

Viral Antigens Recombinant Proteins

Large Scale Manufacturing, R&D and Custom Services



Meridian
Life Science, Inc.

www.MeridianLifeScience.com



Meridian Life Science, (MLS) is an industry leader in the commercial production of critical raw materials for the diagnostic market. MLS has a proven track record gained from over 25 years of cell culture, viral propagation, and protein purification experience. MLS has the expertise to develop and purify recombinant proteins from yeast, *E.coli*, insect or mammalian expression systems at research (mg) to commercial (g) scale. All manufacturing is performed following cGMP guidelines, with corresponding documentation and quality reviews.

ANTIGEN MANUFACTURING

NATIVE & RECOMBINANT

UPSTREAM

Cell and Virus Banking

Expression Systems:

- Mammalian (CHO, Vero, NS0, etc.)
- Bacterial (*E. coli*)
- Yeast (*P. pastoris*, *S. cerevisiae*, *H. polymorpha*)
- Baculovirus in Sf9
- Egg-based Virus Production
- Vaccinia & Adeno

Cell Culture: Flasks, Spinners, Rollers, Cell Factories, WAVE Bioreactors™

DOWNSTREAM

ÄKTA FPLC systems for SEC, Affinity, Ion exchange, HIC

Dialysis, ultracentrifugation, tangential flow

Expanded bed chromatography

Centrifugation, gradient centrifugation

Microfluidization, freeze/thaw, chemical lysis

PRODUCTS

ToRCH: Toxo, Rubella, CMV, HSV, VZV

Hepatitis A (HAV)

Epstein-Barr (EBV)

Measles & Mumps Virus

RSV

Rotavirus

Vaccinia

Hepatitis B Core

Hepatitis C Core, N-p22

HIV-1 gp41; HIV-1 p24

HIV-2 gp36

HSV-1 gG; HSV-1 gD

HSV-2 gG; HSV-2 gD

CKMM, CKMB, CKBB

EGF

PILOT TO COMMERCIAL SCALE

Custom Manufacturing | Yield Optimization | Purification & Testing | Live Virus Production (BSL2) | Virus Inactivation & Antigen Purification

ToRCH ANTIGENS

The acronym ToRCH was introduced in 1971 by Nahmias *et al.* to highlight a group of viral diseases which affect the fetus and newborn. ToRCH stands for *Toxoplasma gondii*, Rubella virus, Cytomegalovirus (CMV), and Herpes Simplex virus (HSV). The ToRCH test is used to screen pregnant women and newborns for antibodies to the infectious diseases included in the panel, if either the mother or newborn has symptoms. The blood test can determine if the person has had a recent infection, a past infection, or has never been exposed. These infections can be serious if they occur during pregnancy because they can cross the placenta from the mother to the developing fetus and can cause congenital defects in the newborn.

Meridian Life Science, Inc. manufactures viral antigens for the ToRCH panel following ISO and GMP regulatory requirements.

TOXOPLASMA ANTIGEN

Toxoplasma Antigen (Toxo) is prepared from the RH strain of *T. gondii* tachyzoites grown in HeLa cells.

8122	Toxo Grade II	1 mg/mL	Partially purified antigen
8131	Toxo Grade III	0.5 mg/mL	Enriched membrane fraction
8608	Toxo lysate	1 mg/mL	Crude Toxo lysate

RUBELLA ANTIGEN

Rubella virus antigen is prepared by the concentration of cell culture fluid from Vero cells infected with Rubella virus strain HPV77.

Various purity grades are prepared by gradient purification.

6076 / 6123	Rubella Grade IV	0.5 mg/mL	Highly purified antigen (>90%), available in TRIS or PBS buffer
6075	Rubella Grade III	0.1-0.2 mg/mL	Highly purified antigen (>90%)

CYTOMEGALOVIRUS ANTIGEN

Cytomegalovirus antigen (CMV) is prepared by the extraction of human fibroblast cells infected with CMV strain AD169. The antigens are purified by various methods of column purification and / or ultracentrifugation to provide various grades of antigen for a variety of assay types.

