



CUSTOM AND BULK PRODUCTS AND SERVICES

Reagents and Materials for IVD Manufacturing



Reagents and Materials for IVD Manufacturing

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IVD MANUFACTURING OVERVIEW

MP Biomedicals offers a full range of raw materials and services that provide solutions to IVD manufacturers regardless of the platform or format employed.

Our offering is supported by quality systems and regulatory expertise that surround our customers with convenience and value. Our worldwide manufacturing and distribution capabilities allow us to provide our global customers with the same lot-to-lot consistency. Our products are backed by rigorous quality control testing under the certified quality systems available for each manufacturing location.

MP Bio is a leader in the manufacture of raw materials, antibodies and reagents for the IVD industry. Our manufacturing capabilities are augmented by a supply chain that can sustain your production needs from small-scale to pilot to large-scale manufacturing. We have in-house expertise available 24 hours a day due to our global coverage with personnel qualified to answer your questions. MP Bio is your one source provider of IVD products and services.

Clinical Chemistry	Coagulation	Microbiology
Point-of-Care	Diabetes Care	Colloidal Gold
Histology	Blood Grouping	Molecular Biology

IVD DEVELOPMENT, MANUFACTURING, REGULATORY & COMMERCIALIZATION

From production and assembly, QC, technical support and regulatory, to the final commercialization of your product, MP Bio is your trusted partner for IVD development and manufacturing. Together with our own subsidiaries in strategic locations, we have built a solid network of trusted distributors around the world to reach global markets. At MP Bio, we can help manage all aspects of your development, manufacturing and commercialization needs and every step in between. Contact us today to explore the endless possibilities.



CONTRACT MANUFACTURING

- Rapid diagnostic tests (RDT)
- ELISA
- Molecular diagnostic tests
- Life science reagents
- Formulation, filling, packaging and kitting



RECOMBINANT PROTEIN DESIGN AND PRODUCTION

- Expression vector design
- Protein expression and purification
- Industrial-scale production



CONTRACT DEVELOPMENT

- Design and development of Rapid Diagnostic Tests
- Prototype verification, process validation, scale-up



PRODUCT COMMERCIALIZATION

- Worry-free product launching
- B2C and B2B networks
- Global logistic solutions



REGULATORY SUPPORT

- Consultation
- Technical dossier compilation
- IVD product registration

OUR IVD FACILITIES

MP Bio has been developing and producing IVD products since 1984 and currently manufactures IVD products in four platforms: Immunoblot, ELISA, Rapid Test, and Real-Time PCR. Our products are used for the detection of antibodies, antigens, analytes and biomarkers associated with diseases and medical conditions. We also develop and produce antigens (recombinant & native proteins) for IVD and research use. Our products are manufactured under the strictest international regulatory standards at both our U.S. and Singapore facilities to meet your requirements.



OUR CAPABILITIES

With more than 35 years of experience in the IVD business, we work with our business partners to develop and produce IVD products from prototype development to finished product. We also provide regulatory advice and services for product registration to the various authorities through the compilation of technical dossier required for registration. Need help with product commercialization? Through various collaborations, we can help our partners distribute products globally through our worldwide subsidiaries and distribution network.



QUALITY IS OUR PRIORITY ▶

Our ISO 13485 certified and FDA registered facilities in Singapore and the U.S. provide customers with a stringent quality management system for medical devices and ensures product specifications are consistently being met. At MP Bio, we have an experienced regulatory team to help deliver customer support on manufacturing documentation under our quality management system guidelines.

ISO 13485

**US FDA cGMP for IVD
(21. CFR Part 820)**

REAGENTS AND MATERIALS FOR IVD MANUFACTURING

BLOCKING AGENTS

It is well known that immunoassays for IVD applications are subject to interference from a range of debris in the sample other than the target analytes, such as proteins, antibodies and molecules, causing false positive or false negative testing results. Blocking reagents are designed to bind to open sites, preventing unbound debris from non-specifically binding. MP Bio offers a wide range of high quality blocking agents for IVD applications. Assay sensitivity can be significantly improved with the presence of these blocking agents by either reduced background signal or increased signal-to-noise ratio for various applications, including ELISA (Enzyme-Linked Immunosorbent Assay), immunohistochemistry, and immunoblotting.

Name	Cat. No.
IgG, Mouse	0864146
IgG, Rabbit	0855944
Purified bovine IgG	0855917
Albumin, bovine serum, immunoassay EIA grade	02180561
Albumin Bovine Fr V pH 7.0	08810025
Casein	02901293
Skim milk powder	02902887
Milk powder, whole	02902363

Alternative blocking agents:

Name	Cat. No.
Whole Human Serum	0855979
Whole Goat Serum	0855984
Normal Goat Serum	0864292
Normal Mouse Serum	0864293

GAMMA GLOBULIN PROTEINS

To support you with a complete workflow for immunoassays, in addition to antibodies, we also offer purified immunoglobulins, proteins, stabilizers and additives. These products are ideal for immunoassay development and manufacturing and are provided in different formats for optimal quality and consistency.

VALIDATED ▶ Know your reagent specificity and cross-reactivity for reliable results

VERSATILE ▶ Choose from multiple formats for immunoassays, microscopy, flow cytometry, protein expression and purification

Name	Cat. No.
Human Gamma Globulin, Fraction II	0882310
Bovine Gamma Globulin, Fraction II	08820414
Mouse Gamma Globulin Fraction	0855861
Purified Human IgG	0855908
Purified Mouse IgG	0855939
Purified Bovine IgG	0855917
Purified Hamster IgG	0855933
Horse IgG	08641441
Bovine Gamma Globulin, NZ Origin	02180625

BUFFERS

Our salts and buffers are ideal for use in IVD manufacturing, as they lack impurities that may interfere with biochemical reactions or give false positives in an assay. From Good buffers to salts that meet ACS, USP or UltraPure grades, MP Bio has a solution for your project.

