
35041 Marburg, Germany
US License No. 1765

Distributed by:
CSL Behring LLC
Kankakee, IL 60901 USA

CSL Behring

℞ **only**

Before prescribing, please consult full prescribing information, a brief summary of which follows:

INDICATIONS AND USAGE

Vivaglobin® Immune Globulin Subcutaneous (Human), is indicated for the treatment of patients with primary immune deficiency (PID).

CONTRAINDICATIONS

As with all immune globulin products, Vivaglobin® Immune Globulin Subcutaneous (Human) is contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations and in persons with selective immunoglobulin A (IgA) deficiency (serum IgA < 0.05 g/L) who have known antibody against IgA.

WARNINGS

Patients who receive immune globulin therapy for the first time, who are switched from another brand of immune globulin, or who have not received immune globulin therapy within the preceding eight weeks may be at risk for developing reactions including fever, chills, nausea, and vomiting. On rare occasions, these reactions may lead to shock. Such patients should be monitored for these reactions in a clinical setting during the initial administration of Vivaglobin® Immune Globulin Subcutaneous (Human).

If anaphylactic or anaphylactoid reactions are suspected, discontinue administration immediately. Treat any acute anaphylactoid reactions as medically appropriate.

Vivaglobin® is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. Because Vivaglobin® is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the CJD agent. The risk that such plasma-derived products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses during manufacture (see **DESCRIPTION** section for virus reduction measures). Stringent procedures utilized at plasma collection centers, plasma-testing laboratories and fractionation facilities are designed to reduce the risk of virus transmission. The primary virus reduction steps of the Vivaglobin® manufacturing process are pasteurization (heat treatment of the aqueous solution at 60°C for 10 hours) and ethanol - fatty alcohol / pH precipitation. Additional purification procedures used in the manufacture of Vivaglobin® also potentially provide virus reduction. Despite these measures, such products may still potentially contain human pathogenic agents, including those not yet known or identified. Thus, the risk of transmission of infectious agents cannot be totally eliminated. Any infections thought by a physician to have been possibly transmitted by this product should be reported by the physician or other healthcare provider to CSL Behring at 1-800-504-5434 (in the US and Canada). The physician should discuss the risks and benefits of this product with the patient.

During clinical trials, no cases of infection due to hepatitis A, B, or C virus, parvovirus B19, or HIV were reported with the use of Vivaglobin®.

PRECAUTIONS

General-Administer Vivaglobin® Immune Globulin Subcutaneous (Human), subcutaneously. **Do not administer this product intravenously.** The recommended infusion rate and amount per injection site stated under **DOSAGE AND ADMINISTRATION** should be followed. When initiating therapy with Vivaglobin®, patients should be monitored for any adverse events during and after the infusion.

Laboratory Tests - After injection of immunoglobulins, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens, e.g., A, B, D may cause a positive direct or indirect antiglobulin (Coombs') test.

Drug Interactions - Immunoglobulin administration can transiently impair the efficacy of live attenuated virus vaccines such as measles, mumps and rubella. The immunizing physician should be informed of recent therapy with Vivaglobin® Immune Globulin Subcutaneous (Human), so that appropriate precautions can be taken.

Vivaglobin® should not be mixed with other medicinal products.

Pregnancy Category C - Animal reproduction studies have not been conducted with Vivaglobin® Immune Globulin Subcutaneous (Human). It is also not known whether Vivaglobin® can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Vivaglobin® should be given to a pregnant woman only if clearly needed.

Pediatric Use - Vivaglobin® was evaluated in 6 children and 4 adolescents in the US and Canada study and in 16 children and 6 adolescents in the non-IND study. There were no apparent differences in the safety and efficacy profiles as compared to adult subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. The safety and efficacy of Vivaglobin® was not studied in pediatric subjects under two years of age.

Geriatric Use - The clinical study of Vivaglobin® Immune Globulin Subcutaneous (Human), did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

In clinical studies, administration of Vivaglobin® Immune Globulin Subcutaneous (Human), has been shown to be safe and well tolerated in both adult and pediatric subjects. Reactions similar to those reported with administration of other immune globulin products may also occur with Vivaglobin®. Rarely, immediate anaphylactoid and hypersensitivity reactions may occur. In exceptional cases, sensitization to IgA may result in an anaphylactic reaction (see **CONTRAINDICATIONS**).

Should evidence of an acute hypersensitivity reaction be observed, the infusion should be stopped promptly, and appropriate treatment and supportive therapy should be administered.

In the US and Canada clinical study, the safety of Vivaglobin® was evaluated for 15 months (3-month wash-in/wash-out period followed by 12-month efficacy period) in 65 subjects with PID. The most frequent adverse reaction was local reaction at the injection site. Table 5 summarizes the most frequent adverse events by subject reported in the clinical study, and Table 6 summarizes the most frequent adverse events by infusion.

Table 5: Most Frequent Adverse Events by Subject *Irrespective* of Causality* in the US and Canada Study

Adverse Events (≥ 10% of subjects)	**No. of Subjects (% of total)**
Adverse Events at the Injection Site	60 (92%)
Non-Injection Site Reactions	
Headache	31 (48%)
Gastrointestinal disorder	24 (37%)
Fever	16 (25%)
Nausea	12 (18%)
Sore throat	11 (17%)
Rash	11 (17%)
Allergic reaction	7 (11%)
Pain	6.7 (10%)†
Diarrhea	6.7 (10%)†
Cough increased	6.7 (10%)†

*Excluding infections

† Due to missing subject diary information, values listed are estimates.