7504	CMV	0.2-0.5 mg/mL	Whole cell extract
7511	CMV-M	0.7-2.0 mg/mL	Nuclear extract
7090	CMV-M	0.3-1.0 mg/mL	Nuclear extract
7517	CMV EXT-2	0.3-0.5 mg/mL	Surface antigen extract
9268	CMV Grade II	1 mg/mL	Purified surface extract contains pp65, p52, pp150 and other key proteins
7507	CMV Grade III	1 mg/mL	Purified surface extract contains pp65, p52 and other key proteins
7508	CMV-NP	1 mg/mL	Nuclear extract
7509	CMVgB	1 mg/mL	Enriched for the CMV gB protein

HERPES SIMPLEX

Herpes Simplex antigen preparations are partially purified to reduce host cell components.

HERPES SIMPLEX TYPE I (HSV-1) NATIVE ANTIGEN

HSV-1 native antigens are prepared by the extraction of Vero cells infected with Herpes Simplex Type 1 strain F

7305	HSV-1	0.2-0.5 mg/mL	Partially purified whole cell lysate
7309	HSV-1 Concentrate	1.5-2.0 mg/mL	Concentrated partially purified whole cell lysate

HERPES SIMPLEX TYPE I (HSV-1) RECOMBINANT ANTIGEN

The HSV-1 recombinant antigens are expressed in yeast.

VTI510	HSV-1gD	>0.5 mg/mL	HSV-1 specific domain of gD gene expressed in yeast
VTI520	HSV-1gG	>0.5 mg/mL	HSV-1 specific domain of gG gene expressed in yeast

HERPES SIMPLEX TYPE 2 (HSV-2) NATIVE ANTIGEN

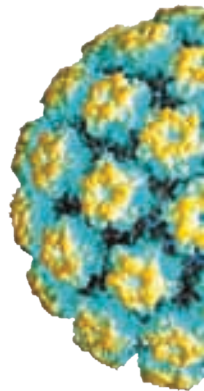
HSV-2 antigens are prepared by the extraction of Vero cells infected with Herpes Simplex Type 2 strain G.

7705	HSV-2	0.2-0.5 mg/mL	Partially purified whole cell lysate
7749	HSV-2 Concentrate	1.5-2.0 mg/mL	Concentrated partially purified whole cell lysate
9287	HSV-2gG Native	25-50 µg/mL	HSV-2 gG protein immunoaffinity purified from cell lysate

HERPES SIMPLEX TYPE 2 (HSV-2) RECOMBINANT ANTIGEN

The HSV-2 recombinant antigens are expressed in yeast

VTI540	HSV-2gD	>0.5 mg/mL	HSV-2 specific domain of gD gene expressed in yeast
VTI530	HSV-2gG	>0.5 mg/mL	HSV-2 specific domain of gG gene expressed in yeast



INFECTIOUS DISEASE ANTIGENS

Meridian Life Science, Inc. infectious disease antigens are used in testing for the presence of antibody to a pathogen. Products are carefully optimized and characterized to ensure high sensitivity and specificity in a variety of antibody detection assay formats. Applications in IVD include ELISA, latex agglutination, rapid tests and automated chemiluminescence. Each of these different testing formats can require a different grade or concentration of antigen for optimal results. The purity of the antigen is assessed by SDS-PAGE, Western Blot, ELISA and protein concentration.