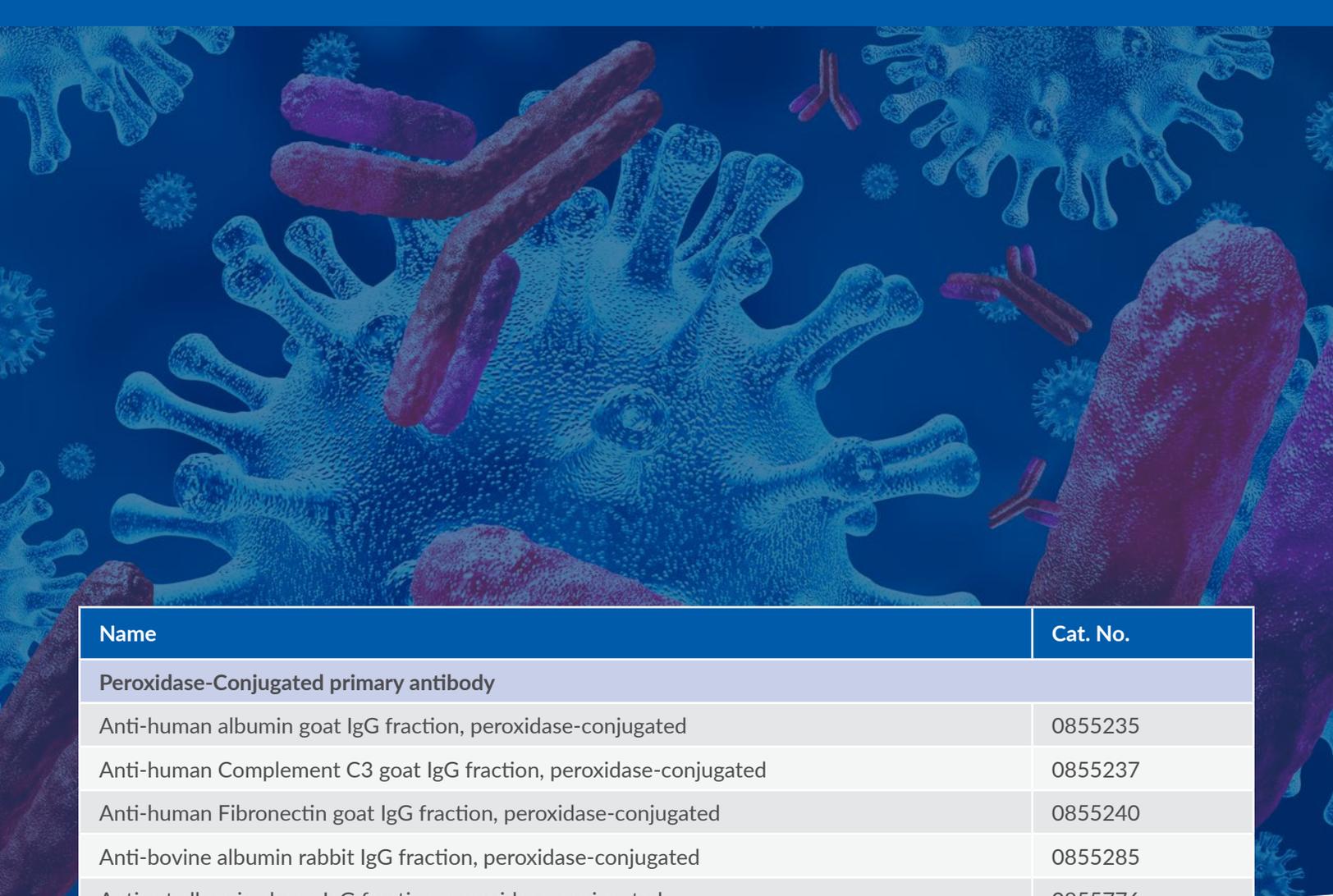
Name	Cat. No.
Bis-Tris Propane	02180943
Bis-Tris Propane, UltraPure	02FC0034
EDTA Disodium Salt Dihydrate, meets ACS/USP	02180978
EDTA Tetrasodium Dihydrate	02194660
HEPES Ultra Pure	02180923
HEPES, ≥99.5%	02FC0088
HEPES, Free Acid	02194827
HEPES, Sodium Salt	02194828
MOPS Sodium Salt >99%	02180998
MOPS, Free Acid, >99%	02180997
PIPES Disodium Salt	02FC0102
Potassium Phosphate Dibasic Trihydrate	02191432
Potassium Phosphate Dibasic Trihydrate	02180944
Potassium Phosphate Monobasic, ACS/NF	02180991
Potassium Phosphate Monobasic, Anhydrous, ACS Grade	02191430
Potassium Phosphate Tribasic, meets ACS/FCC	02180969
Potassium Sulfate, meets EP	02FC0065
Sodium Borate Decahydrate, ACS	02191436
Sodium Phosphate Dibasic Anhydrous, USP	02199802
Sodium Phosphate Dibasic, Anhydrous, meets USP/EP/JP	02180948
Tris	02180904
Tris Hydrochloride	02180905

PRIMARY ANTIBODIES

Primary antibodies are usually unconjugated immunoglobulins that directly bind to a specific antigen of interest, such as a protein, peptide, small molecule, etc. The variable region of the primary antibody recognizes an epitope on the target antigen. Primary antibodies are useful for detecting, purifying and quantifying target molecules in various diagnostic applications, such as ELISA, immunohistochemistry, flow cytometry and western blotting. A good primary antibody needs to recognize and bind the antigen with high affinity and specificity. With over 30 years of experience and expertise serving the antibody research community and in vitro diagnostic industry, MP Bio offers a large range of primary antibodies from various host species, ensuring:

- ▶ Superior overall affinity to antigens
- ▶ High tolerance to changes, such as pH or buffer
- ▶ Robust sensitivity of detection
- ▶ Trusted quality – validated by thousands of scientific publications

Name	Cat. No.
IgG Fraction	
Anti-human albumin goat IgG fraction	0855028
Anti-human complement C3 goat IgG fraction	0855033
Anti-human red blood cells rabbit IgG fraction	0855042
Anti-mouse Complement C3 goat IgG fraction	0855463
Anti-rat albumin sheep IgG fraction	0855729
Anti-rat complement C3 goat IgG fraction	0855730
Anti-sheep red blood cells rabbit IgG fraction	0855806
Anti-human red blood cells rabbit IgG fraction	08550422
FITC-Conjugated primary antibody	
Anti-mouse complement C3 goat IgG fraction, fluorescein-conjugated	0855500
Anti-guinea pig complement C3 goat IgG fraction, fluorescein-conjugated	0855385
Anti-human albumin goat IgG fraction, fluorescein-conjugated	0855162
Anti-human complement C1Q goat IgG fraction, fluorescein-conjugated	0855166
Anti-human complement C3 goat IgG fraction, fluorescein-conjugated	0855167
Anti-human complement C4 goat IgG fraction, fluorescein-conjugated	0855168
Anti-human fibrinogen goat IgG fraction, fluorescein-conjugated	0855169
Anti-rat complement C3 goat IgG fraction, fluorescein-conjugated	0855751
Anti-β-galactosidase (No Cross Anti- <i>E. coli</i>) goat IgG fraction, fluorescein-conjugated	0856030
Anti-β-galactosidase (No Cross Anti- <i>E. coli</i>) rabbit IgG fraction, fluorescein-conjugated	0856032
Anti-mouse complement C3 goat F(Ab') ₂ fragment, fluorescein-conjugated	0855510



