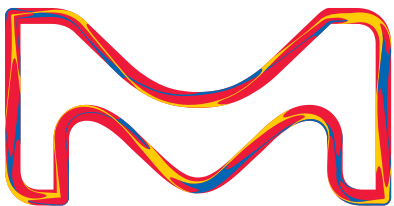


Blood Typing Monoclonal Antibodies FFMU

Blood typing intermediates
for further manufacturing use



MilliporeSigma is the U.S.
and Canada Life Science
business of Merck KGaA,
Darmstadt, Germany.

Millipore®

Preparation, Separation,
Filtration & Monitoring Products



We are your partner for monoclonal blood typing antibodies

MilliporeSigma is one of the leading providers of monoclonal antibodies to the blood typing market. Our large portfolio of standardized antibody intermediates for further manufacturing use allows manufacturers to create and manufacture a wide variety of blood typing reagents and devices. Our ISO-certified, FDA-licensed manufacturing facilities ensure the quality of these antibodies to meet global regulatory requirements.

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Blood Typing Intermediates

Millipore® portfolio of blood typing intermediates for further manufacturing use (FFMU) are standardized cell culture supernatants from cell lines expressing human or murine monoclonal antibodies. These FFMU intermediates are for use in formulating finished blood typing reagents or devices. By dilution, blending (where appropriate) and chemical additions, manufacturers can formulate their own finished reagents or devices with reactivity profiles suitable for their specific applications. The potency of each batch is carefully controlled to match that of an internal reference batch. All FFMUs contain 0.1% (w/v) sodium azide as a preservative.



ABO Intermediates FFMU

Anti-A (clone BIRMA-1) – JH

The BIRMA-1 antibody reacts strongly with all common forms of the A antigen, including A₂B. When used at appropriate concentrations, it will directly agglutinate most examples of A_x. It has the benefit of not agglutinating red cells classified as having the B(A) phenomenon, nor of agglutinating unmodified or enzyme treated B or O red cells. It is a proven raw material for the manufacture of Anti-A reagents and devices.

Anti-B (clone LB-2) – JM

This antibody reacts strongly with all common forms of the B antigen. It has the benefit of not agglutinating unmodified or enzyme treated A or O red cells, or A₁ red cells with the “Acquired B” antigen. JM does not have the same capacity for dilution as JE, due to formation of a cryoprecipitate upon further concentration. It is a proven raw material for the manufacture of Anti-B reagents and devices.

Anti-B (clone ES-4) – JE

ES-4 gives strong reactions with all red cells displaying regular forms of the B antigen. In common with the polyclonal Anti-B found in human group A plasma, this antibody agglutinates A₁ red cells that exhibit the “Acquired B” phenomenon. The major application for this FFMU is as a constituent of a blended Anti-A+B reagent. VK (clone ES-15) is an excellent blending partner for this purpose.

Anti-A(B) (clone ES-15) – VK

This antibody directly agglutinates group A red cells, including the weaker subgroups. It is particularly effective in detection of the weaker forms of A_x. It reacts with B cells to a lesser degree. It can be blended with an Anti-B FFMU such as JM or JE to formulate an Anti-A+B reagent.

All the ABO FFMUs are diafiltered against phosphate buffered saline and are licensed with the US FDA under shared manufacturing agreements.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-A	Murine IgM	BIRMA-1	7.2 ± 0.5	1–11 mg/mL	24 months	1 L Bulk	JH-1L-BK
						10 L Bulk	JH-10L-BK
Anti-B	Murine IgM	LB-2	7.2 ± 0.5	3–15 mg/mL	24 months	1 L Bulk	JM-1L-BK
						10 L Bulk	JM-10L-BK
Anti-B	Murine IgM	ES-4	6.0 ± 0.5	6–17 mg/mL	24 months	1 L Bulk	JE-1L-BK
						10 L Bulk	JE-10L-BK
Anti-A(B)	Murine IgM	ES-15	7.2 ± 0.5	3–15 mg/mL	24 months	1 L Bulk	VK-1L-BK
						10 L Bulk	VK-10L-BK

Anti-D Intermediates FFMU

In the opinion of most experts in the field of transfusion science, the ideal anti-D for typing patients is one that does not react with D category VI cells. Our four IgM Anti-D antibodies do not detect these D^{VI} cells and are therefore good candidates for use in formulating anti-D reagents for patient testing.

