

ALBA

ORIGINAL EQUIPMENT MANUFACTURING

Intermediate and OEM Products
for Immunohematology

AliveDx

A scientist in a white lab coat and hairnet is operating a computer monitor in a laboratory setting. The monitor displays a graph. In the foreground, there is a large stainless steel bioreactor with various pipes and gauges. The background shows more laboratory equipment and a clean, bright environment.

A LONG HISTORY AS AN OEM MANUFACTURER

FOR OVER 30 YEARS, Alba has developed, manufactured and marketed high quality products for use in transfusion diagnostics. Alba provides a range of intermediate products for blood typing that are available to customers on an Original Equipment Manufacturer (OEM) basis.

OEM PRODUCTS INCLUDE:

- Monoclonal antibodies For Further Manufacturing Use (FFMU)
- Ready-for-use bulk or vialled reagents, including Reagent Red Blood Cell Panels, Blood Typing Antisera, Anti-Human Globulin (AHG) products, and Quality Control (QC) products
- 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)

ALBA PROVIDES A RANGE of intermediate monoclonal blood typing antibodies for further manufacturing use (FFMU) from cell lines secreting human or murine monoclonal antibodies.

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.



TO REQUEST A QUOTE OR SAMPLES, SCAN THIS CODE.

Visit us at alivedx.com or email us at Customer.ServiceEU@alivedx.com



The following products are FFMU examples.

Please contact us today to discuss how we can customize a solution to your specific needs.

RARE SPECIFICITIES

PRODUCT	DESCRIPTION
ALBAclone® 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.
ALBAclone® 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.
ALBAclone® Anti-Le^a (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.
ALBAclone® Anti-Le^b (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 LebL and reacts equally with all Leb positive red cells irrespective of the ABO blood group.
ALBAclone® Anti-Lu^a (LU2)	LU2 is a murine IgG1 antibody. This antibody is unique to Alba and is the established market leader for this specificity.

ABO REAGENTS

PRODUCT	DESCRIPTION
ALBAclone® 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.
ALBAclone® 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.

ANTI-D REAGENTS

PRODUCT	DESCRIPTION
ALBAclone® 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.
ALBAclone® Anti-D IgM (LDM3)	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).
ALBAclone® 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.
ALBAclone® 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.

ANTI-HUMAN GLOBULIN REAGENTS (AHG)

PRODUCT	DESCRIPTION
Monoclonal Anti-IgG1 (LG1A)	(LG1A) Monoclonal Anti-IgG1, for use as monospecific reagent.
Monoclonal Anti-IgG3 (LG3A)	(LG3A) Monoclonal Anti-IgG3, for use as monospecific reagent.

BULK READY-TO-USE BLOOD TYPING PRODUCTS

ALBA 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 of bespoke specifications including vials with or without droppers and unlabeled or custom labeled vials.



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The following products are bulk reagent examples.

Please contact us today to discuss how we can customize a solution to your specific needs.

ABO & D REAGENTS

ALBAclone® Anti-A (LA2) Monoclonal Reagent Grade

ALBAclone® Anti-B (LB2) Monoclonal Reagent Grade

ALBAclone® Anti-A,B, (LA2/LB2/ES15)

ALBAclone® Anti-D Blend (direct/indirect agglutinin) finished bulk

RARE SPECIFICITIES

Alba offers a range of rare specificities.
Contact us with your volume request to learn about what products we offer.

ANTI-HUMAN GLOBULIN REAGENTS (AHG)

Polyspecific Anti-Human Globulin, finished bulk

ALBAclone® Anti-C3d, (3G8), finished bulk

Anti-IgG (rabbit), finished bulk

EXTERNAL QUALITY ASSESSMENT SCHEMES (EQA) AND PROFICIENCY TESTING SCHEMES

IMMUNOHEMATOLOGY LABORATORIES should ensure that their test procedures are sensitive and reproducible and that 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 reagents and equipment used in test procedures

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

ALBA HAS BEEN PROVIDING EQA and proficiency materials to international EQA Schemes worldwide for several years. Alba can custom design and manufacture proficiency test materials to meet the needs of your scheme.

ALBA COMPETENCY AND ASSESSMENT KITS can be customized, labeled, and packaged according to your specification. Please contact us today to discuss how we can customize a solution to your specific need.



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ALBACHECK® COMPETENCY TESTING KIT (Z276)



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

Predictable results from a stable, proven sample

Blinded uniquely numbered samples with manager-only answer key access

10 x 2 mL vials per kit

Suitable for testing with multiple antibody identification methods, such as saline, LISS, PEG and gel

BENEFITS

Assess staff competency and proficiency in identifying unknown antibodies

Eliminate sharing of results between staff

Test up to 10 staff members

Ready source of samples for comparability of methods (42 CFR 493.1281 and CAP COM.042501)



SUPPORTING CUSTOMERS



Expert technical support from experienced blood bankers



Samples for reagent evaluations available*

**Not all products may be available in all territories.*



Reliable customer service



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AliveDx

At AliveDx, we empower diagnostic insights, transform patient care, and innovate for life. With over 30-years in in-vitro diagnostics, we put the health of patients first by creating innovative solutions designed for faster disease detection to shorten the time to diagnosis. Alba—our blood bank reagents portfolio—and MosaiQ®—one of the first multiplexing and multimodality automated testing platforms—are designed to make labs more efficient and clinical decision-making more effective. Our journey started as Alba Bioscience, and later, Quotient. Today, as AliveDx, we innovate for life.