Name	Cat. No.
Peroxidase-Conjugated primary antibody	
Anti-human albumin goat IgG fraction, peroxidase-conjugated	0855235
Anti-human Complement C3 goat IgG fraction, peroxidase-conjugated	0855237
Anti-human Fibronectin goat IgG fraction, peroxidase-conjugated	0855240
Anti-bovine albumin rabbit IgG fraction, peroxidase-conjugated	0855285
Anti-rat albumin sheep IgG fraction, peroxidase-conjugated	0855776
Anti-mouse complement C3 goat IgG fraction, peroxidase-conjugated	0855557
Monoclonal primary antibody	
Anti-GFP mouse monoclonal antibody, clone 11E5	08687382
Anti-GFP, mouse monoclonal antibody, clone 3E6 with BSA	08687402
Anti-actin mouse monoclonal antibody, clone C4	08691001
Anti-human collagen type II, mouse (Clone II-4CII) purified IgG	08631713
Anti- β -galactosidase, purified mouse monoclonal antibody	08633651
Anti-human hemoglobin monoclonal antibody from mouse	08634801
Anti-chondroitin-4-sulfate mouse monoclonal antibody	08636511
Anti-chondroitin-6-sulfate mouse monoclonal antibody	08636521
Anti-alpha-smooth muscle actin (mouse ascites fluid), mouse monoclonal antibody, clone 1A4	08637931
Anti-epithelial keratin-AE5 mouse monoclonal antibody	08691431
Anti-epithelial keratin-AE8 mouse monoclonal antibody	08691441
Anti-prostatic specific antigen (PSA) monoclonal antibody (Clone ER-PR8)	08691881
Anti-human B-Lymphocyte LN-3 monoclonal antibody	08693031

SECONDARY ANTIBODIES

Secondary antibodies bind to primary antibodies and can be used in detection and purification of target antigens. Secondary antibodies must have specificity for the antibody species and isotype of the primary antibody for detection to occur.

MP Bio offers a wide variety of Cappel® secondary antibodies with or without enzyme/fluorescence dye conjugation from multiple immunoglobulins, including human, rabbit and mouse. Enzyme (alkaline phosphatase or horseradish peroxidase) conjugated antibodies are

suitable for EIA, ELISA, blot immunostaining and cell/tissue staining, while fluorochrome conjugated antibodies are used for immunofluorescence assays, cell/tissue staining, blot immunostaining and fluorescence-activated cell sorting.

Most primary antibodies are of the IgG class and are produced in a common set of host species that includes rabbit, mouse, goat or chicken. Therefore, anti-mouse IgG, -rabbit IgG, -goat IgG or -chicken polyclonal antibodies are often used as secondary antibodies.

Antibodies to Mouse Immunoglobulins

Product Name	Conjugate	Host	Fraction	Cat. No.
Anti-mouse IgG (whole molecule) goat IgG fraction	None	Goat	IgG	0855455
Anti-mouse immunoglobulins (IgG, IgA, IgM) goat IgG fraction	None	Goat	IgG	0855461
Anti-mouse IgG Fc goat IgG fraction	None	Goat	IgG	0855459
Anti-rat IgG (No Cross Anti-mouse) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855755
Anti-mouse IgG (whole molecule) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855493
Anti-mouse IgG Fc goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855497
Anti-mouse immunoglobulins (IgG, IgA, IgM) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855499
Anti-mouse IgG F(Ab') ₂ goat F(Ab') ₂ fragment, fluorescein-conjugated	FITC	Goat	F(ab') ₂	0855507
Anti-mouse immunoglobulins (IgG, IgA, IgM) goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855556
Anti-mouse IgG F(Ab') ₂ goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855553
Anti-mouse IgG (whole molecule) goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855550
Anti-mouse IgG Fc goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855554

Antibodies to Human Immunoglobulins

Product Name	Conjugate	Host	Fraction	Cat. No.
Anti-human IgA (alpha chain) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855077
Anti-human IgG (whole molecule) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855145
Anti-human IgG goat F(Ab') ₂ fragment, fluorescein-conjugated (whole molecule)	FITC	Goat	F(ab') ₂	0855180
Peroxidase-Conjugated Goat IgG Fraction to Human Secretory IgA	HRP	Goat	IgG	0855215
Anti-human IgG (whole molecule) goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855220
Anti-human IgG Fc goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855226
Anti-human IgG Fc goat F(Ab') ₂ fragment, peroxidase-conjugated	HRP	Goat	F(ab') ₂	0855246

Antibodies to Rabbit Immunoglobulins

Product Name	Conjugate	Host	Fraction	Cat. No.
Anti-rabbit IgG (whole molecule) goat IgG fraction	None	Goat	IgG	0855622
Anti-rabbit IgG (whole molecule) goat IgG fraction, fluorescein-conjugated	FITC	Goat	IgG	0855646
Anti-rabbit IgG (whole molecule) goat F(Ab') ₂ fragment, fluorescein-conjugated	FITC	Goat	F(ab') ₂	0855658
Anti-rabbit IgG F(Ab') ₂ goat F(Ab') ₂ fragment, fluorescein-conjugated	FITC	Goat	F(ab') ₂	0855659
Anti-rabbit IgG (whole molecule) goat Fab fragment, peroxidase-conjugated	HRP	Goat	Fab	0855688
Anti-rabbit IgG F(Ab') ₂ goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855678
Anti-rabbit IgG Fc goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855679
Anti-rabbit IgG (whole molecule) goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855676
Anti-rabbit Immunoglobulins (IgG, IgA, IgM) goat IgG fraction, peroxidase-conjugated	HRP	Goat	IgG	0855682

ENZYME SUBSTRATES

Enzyme substrates are usually chemicals which can generate visible or fluorescent light as signals in the presence of suitable enzymes. Substrates are typically used in combination with primary antibodies or secondary antibodies that are conjugated to enzymatic reporter molecules, such as peroxidase, alkaline phosphatase or beta galactosidase. They are essential reagents in immunoassay to detect and quantify specific targets in life science and diagnostic manufacturing industry. MP Bio offers various enzyme substrates with high performance, stability, consistency, and convenience. Such substrates are designed to propagate the signal in an immunoassay.