HEPATITIS ANTIGEN

Partially purified HAV antigens are prepared from an extraction of FRhK-4 cells infected with Hepatitis A strain pHM175

8198	HAV	<25 µg/mL
8505	HAV 10X Concentrate	20-70 µg/mL

RUBEOLA ANTIGENS

7604	Measles (Rubeola)	0.2-0.5 mg/mL	Partially purified whole cell extract from Vero cells infected with the Measles Edmonston strain
9298	Measles (Rubeola) Recombinant	0.5 mg/mL	Purified recombinant

MUMPS ANTIGEN

Mumps antigens are purified from LLC-MK2 cells infected with the Enders strain

8099	Mumps Antigen	0.4-1.0 mg/mL	Partially purified whole cell extract
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EPSTEIN-BARR ANTIGEN

EBV antigens are extracted from P3HR-1 cells

8180	EBVgp125	40-70 µg/mL	Enriched for the EBV capsid protein gp125
7420	EBV	0.2-0.5 mg/mL	Whole cell extract

VARICELLA-ZOSTER ANTIGEN

VZV antigens are purified from human fibroblast cells infected with the ELLEN strain.

7209	VZV	0.2-0.5 mg/mL	Partially purified whole cell lysate
7740	VZV	0.2-0.5 mg/mL	Partially purified whole cell lysate Detergent Free
7201	VZV - PBS	0.2-0.5 mg/mL	Partially purified whole cell lysate Detergent Free

HUMAN IMMUNODEFICIENCY VIRUS

VTI310	HIV-1 gp41 Recombinant	>0.5 mg/mL	Protein expressed in yeast; 142 amino acids
VTI340	HIV-1 p24 Recombinant	>0.5 mg/mL	Protein expressed in yeast; 231 amino acids
VTI360	HIV-2 gp36 Recombinant	>0.5 mg/mL	Protein expressed in yeast; 134 amino acids



BLOOD BANKING ANTIGENS

HEPATITIS ANTIGENS

VTI610	Hepatitis B Core Recombinant	>0.5 mg/mL	Protein expressed in yeast. Entire core protein, 183 amino acids
VTI710	Hepatitis C Nucleocapsid (p22) Recombinant	>0.5 mg/mL	Protein expressed in yeast, 120 amino acids

HUMAN IMMUNODEFICIENCY VIRUS

VTI310	HIV-1 gp41 Recombinant	>0.5 mg/mL	Protein expressed in yeast; 142 amino acids
VTI340	HIV-1 p24 Recombinant	>0.5 mg/mL	Protein expressed in yeast, 231 amino acids
VTI360	HIV-2 gp36 Recombinant	>0.5 mg/mL	Protein expressed in yeast, 134 amino acids

LIVE VIRUS

MERIDIAN LIFE SCIENCE OFFERS LIVE VIRUSES FOR YOUR PRE-CLINICAL OR RESEARCH NEEDS

The World Health Organization (WHO) published a media release on a Measles (Rubeola) outbreak. Thirty countries in the European Union have reported a total of 6,500 Measles cases in the first four months of 2011. The continued spread of Measles is likely to continue as many people remain unimmunized or do not complete the full immunization schedule. France faces the largest outbreak, with 4,937 Measles cases reported from January to March 2011, a figure almost equal to the total of 5,090 cases reported for the full 2010 year. Measles remains one of the leading causes of death among young children globally, despite the availability of a safe and effective vaccine⁽¹⁾.

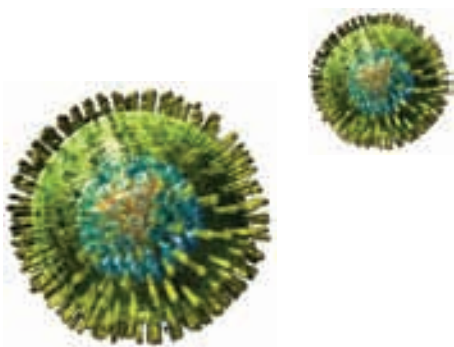
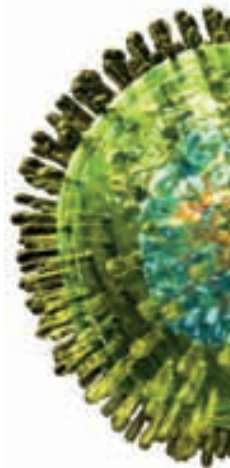
MLS has successfully manufactured the MMR (Measles, Mumps and Rubella) family of viruses for use in pre-clinical trials and immunization studies.

