

# Original Equipment Manufacturing

Intermediate and OEM Products  
for Immunohaematology





## A long history as an OEM manufacturer

For over 30 years, Quotient has developed, manufactured and marketed high quality products for use in transfusion diagnostics. Quotient, through its manufacturing company Alba Bioscience, provides a range of intermediate products for blood typing and others that are available to customers on an Original Equipment Manufacturer (OEM) basis. These products include:

1. **Monoclonal antibodies For Further Manufacturing Use (FFMU)**
2. **Ready for use bulk or vialled reagents, including Reagent Red Blood Cell Panels, Blood Typing Antisera and Quality Control (QC) products**
3. **External Quality Assessment (EQA) and Proficiency Testing Schemes**

Working to cGMP in an ISO certified and FDA licensed manufacturing facility, clients have the reassurance offered by the technical expertise and experience of highly trained staff.





## Monoclonal Blood Typing Intermediates (FFMU)

Quotient provides a range of intermediate monoclonal blood typing antibodies for further manufacturing use (FFMU) from cell lines secreting human or murine monoclonal antibodies. Since these are derived from hybridoma cell lines producing monoclonal antibodies, each batch will have comparable potencies and identical specificity. (Potencies are assessed against reference preparations.)

These can be formulated by the customer to suit specific applications, into finished blood typing reagents by dilution, blending and addition of potentiators, as required. All FFMU intermediates contain 1 g/L sodium azide as a preservative.

### ABO Reagents

Code	Product	Description
Z701	Anti-A (LA2)	Both antibodies react strongly with all common forms of the A antigen and will directly agglutinate examples of Ax. They will not react with enzyme treated group B or group O red cells. LA2 clone has been used in blood typing tests worldwide for over 20 years and is currently licensed in the USA as a final product. Suitable for blending with LB2 or LB3 and ES15 in the manufacture of Anti-A,B.
Z703	Anti-A (ES9)	
Z706	Anti-B (LB2)	Both antibodies react strongly with all common forms of B antigen. They will not react with red cells that exhibit the acquired B antigen nor will they react with enzyme treated group A or group O red cells. LB2 has been used worldwide in blood typing tests for almost 20 years. LB3 is currently licensed in the USA as a final product. Suitable for blending with LA2 and ES15 in the manufacture of Anti-A,B.
Z708	Anti-B (LB3)	
Z712	Anti-A(B) (ES15)	The ES15 antibody will directly agglutinate all common forms of the A antigen including weaker subgroups. It is especially effective in the detection of Ax. Reacts weakly with group B cells but can be blended with LA2 and LB2 or LB3 to formulate an Anti-A,B reagent. This cell line been extensively used in Anti-A,B typing reagents for over 20 years.

### Anti-D Reagents

Code	Product	Description
Z716	Anti-D IgM (LDM1)	These cell lines will detect all weak and partial RhD types except DVI and are, therefore suitable as patient typing reagents. Both LDM1 and LDM3 have same epitope specificity making them ideal for use in situations where two typing reagents from different cell lines are required. Since they have the same epitope specificity they will always give identical typing results when formulated appropriately. LDM1 or LDM3 can also be used in a blended Anti-D reagent in conjunction with ESD1 to provide a reagent (IgM/IgG blend) which will detect partial RhD types including DVI by Indirect Antiglobulin Technique (IAT).
Z718	Anti-D IgM (LDM3)	
Z719	Anti-D IgM (ESD1M)	The ESD1M antibody will directly agglutinate DVI red cells (but not DIV) which makes it a perfect blending partner with LDM1 or LDM3 to create a reagent that will detect most weak RhD and partial RhD types by direct test methods.
Z730	Anti-D IgG (ESD1)	This antibody will detect DVI red cells (but not DIV) by IAT. It is a perfect blending partner with LDM1 or LDM3 to create a reagent that will detect most weak RhD and partial RhD types.

**Supply Quantities** - These products can be supplied in unit volumes of 125 mL, 1 Litre and 5 Litre. 125 mL and 1 Litre only available by special arrangement, please contact Customer Services.