For typing donor blood, detection of D category VI red cells is required. FFMU KK, IgG anti-D made from clone MS-26, reacts with these cells and can be blended with any of the Millipore® IgM FFMUs to create a product that detects most D, weak D and partial D phenotypes.

All Millipore® Anti-D FFMU are diafiltered against phosphate buffered saline, and except for JV RUM-1, are licensed with the US FDA under shared manufacturing agreements.

Anti-D IgM (clone RUM-1) – JV

RUM-1 is the most avid of the four Millipore® IgM Anti-D FFMU intermediates. The fine specificity of this antibody is ideal for the manufacture of an IgM only Anti-D reagent for typing patient samples. RUM-1 is the international Anti-D standard assigned by the World Health Organization (WHO).

Anti-D IgM (clone MS-201) – KU

The antibody from MS-201 has the identical fine specificity as RUM-1. It is slightly less avid in its native state.

Anti-D IgM (clone MAD-2) – JT

MAD-2 was the first monoclonal Anti-D to be licensed by the US FDA. This antibody does not directly agglutinate some examples of weak D or partial D cells.

Anti-D IgM (clone TH-28) – KP

The antibody from clone TH-28 has a capability for detecting weak and partial D phenotypes that are greater than that of MAD-2 and less than that of RUM-1 or MS-201.

Anti-D IgG (clone MS-26) – KK

This antibody reacts with D^{VI} red cells. Since it is IgG, a sensitization technique is required to induce agglutination; e.g., anti-human globulin, enzyme addition or by several automated methodologies. It is an ideal blending partner with any of the Millipore® IgM Anti-D FFMUs to create an IgM/IgG blended reagent.

The results of the fine specificity testing of the Millipore® monoclonal anti-D antibodies are shown below. These results were taken from the proceedings of the Third International Workshop on Monoclonal Antibodies Against Red Blood Cells and Related Antigens in Nantes, 1996. The data for MAD-2 was taken from the original study made by the creators of the clone.

Clone	II	IIIa	IIIb	IIIc	IVa	IVb	Va	VI	VII	DFR	DBT	R ₀ ^{Har}	HMi	Howe	Carr	Casar i	Lore	Sor	1711 844
RUM-1	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+
MS-201	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+
TH-28	+	+	+	+	+	+	+	-	+	-	+	+	+	-	+	+	+	+	+
MS-26	-	+	+	+	-	-	+	+	+	+	-	-	+	+	+	+/-	+	+	+
MAD-2	+	NT	NT	NT	+	NT	(+)	-	+	-	-	-	-	NT	NT	NT	NT	NT	NT

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-D	Human IgM	RUM-1	7.2 ± 0.5	0.5–10 mg/mL	24 months	1 L Bulk	JV-1L-BK
						10 L Bulk	JV-10L-BK
Anti-D	Human IgM	MS-201	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	KU-1L-BK
						10 L Bulk	KU-10L-BK
Anti-D	Human IgM	MAD-2	7.2 ± 0.5	7–22 mg/mL	24 months	1 L Bulk	JT-1L-BK
Anti-D	Human IgM	TH-28	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	KP-1L-BK
						10 L Bulk	KP-10L-BK
Anti-D	Human IgG1	MS-26	7.2 ± 0.5	1–10 mg/mL	24 months	1 L Bulk	KK-1L-BK
						10 L Bulk	KK-10L-BK

Rh-Hr Intermediates FFMU

By offering choices of antibody for most major specificities, with subtle variations in fine specificity and avidity, we give manufacturers a range of options in formulating finished reagents or devices designed for particular applications and for differentiating their products in the market.

Anti-C IgM (clone MS-24) – KG^{1,3}

KG is the established market leader for RH2 phenotyping. Like most polyclonal Anti-C reagents, it gives weaker reactions with the rare R₂R₂ type than other C positive genotypes. MS-24 agglutinates C positive red cells in the presence of C^x or C^w antigens, but testing with rare C negative, C^w positive cells has shown that it does not cross react with the C^w antigen.

Anti-C IgM (clone MS-273) – VP²

The potency and avidity of VP and KG are very similar; however, there are subtle differences in their fine specificities. MS-273 agglutinates C positive red cells but testing with rare C negative, C^w positive cells has shown that it does not cross react with the C^w antigen.