These live viruses are offered:

- Packaged in vials per end-user's titer and testing requirements
- Contract manufacturing turn-around-time is 6-8 weeks
- Tested for endotoxin and bioburden
- Other BSL2 viruses and purified viral antigens are available

In addition to live viruses, MLS expertise includes the manufacture of viral vaccines, viral challenge materials, virus-like particles (VLP), recombinant proteins, antigens, antibodies, proteins and immunoassay reagents.

⁽¹⁾ Press release from the World Health Organization, regional office for Europe on April 20, 2011.
www.euro.who.int/en/home



WHY PARTNER WITH MLS?

- Unparalleled experience and proven track record (25+ yrs)
- Core expertise in cell culture, ascites, protein production and purification
- Flexibility in scale and production systems
- Complete R&D and Process Development service
- Dedicated project management
- All manufacturing conducted under ISO 9001:2008 and cGMP
- Complete confidentiality

ANTIGEN USAGE

Native Product	Catalog #	Concentration	Assay Format	Lateral Flow	Dot Blot	Agglutination	Solid Phase	ELISA	Auto Analyzer	As a Control
Rubella Antigens										
Rubella III	6075	0.1-0.2 mg/mL	IgG	●	●	▲	●	●	●	▲
			IgM	■	●	■	●	●	●	▲
Rubella IV	6076	0.45-0.55 mg/mL	IgG	●	●	●	●	●	●	▲
			IgM	●	●	●	●	●	●	▲
Rubella IV PBS	6123	0.45-0.55 mg/mL	IgG	●	●	●	●	●	●	▲
			IgM	●	●	●	●	●	●	▲
Hepatitis A antigens										
HAV	8198	<25 µg/mL	IgG	▲	●	■	●	●	●	■
			IgM	▲	●	■	▲	▲	●	■
HAV Concentrate	8505	20-70 µg/mL	IgG	●	●	■	●	●	●	■
			IgM	●	●	■	●	●	●	■
Cytomegalovirus Antigen										
CMV	7504	0.2-0.5 mg/mL	IgG	▲	●	▲	●	●	●	■
			IgM	■	●	■	▲	▲	■	■
CMV-M	7090	0.5-0.7 mg/mL	IgG	▲	●	▲	●	●	●	■
			IgM	▲	●	■	●	●	●	■
CMV-M Concentrate	7511	1.5-2.0 mg/mL	IgG	●	●	▲	●	●	●	■
			IgM	●	●	▲	●	●	●	■
CMV-E-T 2	7517	0.4-0.6 mg/mL	IgG	▲	●	●	●	●	●	■
			IgM	■	●	▲	▲	▲	▲	■
CMV-III	7507	1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	●	●	●	●	●	●	■
CMV-II	9268	1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	●	●	●	●	●	●	■
CMV-NP	7508	1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	●	●	●	●	●	●	■
Herpes Antigens										
HSV-1	7305	0.2-0.5 mg/mL	IgG	▲	●	■	●	●	●	■
			IgM	■	●	■	■	■	■	■
HSV-1 Concentrate	7309	1.5-2.0 mg/mL	IgG	●	●	■	●	●	●	■
			IgM	▲	●	■	▲	▲	▲	■
HSV-2	7705	0.2-0.5 mg/mL	IgG	▲	●	■	●	●	●	■
			IgM	■	●	■	■	■	■	■
HSV-2 Concentrate	7749	1.5-2.0 mg/mL	IgG	●	●	■	●	●	●	■
			IgM	▲	●	■	▲	▲	▲	■
HSV-2gG Native	9287	25-50 µg/mL	IgG	●	●	▲	●	●	●	■
			IgM	●	●	▲	●	●	●	■
Varicella Zoster Antigens										
VZV	7209	0.5-1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	■	●	■	■	■	■	■
VZV II	7740	0.5-1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	▲	●	▲	▲	▲	▲	■
VZV PBS	7201	0.5-1.0 mg/mL	IgG	●	●	●	●	●	●	■
			IgM	■	●	■	■	■	■	■