Colorimetric substrates for ELISA	Name	Cat. No.
	TMB powder (3,3',5,5'-Tetramethylbenzidine)	0898050
	3,3',5,5'-Tetramethylbenzidine Liquid Substrate	04821808
	3,3',5,5'-Tetramethylbenzidine Liquid Substrate	02152346
	2,2'-Azino-bis-(3-ethyl-benzthiazoline-6-sulfonic acid) solution	04821809
	2,2'-Azino-bis-(3-ethyl-benzthiazoline-6-sulfonic acid) (ABTS powder)	02195023
	P-Nitrophenyl phosphate di(tris) salt, powder	02151766
O-Nitrophenyl- β -D-galactopyranoside	02102473	
Colorimetric substrates for Blotting	Name	Cat. No.
	BCIP/NBT, liquid substrate plus	0898077
	BCIP/NBT, stable alkaline phosphatase substrate	08980621
	5-Bromo-4-chloro-3-indolyl phosphate, disodium salt, powder	02150042
P-Nitro blue tetrazolium chloride, powder	02100416	
Colorimetric substrates for Immunohistochemistry	Name	Cat. No.
	3,3-Diaminobenzidine Tetrahydrochloride, powder	02150825
	3,3-Diaminobenzidine tablets	08980681



ENZYMES

MP Bio is quickly becoming the partner of choice in assay development, particularly in the IVD market. Our collection of enzymes with proven lot-to-lot consistency and stable supply chain are paramount in your manufacturing processes.

Clinical Chemistry	Name	Cat. No.
	Alcohol Dehydrogenase, 2× Crystalline	02100161
	α-Amylase	02100447
	Carbonic Anhydrase	02153879
	α-Chymotrypsin, 1× Crystallized	02152272
	α-Chymotrypsin, 3× Crystallized	02100461
	Hyaluronidase, from Bovine Testes	02100740
	Papain, from Papaya Latex	02100921
	Pepsin, Porcine, 1:10,000 NF	02FC0133
Superoxide Dismutase	02190117	
Coagulation/ Hematology	Name	Cat. No.
	Thrombin, Bovine	02101141
	Thrombin, Bovine, High Purity Grade	02154163
	Thrombin, Bovine, Low Specific Activity, NZ origin	02FC0098
	NZ Bovine Thrombin, Low Specific Activity	02199907
	NZ Bovine Thrombin, High Specific Activity	02180539
Trypsin, Porcine, 1-250, Virus free	02180914	
Histology	Name	Cat. No.
	Collagenase, type I, from <i>Clostridium histolyicum</i>	02195109
	Collagenase, type II, from <i>Clostridium histolyicum</i>	02100502
	Collagenase, type 3, from <i>Clostridium histolyicum</i>	02150704
Collagenase, type 4, from <i>Clostridium histolyicum</i>	02190110	
Lab Testing/Diabetes	Name	Cat. No.
	Glucose-6-Phosphate Dehydrogenase, from <i>Leuconostoc Mesenteroides</i>	02151187
	Glucose Oxidase, from <i>Aspergillus Niger</i>	02195196
β-Glucuronidase, from <i>Helix Pomatia</i>	02152284	
Molecular Diagnostics	Name	Cat. No.
	Deoxyribonuclease I, from Bovine Pancreas	02190062
	Proteinase K	02193504
	rProteinase K	02180660
	Ribonuclease A	02101076
	Ribonuclease A, Molecular Biology reagent	02193980
	Ribonuclease, DNase free	02FC0003
Streptokinase	02101114	

EMPOWERED™ RAW MATERIALS

Enhanced Quality Documentation, from small scale research to large scale manufacturing