Anti-c IgM (clone MS-33) – VR^{1,3}

Of all the antigens in the Rh Hr system, c shows the least variation. Examples of partial c are very rare; however, this antibody did react with the one example we were able to source.

Anti-c IgM (clone MS-35) – JR¹

JR is offered as an alternative to VR. There are no known differences in potency, specificity or avidity between these two Anti-c FFMU intermediates.

Anti-c IgG (clone MS-40) -JA²

JA FFMU is an intermediate containing Human IgG monoclonal anti-c reactive by an indirect antiglobulin test method.

Anti-E IgM (clone MS-12) – KC^{2,3}

Of the four Anti-E FFMUs, KC has the least capacity for dilution. Because of the incidence of weak and variant forms of E antigen expression, manufacturers may need to blend Millipore® Anti-E antibodies in order to formulate a balanced reagent with a broad spectrum of antigen recognition.

Anti-E IgM (clone MS-260) – KW^{2,3}

KW is our most potent Anti-E and therefore has the greatest capacity for dilution. Unlike many potent IgM monoclonal antibodies, it does not react with enzyme treated antigen negative red cells.

Anti-E IgM (clone MS-80) – KX²

KX has a potency level that is more than KC, but less than KW.

Anti-E IgM (clone MS-258) – KT^{2,3}

KT has a potency level roughly equivalent to KX.

¹ Non-diafiltered, minimal pH buffering.

² Diafiltered against phosphate buffered saline.

³ Licensed with the US FDA under shared manufacturing agreement.

Anti-e IgM (clone MS-16) – KZ^{1,3}

MS-16 may have the broadest specificity of the five Anti-e antibodies. Reactions are influenced by the presence or absence of the C antigen, which makes it similar to an Anti-Ce. It has been reported as giving negative reactions with RH:-34.

Anti-e IgM (clone MS-21) – KL^{2,3}

MS-21 has a broad but subtly different specificity to MS-16. It reacts with some e-variants (including RH:-34, which MS-16 does not agglutinate). It has been reported as giving negative reactions with RN/RN samples.

Anti-e IgM (clone MS-63) – KQ^{2,3}

KQ is the most avid and potent of the five Anti-e FFMUs. It has a narrower specificity and has been reported as giving negative reactions with RH:-19 (hrs-) cells and with some examples of RH:-34.

Anti-e IgM (clone MS-62) – JW²

JW's fine specificity is very similar, but not identical, to KQ.

Anti-e IgM (clone MS-69) – JX²

JX has reactivity which is greatly enhanced by chemical potentiation. The specificity of MS-69 is broader than MS-62 and MS-63. It has been reported that at least one example of a rare e-variant was agglutinated by this antibody and not by the other four.