Table 6: Most Frequent Adverse Events by Infusion *Irrespective* of Causality* in the US and Canada Study

Adverse Events (≥ 1% of infusions) (Number of Infusions: 3656)	**No. of Adverse Events** (Rate**)
Adverse Events at the Injection Site	1789 (49%)
Mild	1112 (30%)
Moderate	601 (16%)
Severe	65 (2%)
Unknown Severity	11 (< 1%)
Non-Injection Site Reactions	
Headache	159 (4%)
Gastrointestinal disorder	40.3 (1%)†

*Excluding infections

**Rate = number of reactions/infusion

†Due to missing subject diary information, values listed are estimates.

Table 7 summarizes the most frequent related adverse events by subject reported in the clinical study, and Table 8 summarizes the most frequent related adverse events by infusion.

Table 7: Most Frequent Related Adverse Events by Subject* in the US and Canada Study

Related Adverse Event (≥ 2 subjects)	**No. of Subjects (% of total)**
Adverse Events at the Injection Site	60 (92%)
Non-Injection Site Reactions	
Headache	21 (32%)
Nausea	7 (11%)
Rash	4 (6%)
Asthenia	3 (5%)
Gastrointestinal disorder	3 (5%)
Fever	2 (3%)
Skin disorder	2 (3%)
Tachycardia	2 (3%)
Urine abnormality	2 (3%)

*Excluding infections

Table 8: Most Frequent Related Adverse Events by Infusion* in the US and Canada Study

Related Adverse Event (≥ 2 AEs) (Number of Infusions: 3656)	**No. of AEs (Rate**)**
Adverse Events at the Injection Site	1787 (49%)
Non-Injection Site Reactions	
Headache	59 (1.6%)
Rash	9 (0.2%)
Nausea	9 (0.2%)
Nervousness	4 (0.1%)
Asthenia	3 (0.1%)
Gastrointestinal disorder	3 (0.1%)
Skin disorder	3 (0.1%)
Urine abnormality	3 (0.1%)
Fever	2 (0.1%)
Dyspnea	2 (0.1%)
Gastrointestinal pain	2 (0.1%)
Tachycardia	2 (0.1%)

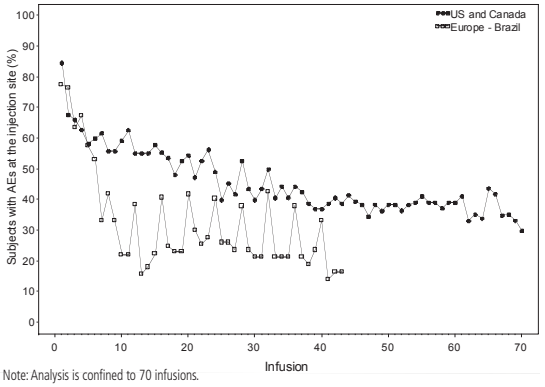
*Excluding infections

**Rate = number of reactions/infusion

In the non-IND Europe and Brazil clinical study, the safety of Immune Globulin Subcutaneous (Human), Vivaglobin® was evaluated for 10 months in 60 subjects with PID. The adverse events and their rates reported in this study were similar to those reported in the US and Canada study, with two notable exceptions for the related adverse events. These events were 59 episodes of headache (1.6%) and 2 episodes of fever (0.1%) in the US and Canada study and no episodes of headache and 18 episodes of fever (0.8%) in the Europe and Brazil study.

Local (Injection Site) Reactions - Local injection site reactions consisting of mostly mild or moderate swelling, redness and itching, have been observed with the use of Vivaglobin®. No serious local site reactions were observed. The majority of injection site reactions resolved within four days. Additionally, the number of subjects reporting local injection site reactions decreased substantially after repeated use (see Figure 1). Only three subjects in the US and Canada study and one subject in the Europe and Brazil study discontinued due to local site reactions.

Figure 1: Subjects Reporting Local Site Reactions By Infusion



Note: Analysis is confined to 70 infusions.

After administration, discard any unused solution and administration equipment in accordance with biohazard procedures.

HOW SUPPLIED

Vivaglobin® Immune Globulin Subcutaneous (Human), is supplied in single-use vials containing 160 mg IgG per mL. The following dosage forms are available:

NDC 0053-7596-03	Box of ten 3 mL vials
NDC 0053-7596-10	10 mL vial
NDC 0053-7596-15	Box of ten 10 mL vials
NDC 0053-7596-20	20 mL vial
NDC 0053-7596-25	Box of ten 20 mL vials

STORAGE

Store in the refrigerator at 2 - 8°C (36 - 46°F). Vivaglobin® Immune Globulin Subcutaneous (Human), is stable for the period indicated by the expiration date on its label. Do not freeze. Keep vials in storage box until use.

Based on April 2007 revision

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IL5, human
IL6, human
IL7, human
IL9, human
IL16, human
IL22, human
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