PRODUCT SPECIFICATION

CERTIFICATE OF ORIGIN

BSE/TSE, GMO, MELAMINE,
AND SHELF LIFE STATEMENT

SUPPLY CHAIN INFORMATION

SUSTAINABILITY, TRANSPARENCY,
STABILITY

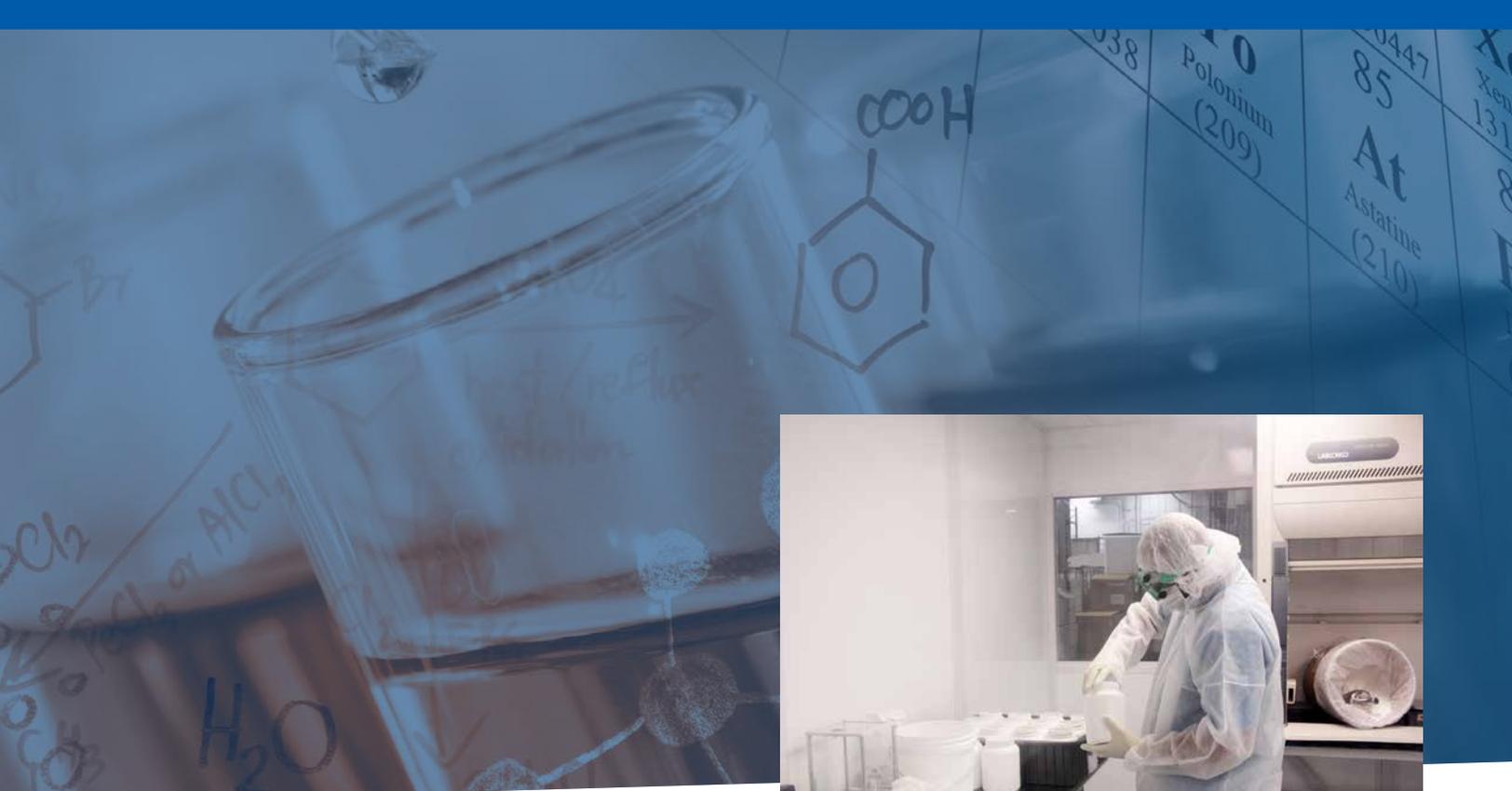
CHANGE CONTROL, SUPPLIER-CERTIFIED
QUALITY SYSTEMS

UNCOMPROMISED RELIABILITY FOR BIOPHARMACEUTICAL RAW MATERIALS ▶

Discover maximum potential for your biopharmaceutical raw materials with our eMPowered™ Raw Materials. Ever-increasing regulatory guidelines now place the risk management responsibility on drug manufacturers. With our eMPowered™ Raw Materials, you can minimize those risks, while saving time and money. Extensive documentation on manufacturing source, origin, purity, testing procedures and benchmark supply chain integrity are hallmarks of our eMPowered™ Raw Materials.

SELECTION, QUALITY, SERVICE AND ACCOUNTABILITY DELIVER VALUE FOR YOU ▶

Our showcase of more than 200 eMPowered™ Raw Materials enables us to partner with you by providing regulatory-certified raw materials with complete supply chain documentation. Our Supplier-Certified Quality System provides you with uncompromised reliability, supply chain transparency and sustainability that allow you to accelerate your biopharmaceutical product qualification while minimizing risk. High quality products with full documentation and on-time delivery bring optimum value to your program.



CONFIDENTIALITY DISCLOSURE AGREEMENTS ▶

We require and provide Confidentiality Disclosure Agreements for our eMPowered™ Raw Materials to ensure protection of your product and the integrity of our raw materials. Complete specifications, including Certificates of Origin, GMO declarations, shelf-life statements, change control and specialty testing are available and covered in the Confidentiality Disclosure Agreements.

TANGIBLE BENEFITS ▶

eMPowered™ Raw Materials eliminate risk from your supply chain. Our major production capabilities and historical expertise provide timely delivery of regulatory-documented products to speed up qualification and help you bring your products to market quicker. Supply chain transparency provides sustainability and change control for your manufacturing processes. Confidentiality Disclosure Agreements assure you of continued raw material product integrity. Together, these criteria provide you tangible benefits in real savings of time and money.

CHOOSE MAXIMUM PERFORMANCE ▶

Select from our continually growing showcase of eMPowered™ Raw Materials for maximum performance in biopharmaceutical manufacturing. Minimize risk and maximize supply chain security for a faster, safer and better way to take your products to market. Choose eMPowered™ Raw Materials, only available from MP Bio.

DEDICATED CLEANROOMS ▶

MP Bio recognizes the continuous improvements necessary to support the growing needs in today's regulated market. Operating under certified quality systems, with production sites regulated under ISO 9001:2015 as a minimum, MP Bio's eMPowered raw materials are sampled in a controlled environment and repacked in dedicated clean rooms (ISO Class 6) for animal origin (AO) and for non-animal origin (NAO), respectively. MP Bio strives to provide its customers with the quality and compliance needed in this highly regulated, quality-driven industry.

Salts & Buffers

Name	Cat. No.
2-Mercaptoethanesulfonic acid Sodium Salt	180928
α-Ketoglutaric Acid	180931
Ammonium Citrate Dibasic, Anhydrous; ACS	180967
Ammonium Sulfate	180900
Barium chloride dihydrate, ACS	183008
Bis-Tris Propane	180943
Bis-Tris Propane, UltraPure	FC0034
Calcium Pantothenate, meets USP	FC0094
Cetyltrimethylammonium bromide	FC0002
Choline Chloride	194639
Choline chloride, meets USP	FC0024
EDTA Disodium Salt Dihydrate, meets ACS/USP	180978
EDTA Tetrasodium Dihydrate	194660
Ferrous sulfate heptahydrate, meets ACS/USP	FC0013
Ferric Ammonium Citrate	158040
Ferric Chloride, ACS	194045
Ferric Citrate	195181
Ferric Citrate, Purified Powder	180579
HEPES Ultra Pure	180923
HEPES, ≥99.5%	FC0088
HEPES, Free Acid	194827
HEPES, Free Acid, >99.5%	180989
HEPES, Sodium Salt	194828
Linoleic Acid Sodium Salt	199875
Magnesium sulfate anhydrous	FC0012
Monosodium Glutamate Monohydrate, meets FCC	FC0101
MOPS Sodium Salt >99%	180998
MOPS, Free Acid, >99%	180997
PIPES Disodium Salt	02FC0102
Poly-L-Lysine HBr, MW 1000-5000	180932
Potassium bromide, meets ACS/USP	FC0048
Potassium Phosphate Dibasic Trihydrate	191432
Potassium Phosphate Dibasic Trihydrate	180944
Potassium Phosphate Monobasic, ACS/NF	180991
Potassium Phosphate Monobasic, Anhydrous, ACS Grade	191430
Potassium Phosphate Tribasic, meets ACS/FCC	180969
Potassium Sulfate, meets EP	FC0065
Rhodium (III) chloride hydrate	180942
Sodium Benzoate	180592
Sodium Borate Decahydrate, ACS	191436
Sodium Bromide, meets USP/EP/BP/JP	180968
Sodium Phosphate Dibasic Anhydrous, USP	199802
Sodium Phosphate Dibasic, Anhydrous, meets USP/EP/JP	180948
Sodium pyruvate	FC0042
Thioglycolic Acid Sodium Salt	102933
Tricine	194556
Tris	180904
Tris Hydrochloride	180905
Tris(2-carboxyethyl)phosphine hydrochloride	180927
Urea	180903
Urea, ACS, Prilled	180954
Urea, Ultra Pure	821519