Anti-C^w IgM (clone MS-110) – JP^{2,3}

JP is a potent antibody which directly agglutinates red cells carrying the C^w (RH8) antigen.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-C	Human IgM	MS-24	7.2 ± 0.5	3–12 mg/mL	24 months	125 mL Bulk	KG-125ML-BK
						1 L Bulk	KG-1L-BK
Anti-C	Human IgM	MS-273	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	VP-125ML-BK
						1 L Bulk	VP-1L-BK
Anti-c	Human IgM	MS-33	7.2 ± 0.5	TBA mg/mL	24 months	125 mL Bulk	VR-125ML-BK
						1 L Bulk	VR-1L-BK
Anti-c	Human IgM	MS-35	7.2 ± 0.5	1–15 mg/mL	24 months	125 mL Bulk	JR-125ML-BK
						1 L Bulk	JR-1L-BK
Anti-c	Human IgG	MS-40	7.0 ± 0.5	10–25 mg/mL	24 Months	125 mL Bulk	JA-125ML-BK
						1L Bulk	JA-1L-BK
Anti-E	Human IgM	MS-12	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	KC-125ML-BK
						1 L Bulk	KC-1L-BK
Anti-E	Human IgM	MS-260	7.2 ± 0.5	5–16 mg/mL	24 months	125 mL Bulk	KW-125ML-BK
						1 L Bulk	KW-1L-BK
Anti-E	Human IgM	MS-80	7.2 ± 0.5	2–25 mg/mL	24 months	125 mL Bulk	KX-125ML-BK
						1 L Bulk	KX-1L-BK
Anti-E	Human IgM	MS-258	7.2 ± 0.5	4–12 mg/mL	24 months	125 mL Bulk	KT-125ML-BK
						1 L Bulk	KT-1L-BK
Anti-e	Human IgM	MS-16	7.2 ± 0.5	3–14 mg/mL	18 months	125 mL Bulk	KZ-125ML-BK
						1 L Bulk	KZ-1L-BKK
Anti-e	Human IgM	MS-21	7.2 ± 0.5	6–16 mg/mL	24 months	125 mL Bulk	KL-125ML-BK
						1 L Bulk	KL-1L-BK
Anti-e	Human IgM	MS-63	7.2 ± 0.5	1–10 mg/mL	24 months	125 mL Bulk	KQ-125ML-BK
						1 L Bulk	KQ-1L-BK
Anti-e	Human IgM	MS-62	7.2 ± 0.5	6–26 mg/mL	24 months	125 mL Bulk	JW-125ML-BK
						1 L Bulk	JW-1L-BK
Anti-e	Human IgM	MS-69	7.2 ± 0.5	6–29 mg/mL	24 months	125 mL Bulk	JX-125ML-BK
						1 L Bulk	JX-1L-BK
Anti-C ^w	Human IgM	MS-110	7.2 ± 0.5	5–25 mg/mL	24 months	125 mL Bulk	JP-125ML-BK
						1 L Bulk	JP-1L-BK



Rare Specificity Intermediates FFMU

Anti-K IgM (clone MS-56) – KO^{2,3}

MS-56 is a human IgM antibody which is the established market leader for this specificity. Manufacturers wishing to make a final reagent suitable for use by the slide method should add chemical potentiators and take care to avoid a prozone phenomenon.

Anti-K IgM (clone AEK4) – KE²

KE FFMU also contains a human IgM Anti-K. This FFMU is offered as an alternative to KO. There is no known significant difference in potency, fine specificity or avidity between the two Anti-K FFMUs.

Anti-k IgG (clone P3A118OL67) – FA^{2,3}

FA FFMU is a high titre intermediate containing human IgG monoclonal Anti-k reactive by an indirect antiglobulin test method. The reactivity of this Anti-k has been confirmed against cells of the K+,k+,Kp(a+) phenotype.

Anti-Jk^a IgM (clone MS-15) – JL^{2,3}

JL is a direct agglutinating human IgM antibody. Anti-Jk^a reagents made from JL have generally replaced human, polyclonal, plasma-based products in the market.

Anti-Jk^b IgM (clone MS-8) – JK^{2,3}

MS-8 is also a direct agglutinating human IgM antibody.

Anti-Fy^a IgG (clone P3TIM) – VL^{2,3}

VL FFMU is presented as a high titre intermediate made from a human monoclonal IgG anti-Fy^a. It is capable of making a strong reacting Anti-Fy^a reagent for use in indirect antiglobulin techniques including use on gel and column IgG cards.

Anti-Fy^b IgM (clone SpA264LBg1) – FF^{2,3}

This long awaited monoclonal specificity is a human IgM direct agglutinin.

Anti-M IgG (clone LM110/140) – KS¹

KS FFMU contains a murine IgG direct agglutinating antibody. The optimal pH of an Anti-M finished reagent made from this antibody is 8.4. At pH values below 8.0 the antibody will react with NN red cells.

Anti-N IgG (clone BO3) – FD^{2,3}

This murine IgG is a direct agglutinating antibody, with strong reactivity, even with heterozygous cells. Formulation or dilution of this FFMU is required to ensure non-reactivity with the "N" antigen found on GPB.

Anti-S IgM (clone MS-94) – JN^{2,3}

MS-94 is a human IgM antibody. JN is a potent FFMU capable of being formulated into direct agglutinating reagents or devices.

Anti-s IgM (clone P3BER) – FE^{2,3}

This human IgM antibody is a direct agglutinin, offering superior performance over monoclonal and polyclonal IgG raw materials.

Anti-Le^a IgM (clone P3N20V3) – FB²

Unlike most Anti-Le^a monoclonal antibodies, this strongly reactive product is of human rather than murine origin.