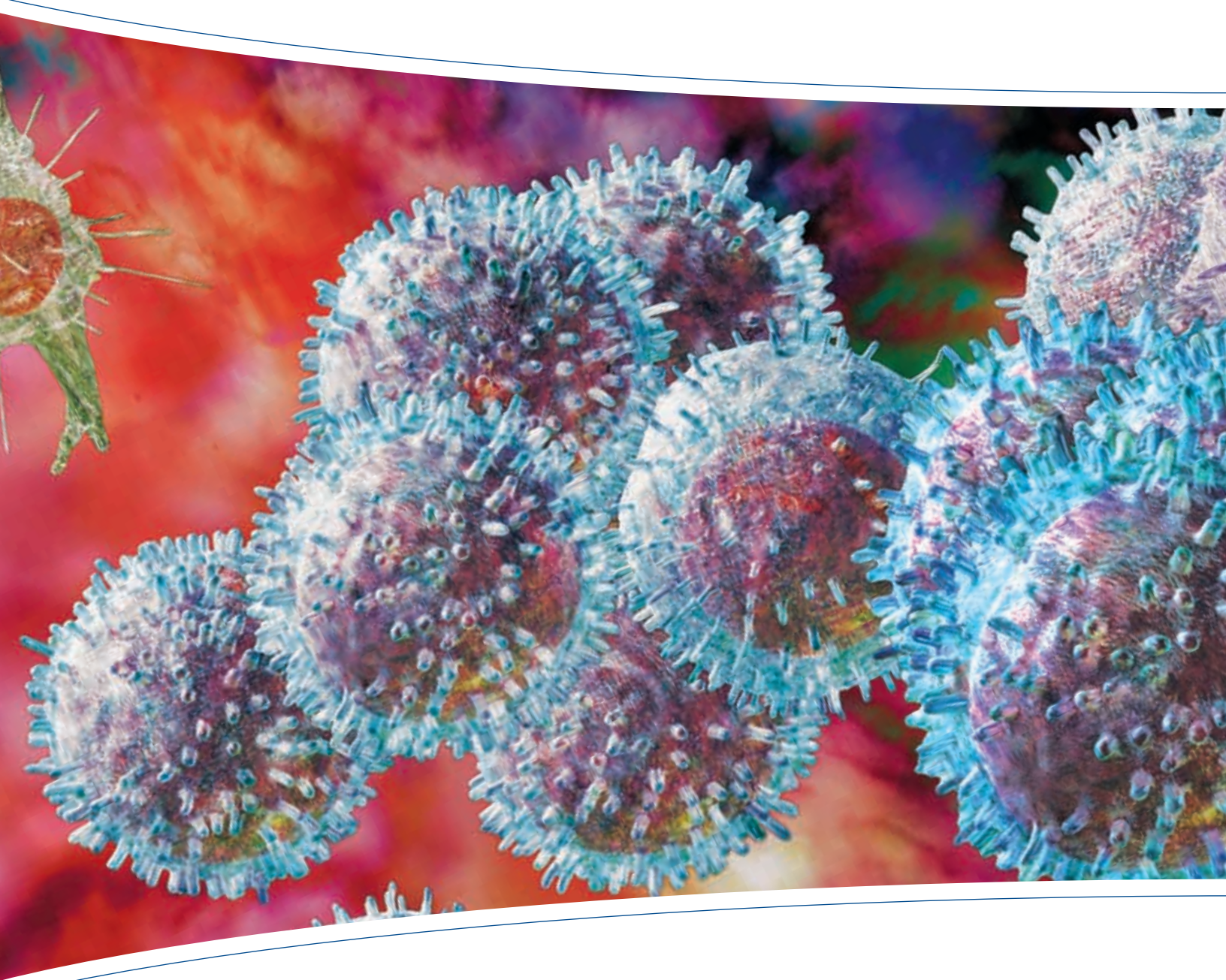
For More Information on Contract Manufacturing and Custom R&D Development, Contact a MLS Representative at contract-mfg@meridianlifescience.com.