Amino Acids & Enzymes

Name	Cat. No.
β-Alanine	183006
β-Glucuronidase	152284
Catalase, Human	191341
DL-Serine	102868
Glycine 99.5%	180901
Glycine, meets USP/EP	FC0105
Glycyl-L-glutamine hydrate GMP grade	180624
L-Ascorbic Acid	100769
L-Asparagine Monohydrate, meets NF/EP	FC0061
L-Asparagine, Anhydrous	180661
L-Aspartic Acid Sodium Salt Monohydrate	180982
L-Aspartic Acid, meets USP/EP	FC0062
L-Cysteine	FC0171
L-Cystine	101454
L-Cystine Dihydrochloride	105576
L-Cystine Dihydrochloride, 98%	180681
L-Cystine, meets USP	183000
L-Glutamic acid	180925
L-Histidine, Free base, meets USP/EP	180996
L-Hydroxyproline	FC0120
L-Lysine, Anhydrous	180980
L-Methionine, meets EP	FC0016
L-Proline, meets USP/EP/JP	FC0089
L-Tyrosine disodium salt dihydrate, ≥98%	183010
L-Valine, meets USP/EP/JP	FC0090
N-Acetyl-L-Cysteine, USP	180983
Proteinase K	193504
rCatalase from <i>E. Coli</i>	180733
Ribonuclease A	101076
Ribonuclease A, Molecular Biology reagent	193980
Ribonuclease, DNase free	FC0003
rProteinase K	180660
Streptokinase	101114
Superoxide Dismutase	190117
Thrombin, Bovine	101141

Nucleosides & Nucleotides

Name	Cat. No.
2-Deoxycytidine Hydrochloride	101483
5-Methyl-2'-deoxycytidine	180922
Adenine hemisulfate dihydrate	FC0023
Adenine Hydrochloride, Cell Culture Reagent	194608
Adenine, USP	199905
Adenosine, USP	199803
Cytidine, ≥99.6%	180694
Cytidine, Free base	194651
Guanine Hydrochloride	180689
Thymidine	194754
Thymine	103060
Uridine	103216
Uridine, Cell Culture Reagent	194763

Specialty Chemicals

Name	Cat. No.
2-Deoxy-D-Ribose	FC0019
2'-Deoxyguanosine Monohydrate	FC0052
3-Aminopropyltriethoxysilane	FC0025
Agar, meets NF	FC0092
α-Cyclodextrin	180930
Aluminum Isopropoxide, >99.99	180929
Ascorbic Acid, meets USP/BP	FC0047
Bentonite, EP	180649
BOC-Asp(OMe)-Fluoromethyl-Ketone	FK011
BOC-Val-Ile-[(S)-4-Amino-2,2-Difluoro-3-Oxo-Pentanoyl]-Val-Ile-OMe	DFK167
Capreomycin Sulfate, meets USP	180699
Caprylic acid sodium salt, meets EP	180716
Cellnest™ (Liquid)	180946
Cellnest™ (Powder)	180947
Cephalothin	194155
CHAPS	190319
CHAPSO	190320
Chloramphenicol, meets EP	180919
Cholesterol NF (animal origin)	180673
Cholesterol, semi-synthetic, meets EP	180714
D-(-)-Ribose	183016
D-(+)-Maltose monohydrate, meets USP	FC0009
D-(+)-Raffinose pentahydrate, 99%	FC0083
Demecolone	190195
Dextran Sodium Sulfate, MW=6,000–8,000	101518
Dextran, MW=60,000–90,000	183009
Dextran, MW=150,000	183014
Dextran, MW=35,000–50,000	101508
Dextran, MW=60,000–90,000	180140
Dextrose Monohydrate, meets USP	FC0026
Dextrose, Anhydrous, meets USP	FC0044
D-Glucosamine Hydrochloride, USP Grade	199893
D-Glucose, meets USP	180977
D-Mannitol, ACS	152540
D-Mannitol, meets USP/EP/BP	180966
Doxycycline Hyclate, USP	198955
D-Xylose, meets USP	FC0032
Flavine adenine dinucleotide, disodium (FAD, Na ₂)	180680
Galactose, Meets EP, plant origin	180648
Glutathione Reduced, >99%	180990
Guanidine Hydrochloride	194826
Guanidine Thiocyanate	180902
Guanosine, ≥98%	FC0095
Human recombinant Insulin, meets EP	FC0100
Hypotaurine	159711
Hypoxanthine Disodium Salt	105451
Hypoxanthine, 99%	FC0085
Imidazole	194829

Name	Cat. No.
Inosine	180679
Lactose monohydrate, meets NF/EP/JP	FC0033
L-Carnosine	FC0060
Linoleic Acid, ≥98%	FC0096
L-Ornithine Hydrochloride	194718
Lutrol F68, meets NF	180999
Methotrexate, USP/EP Grade	199855
Myristic Acid	FC0078
N-Acetyl-L-Cysteine, meets USP	180945
Niacin, meets EP	FC0134
Niacin, meets USP	FC0172
Niacinamide, meets EP	FC0084
Niacinamide, meets USP	183001
N-Lauroyl Sarcosine Sodium Salt	190289
Oleic Acid, >90%	102500
Oleic Acid, 99%	151781
Paclitaxel, meets USP	180910
Pancreatin 4X, USP	193975
Periodic Acid, ACS	183019
Phenol red sodium salt, ACS Grade	FC0031
Phenol Red, Free Acid, meets EP	183003
Pluronic F-68	FC0099
Polymyxin B Sulfate, meets USP/EP	180981
Potassium bromide, meets ACS/USP	FC0048
Pyridoxal hydrochloride	FC0015
Retinyl acetate	FC0014
Riboflavin, meets USP/EP	FC0091
rTrypsin, from E.Coli	180949
Sodium diatrizoate, meets USP	183012
Sodium Gluconate, meets USP	183002
Spermine	152070
Spermine Tetrahydrochloride	100474
Streptomycin sulfate, meets EP	180986
Sucrose, meets NF	FC0017
Sulfamethoxazole, USP	180639
Taurine, meets USP	180899
Thiamphenicol, 0.3%, Sterile	FC0006
Thiamphenicol, meets BP	180734
TIC10	180727
Tomatidine Hydrochloride	193506
Tranexamic Acid, meets USP	180973
Trimethoprim, USP	180638
Uracil	FC0063
Urea, meets USP	FC0093
Violacein	180907
Vitamin D3	FC0022
Z-Asp-Glu-Val-Asp-7-Amino-4-Trifluoromethyl-Coumarin	AFC138Z
β-D-Glucose, purity ≥97%	180691

NEW ZEALAND PROTEINS

MP Bio New Zealand Limited is a specialized manufacturer of high quality bovine proteins and a preferred supplier to global customers in the diagnostic, biopharmaceutical and animal health industry.

MP Bio New Zealand has an ISO 9001:2015 certification in place, and its Quality Systems are audited to cGMP standards. MP Bio is also an Approved Exporter and has a Risk Management Programme (RMP/HACCP) in place, approved by New Zealand's Ministry of Primary Industries (MPI). This gives customers the assurance of complete traceability of the products that MP Bio manufactures and supplies.