Anti-Le^b IgA (clone P3F234MD4) – FC²

FC is a potent, direct-agglutinating, human monoclonal IgA antibody. Formulation with potentiators will increase its dilutability and strengthen its reactivity with all ABO phenotypes.

¹ Non-diafiltered, minimal pH buffering.

² Diafiltered against phosphate buffered saline.

³ Licensed with the US FDA under shared manufacturing agreement.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-K	Human IgM	MS-56	7.2 ± 0.5	5–13 mg/mL	24 months	125 mL Bulk	KO-125ML-BK
						1 L Bulk	KO-1L-BK
Anti-K	Human IgM	AEK4	7.2 ± 0.5	10–30 mg/mL	24 months	125 mL Bulk	KE-125ML-BK
						1 L Bulk	KE-1L-BK
Anti-k	Human IgG	P3A1180L67	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	FA-125ML-BK
						1 L Bulk	FA-1L-BK
Anti-Fy ^a	Human IgG	P3TIM	7.2 ± 0.5	5–15 mg/mL	24 months	125 mL Bulk	VL-125ML-BK
						1 L Bulk	VL-1L-BK
Anti-Fy ^b	Human IgM	SpA264LBg1	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	FF-125ML-BK
						1 L Bulk	FF-1L-BK
Anti-Jk ^a	Human IgM	MS-15	7.2 ± 0.2	6–23 mg/mL	24 months	125 mL Bulk	JL-125ML-BK
						1 L Bulk	JL-1L-BK
Anti-Jk ^b	Human IgM	MS-8	7.2 ± 0.5	2–25 mg/mL	24 months	125 mL Bulk	JK-125ML-BK
						1 L Bulk	JK-1L-BK
Anti-Le ^a	Human IgM	P3N20V3	7.2 ± 0.5	5–15 mg/mL	24 months	125 mL Bulk	FB-125ML-BK
						1 L Bulk	FB-1L-BK
Anti-Le ^b	Human IgA	P3F234MD4	7.2 ± 0.5	11–40 mg/mL	24 months	125 mL Bulk	FC-125ML-BK
						1 L Bulk	FC-1L-BK
Anti-M	Murine IgG	LM110/140	7.2 ± 0.5	0.5–10 mg/mL	24 months	125 mL Bulk	KS-125ML-BK
						1 L Bulk	KS-1L-BK
Anti-N	Murine IgG	BO3	7.2 ± 0.5	0.5–10 mg/mL	24 months	125 mL Bulk	FD-125ML-BK
						1 L Bulk	FD-1L-BK
Anti-S	Human IgM	MS-94	7.2 ± 0.5	5–24 mg/mL	24 months	125 mL Bulk	JN-125ML-BK
						1 L Bulk	JN-1L-BK
Anti-s	Human IgM	P3BER	7.2 ± 0.5	10–25 mg/mL	24 months	125 mL Bulk	FE-125ML-BK
						1 L Bulk	FE-1L-BK