FOR RESEARCH AND FURTHER MANUFACTURE USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.

Native Product	Catalog #	Concentration	Assay Format	Lateral Flow	Dot Blot	Agglutination	Solid Phase	ELISA	Auto Analyzer	As a Control
Toxoplasma Antigen										
Toxo II	8122	1.0 mg/mL	IgG	●	●	▲	●	●	●	■
			IgM	▲	●	▲	▲	●	●	■
Toxo III	8131	0.5 mg/mL	IgG	●	●	▲	●	●	▲	■
			IgM	●	●	▲	●	●	▲	■
Toxo Lysate	8608	1.0 mg/mL	IgG	■	●	■	●	●	■	■
			IgM	■	●	■	■	■	■	■
Epstein-Barr Antigen										
EBVgp125	8180	40-70 µg/mL	IgG	●	●	▲	●	●	●	■
			IgM	●	●	▲	●	●	●	■
EBV	7420	0.2-0.5 mg/mL	IgG	▲	▲	■	●	●	▲	■
			IgM	■	▲	■	▲	▲	▲	■
Other Native Antigens										
Mumps	8099	0.4-1.0 mg/mL	IgG	▲	●	▲	●	●	●	■
			IgM	●	●	▲	■	■	■	■
Rotavirus	7844	0.4-0.6 mg/mL	IgG	●	●	▲	●	●	●	●
			IgM	■	●	▲	▲	▲	●	●
RSV	8175	0.4-0.6 mg/mL	IgG	●	●	▲	●	●	●	●
			IgM	■	●	▲	▲	●	●	●
Rubeola (Measles)	7604	0.2-0.5 mg/mL	IgG	▲	●	■	●	●	●	●
			IgM	■	■	■	■	▲	▲	■
Recombinant Proteins										
Rubeola Recombinant Antigen	9298	0.4-0.6 mg/mL	IgG	●	●	■	●	●	●	●
			IgM	●	●	■	●	●	●	●
HIV Recombinant Antigens										
HIV-1 gp 41	VTI310	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
HIV-1 p24	VTI340	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
HIV-2 gp36	VTI360	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
Herpes Simplex Recombinant Antigens										
HSV-1gG	VTI520	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
HSV-1gD	VTI510	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
HSV-2gG	VTI530	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
HSV-2gD	VTI540	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
Hepatitis Recombinant Antigens										
Hepatitis B Core (HBVc)	VTI610	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
Hepatitis C Nucleocapsid (p22)	VTI710	>0.5 mg/mL	IgG	●	●	■	●	●	●	●
Human Creatine Kinase Recombinant Enzymes										
CK-BB	VTI830	>0.5 mg/mL	>500 U/mg	●	●	●	●	●	●	●
CK-MB I	VTI840	>0.5 mg/mL	>500 U/mg	●	●	●	●	●	●	●
CK-MB II	VTI810	>0.5 mg/mL	>700 U/mg	●	●	●	●	●	●	●
CK-MM I	VTI850	>0.5 mg/mL	>500 U/mg	●	●	●	●	●	●	●
CK-MM II	VTI820	>0.5 mg/mL	>500 U/mg	●	●	●	●	●	●	●
Human Epidermal Growth Factor (EGF)										
EGF	VTI880	>0.5 mg/mL	N/A	●	●	●	●	●	●	●
EGF Isoform B Enriched	VTI882	>0.5 mg/mL	N/A	●	●	●	●	●	●	●

● Recommended
▲ Assay Platform Based
■ Insufficient Data

IgM Assay performance may be enhanced by incorporating #8120 IgM Assay Diluent into the assay protocol
The above analysis is provided for information only
The information provided in the table above is based off of customer feedback
Performance of antigen is dependent on the assay platform and the additional assay components



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