The heart of the process at MP Bio New Zealand is the use of chromatographic extraction for separation of various proteins from bovine blood plasma. This technology enables separation of different proteins based on ionic strength and affinity of the molecule. The secret to MP Bio's process is to NEVER denature the protein at any stage. Therefore, proteins are maintained in solution during the entire chromatographic process, which excludes the use of precipitation, heat or solvents to extract proteins. The outcome is a highly intact protein which retains all the necessary components needed for critical downstream applications.

MP Bio New Zealand manufactures a range of products that are used by the IVD industry. These include various grades of Albumin, Thrombin, Immunoglobulin G, Fibrinogen, and Transferrin.



BOVINE SERUM ALBUMIN (BSA)

MP Bio New Zealand manufactures various grades of BSA useful to the IVD industry. The grades include low endotoxin, essentially protease free, low free fatty acid, low IgG, and an ultra-low IgG grade BSA. The specification limits for free fatty acid content and IgG content are among the lowest available commercially.

- ▶ Custom pack sizes ranging from 5 gm to 5 kg
- ▶ Excellent lot-to-lot consistency
- ▶ Wide range of BSA grades to suit various applications in biopharmaceuticals, mammalian cell culture, fish vaccines, membrane testing, diagnostics, and a host of other applications
- ▶ The lowest free fatty acid and IgG content BSA available commercially
- ▶ Standard lot size is 80 kg; lot sizes of up to 160 kg can be manufactured upon request
- ▶ EDQM TSE Certificate of Suitability (CEP) is available for BSA
- ▶ All BSA grades can be gamma irradiated to 25 kgy or 50 kgy upon request

BOVINE THROMBIN

Thrombin is used throughout the diagnostics industry in a variety of coagulation assays, clotting factor tests and for defibrinating blood or plasma for serum controls. Thrombin is also used for site specific cleavage of recombinant fusion proteins and in biochemical and medical research applications.

MP Bio New Zealand manufactures both Low Specific Activity and High Specific Activity Bovine Thrombin. Prothrombin from bovine plasma is activated with thromboplastin extracted from bovine lung tissue. The product is manufactured at the Auckland facility with plasma sourced from New Zealand's Ministry of Primary Industries (MPI) approved abattoirs.

- ▶ The only bovine thrombin available from Oceania
- ▶ EDQM TSE Certificate of Suitability (CEP) for low specific activity Thrombin
- ▶ Available as a lyophilized powder in vials and as a bulk powder
- ▶ Large SKU range from 5 KU to 150 MU; Thrombin up to 1 MU is packaged in glass vials, and higher quantities as bulk powder
- ▶ Very competitively priced
- ▶ Thrombin is freeze dried in specially designed lyophilization trays to avoid operator exposure and product contamination
- ▶ Used by large global diagnostic companies as their primary source in high-end Coagulation Dx

IMMUNOGLOBULIN G (IgG)

Useful as a blocking agent in certain immunoassays that involve small hydrophobic analytes, steroids and hormones. It has replaced BSA in certain assays due to its higher molecular weight and potentially due to its tendency to help reduce cross reactivity with the molecule being tested. Lot sizes up to 25 kg are available in stock.

Name	Cat. No.
AlbumiNZ™ Bovine Albumin Microbiological Grade	02180620
AlbumiNZ™ Bovine Albumin Low Endotoxin	02199896
AlbumiNZ™ Bovine Albumin Low IgG	02199897
AlbumiNZ™ Bovine Albumin Essentially Protease Free	02199898
AlbumiNZ™ Bovine Albumin Low Free Fatty Acid	02199899
AlbumiNZ™ Ultra Low IgG BSA	02FC0076
Bovine Fibrinogen 90% Clottable	0882022
Bovine Fibrinogen 90% Clottable - Bulk	02FC0097
Bovine Thrombin, Low Specific Activity	02199907
Bovine Thrombin (Bulk), Low Specific Activity	02FC0098
Bovine Thrombin, High Specific Activity	02180539
IgG - Bovine Immunoglobulin G (pH 4.5–5.5)	0864140
Bovine Transferrin Iron Poor (Apo) (Heat Treated)	02152334
Bovine Transferrin Iron Saturated (Holo) (Heat Treated)	02152335

RECOMBINANT PROTEIN DESIGN AND PURIFICATION

MP Bio's recombinant antigens, native HBsAg antigens and Guinea-pig anti-HBs are produced at our ISO 13485:2016 certified and state-of-the-art facility in Singapore. We have been developing and producing these protein products for more than 20 years.

The recombinant proteins we have developed by cloning and production in *E. coli* cultures have been used in the development of diagnostic assays in Immunoblots, ELISA, and Rapid Tests (see Table 1).

Tests conducted to ensure batch-to-batch quality and consistency in recombinant proteins include:

- ▶ Protein Concentration A_{280}
- ▶ Identity: Western Blot/Manual Slotting
- ▶ Ratio of A_{260}/A_{280}
- ▶ SDS-PAGE (Coomassie Blue, Silver Stain)

CUSTOM DESIGN & PURIFICATION OF RECOMBINANT PROTEINS

MP Bio partners with scientists on custom design services to develop and mass produce recombinant proteins. Our development and production turnaround times are 4-6 weeks and 6-8 weeks, respectively, with each batch yielding 50-100 mg of recombinant protein. Turnaround times are dependent on production quantity, arising production issues, and QC testing procedures.