# Monoclonal Blood Typing Intermediates FFMU

## Rare Specificities

Code	Product	Description
Z770	Anti-M (LM1)	LM1 is a murine IgG direct agglutinating antibody. Manufacturers wishing to make final reagent need to ensure formulation at the appropriate pH in order to maintain specificity. Optimal pH is 8.5 - below pH 8.0 the antibody will react with NN red cells.
Z776	Anti-N (LN3)	LN3 is a murine IgG direct agglutinating antibody, which is not pH dependent.
Z752	Anti-k (LK1)	Lk1 is a murine IgM antibody. Manufacturers wishing to make final reagent need to ensure formulation at the appropriate pH in order to maintain specificity. Optimal pH is 5.2, above pH 5.6 the antibody may react occasionally with KK red cells.
Z781	Anti-Le <sup>a</sup> (LEA1)	LEA1 is a murine IgM antibody. Manufacturers should be aware that potentiators are required to produce a finished reagent that acts as a direct agglutinin.
Z780	Anti-Le <sup>a</sup> (LEA2)	LEA2 is a murine IgM antibody. Manufacturers should be aware that potentiators are required to produce a finished reagent that acts as a direct agglutinin.
Z783	Anti-Le <sup>b</sup> (LEB1)	LEB1 is a murine IgM antibody. Manufacturers should be aware that potentiators are required to produce a finished reagent that acts as a direct agglutinin. The specificity of this antibody is Le <sup>b</sup> L and reacts equally with all Le <sup>b</sup> positive red cells irrespective of the ABO blood group.
Z784	Anti-Le <sup>b</sup> (LEB2)	LEB2 is a murine IgM antibody. Manufacturers should be aware that potentiators are required to produce a finished reagent that acts as a direct agglutinin. The specificity of this antibody is Le <sup>b</sup> H which reacts preferentially with Le <sup>b</sup> positive red cells from group O individuals.
Z791	Anti-Lu <sup>b</sup> (LU2)	LU2 is a murine IgM antibody. This antibody is unique to Quotient and is the established market leader for this specificity.

## AHG Reagents

Code	Product	Description
G795	Polyclonal (Rabbit) Anti-Human IgG	Rabbit Anti-Human IgG, manufactured using serum from a USDA licensed facility derived from rabbits immunised with an immunogen prepared by Quotient.
Z797	Anti-IgG1 (LG1A)	Monoclonal Anti-IgG1, for use as monospecific reagent.
Z799	Anti-IgG3 (LG3A)	Monoclonal Anti-IgG3, for use as monospecific reagent.
Z796	Anti-C3 (3G8)	Purified monoclonal Anti-C3, for blending with Anti-IgG or use as monospecific reagent. Provided at a concentration of 1 g/L. The Anti-C3 is specific for the C3d component of complement.

**Supply Quantities** - These products are supplied in unit volumes of 125 mL and 1 Litre.





# Ready to use Blood Typing Reagents

Quotient has formulated a wide range of Blood Typing Reagents which meet the requirements of the European Union *in vitro* Diagnostics Directive 98/79/EC. ABO & D reagents are offered in bulk quantities as well as standardised vials with or without droppers, other reagents are available as vialled reagents. Depending on the quantities required, Quotient can label these products in your own trade dress and assist with regulatory filings.

## Typing Reagent

### ABO & D Reagents

Code	Description (Volume 10 mL)	Unit Volume	Minimum Order Quantity
FD001	Anti-A (LA2)	10 mL	3000
FD011	Anti-B (LB2)	10 mL	3000
FD021	Anti-A,B (LA2, LB2, ES15)	10 mL	2000
FD031	Anti-D IgM (LDM1)	10 mL	2000
FD036	Anti-D IgM (LDM3)	10 mL	2000
FD039	Anti-D IgM/IgM (LDM1, ESD1M)	10 mL	1000
FD041	Anti-D IgM/IgG (LDM3, ESD1)	10 mL	2000

### Anti-Human Globulin Reagents (AHG)

Code	Description	Unit Volume	Minimum Order Quantity
FD350	Polyspecific AHG	10 mL	3000
FD356	Monospecific Anti-Human IgG	10 mL	1000
FD360	Anti-Human C3 (Monoclonal)	3 mL	3000

## Reagent Red Blood Cells

### For Conventional Tube Testing

Code	Description	Unit Volume	Minimum Order Quantity
FD401	A <sub>1</sub> Cells (2-3%)	10 mL	300
FD406	A <sub>2</sub> Cells (2-3%)	10 mL	200
FD411	B Cells (2-3%)	10 mL	300
FD416	O R <sub>1</sub> r Cells (2-3%)	10 mL	200
FD421	O rr Cells (2-3%)	10 mL	100
FD427	DVI Reagent Red Cells (2-3%)	5 mL	100
FD451	3 Cell Antibody Screen (2-3%)	3 x 10 mL	200
FD454	2 Cell Antibody Screen (2-3%)	2 x 10 mL	200
FD471	10 Cell Antibody Identification (2-3%)	10 x 5 mL	100
FD472	10 Cell Antibody Identification - papainised (2-3%)	10 x 5 mL	50
FD441	IgG Sensitised Cells (3-5%)	10 mL	500
FD482	C3 coated Red Cells	5 mL	200

### For Column Agglutination Techniques

Product Code	Description	Unit Volume	Minimum Order Quantity
FD402	A <sub>1</sub> Cells	10 mL	300
FD412	B Cells	10 mL	300
Z455	Antibody Screening Panel	3 x 10 mL	200
Z466	RhD Negative Antibody Screening Panel	3 x 5 mL	100
Z458	Antibody Identification (Native)	11 x 4 mL	100
Z459	Antibody Identification (Papainised)	11 x 4 mL	50



## ALBCheck® BGS Control Reagents

This is a range of Blood Group Serology (BGS) Control Reagents to enable the user to validate and control testing on an individual or batch basis. Our range includes products suitable for control of blood grouping platforms, as well as Simulated Whole Blood Control Samples.