Anti-Human Globulin Intermediates FFMU

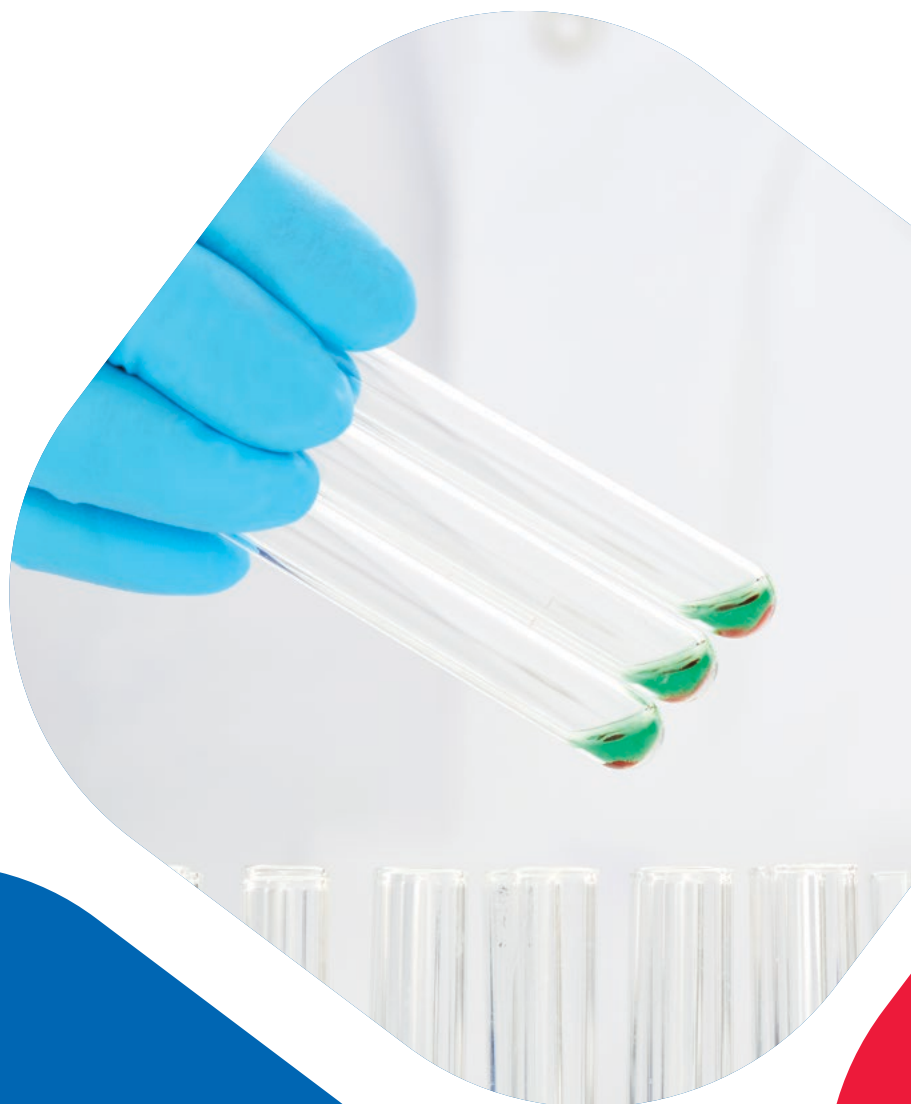
Anti-Human IgG (clone MS-278) – JZ

MS-278 is a murine IgM antibody which reacts with all four subtypes of human IgG. The FFMU is diafiltered with phosphate buffered saline.

Anti-Human C3d (clone BRIC-8) – JU

Detection of complement activation can aid in the diagnosis of autoimmune haemolytic anaemia, or the detection of some blood group allo-antibodies, particularly within the Kidd System. BRIC-8 is a murine IgM antibody that has been widely used for over 20 years as a constituent of a blended broad spectrum Anti-Human Globulin Reagent. JU is diafiltered with phosphate buffered saline and is licensed with the US FDA under shared manufacturing agreement.

Product	Ig Type	Clone	pH Range	Protein Range	Shelf Life	Volume	Catalogue No.
Anti-Human IgG	Murine IgM	MS-278	7.2 ± 0.5	2–15 mg/mL	24 months	125 mL Bulk	JZ-125ML-BK
						1 L Bulk	JZ-1L-BK
Anti-Human C3d	Murine IgM	BRIC-8	7.2 ± 0.5	2–10 mg/mL	24 months	125 mL Bulk	JU-125ML-BK
						1 L Bulk	JU-1L-BK



Human IgG Monoclonal Antibodies for Research Use

The Human IgG Monoclonal Antibodies for Research Use are clarified cell culture supernatants from cell lines expressing Human IgG monoclonal blood typing antibodies that are reactive by an indirect antiglobulin test method. These products are intended for use by manufacturers wishing to make non-IVD reagents or devices such as proficiency kits, internal test controls or educational samples.

Product	Ig Type	Clone	Volume	Catalogue Number
Anti-c	Human IgG	MS-40	125 mL Bulk	CB-125ML-RU
Anti-C ^w	Human IgG	MS-353	125 mL Bulk	CC-125ML-RU
Anti-E	Human IgG	MS-78	125 mL Bulk	CD-125ML-RU
			1 L Bulk	CD-1L-RU
Anti-Fy ^a	Human IgG	P3TIM	125 mL Bulk	CE-125ML-RU
Anti-K	Human IgG	MS-59	125 mL Bulk	CF-125ML-RU

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