AUTOMATED RECOMBINANT PROTEIN PRODUCTION PROCESS



Bioreactor



Cell disruptor



AKTA Start

AKTA Pure

Sn	Microbes / Protein	Product Name	Unit	Product Description
1	HTLV-I	MTA-I	mg	rgp46-I - Recombinant env glycoprotein
2	HTLV-I	GD21	mg	rgp21-I - Recombinant transmembrane env protein
3	HTLV-II	K55	mg	rgp46-II - Recombinant env glycoprotein
7	HEV	pET2.1	mg	HEV recombinant antigen from the ORF 2 of HEV genotype 1 (Chinese strain), C-terminal of Capsid Protein
8	HEV	HEV 406.3-2	mg	Structural protein from ORF2 from Mexican Strain
9	HEV	HEV 406.4-2	mg	Structural protein from ORF3 from Mexican Strain
10	HEV	HEV 6-1-4	mg	Structural protein from ORF3 of Burmese Strain
11	GST Tag (fusion protein)	SJ26	mg	Glutathione-S-transferase
5	HCV	409-1-1	mg	NS3-1
6	HCV	33u	mg	NS3-2
7	HCV	5-1-1	mg	NS4
8	HCV	Clone 36	mg	NS5
9	HCV	CAP450	mg	Core / Capsid
10	HCV	HCV Core	mg	Core, Immunological domain (8 to 56)
11	HCV	HCV NS3	mg	NS3, Immunological domain (1192 to 1457)
12	HCV	HCV NS4	mg	NS4, Immunological domain (1916 to 1947)
13	HCV	HCV NS5	mg	NS5, Immunological domain (2212 to 2313)
14	TB (<i>Tubercle bacillus</i>)	TbDp	mg	Alanine and proline rich secreted protein, Apa
15	TB (<i>Tubercle bacillus</i>)	TbF6	mg	Fusion of different regions of the TB genome, Tetrafusion protein
16	HIV-2	HIV-2 gp36	mg	ENV protein
17	HIV-1	HIV-1 gp41	mg	ENV protein
18	HIV-1	HIV-1 p24	mg	GAG protein
19	Zika	Zika Envelop	mg	Env protein
20	Zika	Zika NS-1 N-Terminus	mg	NS1
21	Zika	Zika NS1 C-Terminus	mg	NS1
22	<i>Mycoplasma pneumoniae</i>	P1	mg	C-Terminal of Cytadhesin, P1, Type 1
23	<i>Chlamydia pneumoniae</i>	P54-N-Terminus	mg	P54 protein
24	<i>Chlamydia pneumoniae</i>	P54-Middle-Terminus	mg	P54 Protein
25	<i>Chlamydia pneumoniae</i>	Cpaf-m	mg	Chlamydia Protease Activating Factor-N terminal
26	<i>Chlamydia pneumoniae</i>	Cpaf-c	mg	Chlamydia Protease Activating Factor-C terminal
27	Dengue	NS1 (Type 1)	mg	NS1
28	Dengue	NS1 (Type 2)	mg	NS1
29	Dengue	NS1 (Type 3)	mg	NS1
30	Dengue	NS1 (Type 4)	mg	NS1

Table 1. Recombinant proteins produced by cloning and *E. coli* cultures

HEPATITIS SURFACE ANTIGENS AND COMPLEMENTING ANTIBODIES PRODUCTION

NATIVE HBSAG AND GUINEA PIG ANTI-HBS

MP Bio offers native HBsAg antigens purified from human plasma, which are often used for purposes such as controls, calibrators, immunogens for raising antibodies, assay development, and R&D. The human plasma used for HBsAg purification is drawn at licensed facilities, tested and found negative for antibodies to HIV-1/2 and HCV, non-reactive to HIV-1 RNA and HCV RNA by Nucleic Acid Test, and highly reactive to HBsAg (see Table 2).

Product (subtype)	Cat. No.	Unit	Description
HBsAg (ad)	07COMM9002	mg	Heat inactivated purified HBsAg, subtype "ad" in PBS, pH 7.2, 5% Sucrose, 0.01% Sodium azide
HBsAg (ad)	07COMM9004	mg	Heat inactivated purified HBsAg, subtype "ad" in PBS, pH 7.2, 5% Sucrose
HBsAg (ay)	07COMM9012	mg	Heat inactivated purified HBsAg, subtype "ay" in PBS, pH 7.2, 5% Sucrose, 0.01% Sodium azide
HBsAg (ay)	07COMM9014	mg	Heat inactivated purified HBsAg, subtype "ay" in PBS, pH 7.2, 5% Sucrose
Anti-HBs (ad)	07COMM9051	mg	Non-heat inactivated guinea pig anti-HBs, subtype "ad" in PBS, pH 7.2, 5% Sucrose, 0.1% Sodium azide
Anti-HBs (ay)	07COMM9061	mg	Non-heat inactivated guinea pig anti-HBs, subtype "ay" in PBS, pH 7.2, 5% Sucrose, 0.1% Sodium azide

Table 2. Native HBsAg antigens produced by extraction from human plasma and guinea pig anti-HBs raised against these proteins

QUALITY ▶

Product quality is assured from sourcing of plasma to the finished product.

The following tests are conducted to ensure batch to batch quality and consistency.

HBsAg:

- ▶ Protein Concentration A_{280} (E = 3.726)
- ▶ Activity End-Point Titration (1 mg/mL solution)
- ▶ Identity: Western Blot
- ▶ SDS-PAGE (Silver Stain)
- ▶ Purity: SE-HPLC

Anti-HBs:

- ▶ Protein Concentration A_{280} (E = 3.726)
- ▶ Activity End-Point Titration (1 mg/mL solution)
- ▶ SDS-PAGE (Silver Stain)

DEPENDABILITY DELIVERED.

In addition to our extensive portfolio of reagents and materials for IVD manufacturing, MP Bio also offers a collection of general and niche life science products, chemical services, diagnostic kits and reagents, custom adsorbents and dosimetry products and services. Our focus is on reducing the day-to-day complexities and uncertainties that scientists face so that you can move your projects forward quickly and confidently.

Our robust, easy-to-use instruments and reagents can be counted on to work every time, delivering high quality samples and data, day-in and day-out.

Our global reach ensures that we can source the reagents you need, consistently and uninterruptedly, even when other vendors simply can't deliver. Our flexibility and ability

to customize orders gives you the products and services that work best for your projects and not just the products that we've configured to meet the lowest common denominator. And our fast response time to customer inquiries ensures that your workflows keep on flowing.

When you choose MP Bio, you know you can worry less and discover more. That's because with MP Bio, dependability is always delivered. From small scale research to large scale manufacturing, we have been advancing science for over 50 years.

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New Zealand Bovine Proteins

MP Bio New Zealand Proteins are Chromatographically Extracted from Bovine Plasma under Quality Systems that are ISO Certified and Audited to cGMP Principles.

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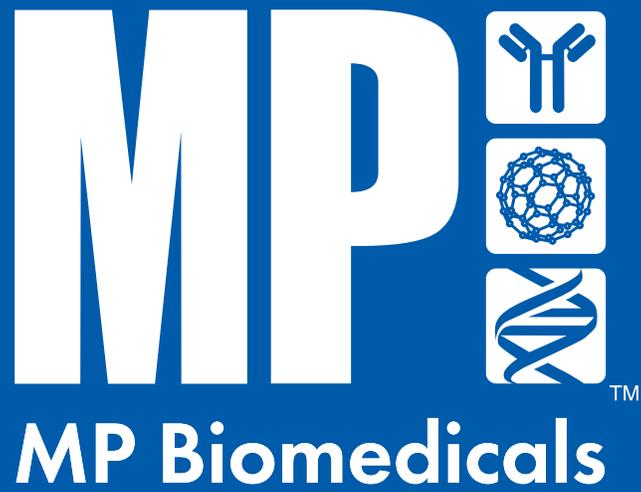
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