### ALBCheck® BGS Control Reagents

Code	Description	Unit Volume	Minimum Order Quantity	Use
FD483	Duo-Simulated Whole Blood Controls	2 x (2 x 6 mL)	200	Automated blood grouping platforms
FD489	Simulated Whole Blood Controls*	4 x 6 mL	200	Automated blood grouping platforms
FD276	Competency Kit	10 x 2 mL	200	Internal, self-assessment
FD251	Anti-D 0.3 iu/mL	10 mL	300	Sensitivity Control
FD262	Anti-D 0.1 iu/mL	5 mL	300	Sensitivity Control for patient screening
FD263	Anti-D 0.05 iu/mL	5 mL	300	Sensitivity Control
FD252	Anti-c (weak)	5 mL	100	Sensitivity Control for column agglutination technology
FD253	Anti-Fy <sup>a</sup> (weak)	5 mL	100	Sensitivity Control for column agglutination technology
FD250	ALBASure™ Sensitivity Kit	4 x 5 mL	100	Sensitivity Control Kit - Anti-K, Anti-c, Anti-E, Anti-S
FD281	AB Serum (Human)	5 mL	200	Test Control
FD256	Enzyme Control	10 mL	200	Positive control for enzyme tests (glycine soja)

\*contains ABO, Rh & K typed red cells plus ABO, Rh & K antibodies.



## External Quality Assessment Schemes (EQA) and Proficiency Testing Schemes

Immunohaematology laboratories should ensure that their test procedures are sensitive and reproducible and that their staff are fully trained and competent to carry out tests. Consequently it is essential that laboratory managers can demonstrate:

- Staff competence
- Sensitivity of test procedures
- Performance of the reagents and equipment used in the test procedures

EQA Schemes and staff competency assessment kits are ideal for this purpose.

Quotient has been providing EQA and proficiency materials to international EQA Schemes worldwide for several years. If the demand is sufficient, Quotient can custom design and manufacture proficiency test materials to meet the needs of your scheme.



## Format of Standard EQA Scheme

Samples include but are not limited to:

### Simulated Whole Blood Samples

Constructed samples which mimic donor or patient blood samples i.e. red blood cells and simulated plasma. Samples can be provided at a suitable haematocrit for both automated and manual testing. These samples can be manufactured using red blood cells exhibiting rare antigens or plasma containing irregular blood group antibodies and can also be prepared to give anomalous results e.g. missing reverse group antibodies.

### Type, Screen and Compatibility Testing

A combination of red blood cell and simulated plasma samples provided ready for use. Samples can include simulated patient red blood cells for cell typing, simulated patient serum for antibody screening and/or identification and donor cells for compatibility testing. Cases can be straight-forward or can be designed with complications e.g. multiple antibodies.

### Direct Antiglobulin Test (DAT) Samples

Red blood cell samples can be negative, sensitised with IgG antibodies or C3.

Our standard EQA Typing and Antibody Screen Kit contains 10 samples:

Whole Blood Sample	Patient 1	4 mL Simulated Whole Blood (13-17%) containing appropriate ABO and other irregular blood group antibodies. For assessment of blood typing and antibody screening procedures.
	Patient 2	4 mL Simulated Whole Blood (13-17%) containing appropriate ABO and other irregular blood group antibodies. For assessment of blood typing and antibody screening procedures.
Antibody screen and compatibility testing	Serum 1	2mL serum, vial - with or without irregular blood group antibodies.
	Serum 2	
	Donor 1	2 mL red blood cells (3-5%).
	Donor 2	
	Donor 3	
Donor 4		
Direct Antiglobulin Test	Sample 1	2 mL cells (3-5%) Can be DAT negative or sensitised with IgG, or C3.
	Sample 2	

Schemes can be customised, labelled, bar-coded and packaged according to your specifications. Our experienced staff at Quotient are happy to discuss your requirements and the design of the scheme.

## Note

Quotient does not administer EQA proficiency programmes. Scheme organisers must collate and process data for participants.

## BGS Competency Testing Kit (FD276)

This kit is a set of 10 randomly selected serum samples. It is intended for use as an internal, self-assessment, Quality Assurance Scheme for the detection of weak blood group antibodies. Use of this product is solely at the discretion of the Laboratory Manager/QC Manager. There is, therefore, no need to submit results externally and wait for performance assessment. Each sample has a unique identifier and the result information is available electronically to Laboratory Managers.

Features	Benefits
Pack contains 10 randomly numbered vials	Blind Assessment
Specificity information supplied on website (in password protected area)	Self-assessment
Presented in 2 mL vials	Ideal for training purposes
Completely unknown antibody specificities	Can be used in column agglutination
Polyclonal material	Represents a normal weak sample

*'We use Quotient's Competency Kit across our three laboratories to monitor staff performance and reliability of test procedures. This kit is ideal for in-house self-assessment as the specificity of each test sample is only known to the lab manager due to the individual numbering of the vials.'*

*Peter Clinton, Technical Manager Blood Transfusion, NHS Lanarkshire.*

*For details of our full range of products and services, or assistance with any of our products, please contact us using the details below.*

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