

DIAGAST O.E.M. OFFER

TECHNICAL SHEETS

For Safety Transfusion



DIAGAST Mission – Ensure blood transfusion safety.

DIAGAST is a leader & a specialist in the field of **Immuno-haematology** with 30 years of expertise.

DIAGAST is one of the sole companies that carries out all operations relating to research, manufacturing and marketing for all of its products.

DIAGAST provides reagents to perform worldwide 110 000 000 blood grouping per year.

Our know-how:

- **Independence with :**

- Owned cell clones
- On site production of monoclonal antibodies
- Original development of reagents
- Specific reagent formulation for automation platforms

- **Development, production and marketing of Blood Group Serology systems:**

Blood Grouping, Phenotyping, Antibody Screening and Cross-Matching: manual and automated ranges thanks to E.M.®Technology.

- **Production:**

All reagents are produced in our facility in LOOS, FRANCE.

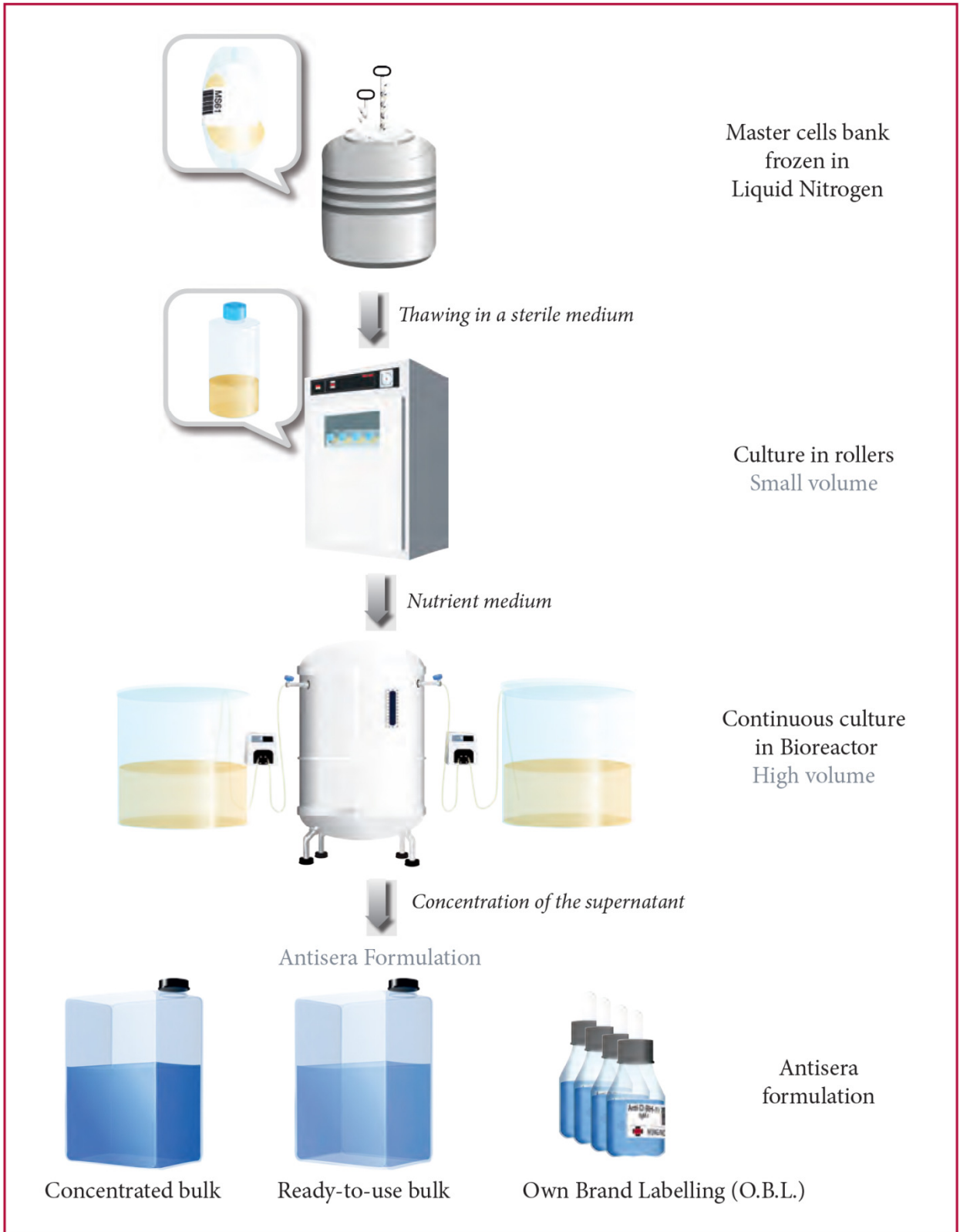
- **Classification:**

Our products are CE marked.

Our premises are certified ISO 9001/ 13485 approved for productions under FDA Licensing

Your O.E.M. partner using tomorrow's technology for optimum safety transfusion.

- From ABO-D blood grouping to extended phenotyping
- Concentrated bulk For Further Manufacturing Use (F.F.M.U)
- Ready to use bulks
- Filling and packaging under your specifications



CONCENTRATED BULK
Grouping

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-A CONCENTRATE BULK	0113D10	70115	IgM	22 months
ANTI-B CONCENTRATE BULK	9621A8	70215	IgM	22 months
ANTI-A,B CONCENTRATE BULK	152D12 + 9113D10	70315	IgM	22 months
ANTI-D IGG CONCENTRATE BULK	P3x290	71105	IgG	11 months
ANTI-D IGM CONCENTRATE BULK	P3x61	71115	IgM	22 months
ANTI-D IGM CONCENTRATE BULK	P3x21223B10	71125	IgM	11 months
ANTI-D IGG CONCENTRATE BULK	P3x35	71135	IgG	22 months
ANTI-D IGM CONCENTRATE BULK	HM10	80460	IgM	11 months
ANTI-D IGG CONCENTRATE BULK	HM16	80461	IgG	11 months

Phenotyping

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-C (RH2) CONCENTRATE BULK	P3x25513G8	71150	IgM	11 months
ANTI-E (RH3) CONCENTRATE BULK	906	71152	IgM	17 months
ANTI-c (RH4) CONCENTRATE BULK	951	80446	IgM	11 months
ANTI-e (RH5) CONCENTRATE BULK	P3GD512	80445	IgM	11 months
ANTI-K (KEL1) CONCENTRATE BULK	601	80447	IgG	11 months

Rare Sera

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-P1 CONCENTRATE BULK	650	71140	IgM	35 months
ANTI-Fyb (FY2) CONCENTRATE BULK	SpA264LBg1	80477	IgM	<i>In progress</i>

Diluent

Product Name	Reference	Expiry date
DILUTION BUFFER (X5)	80555	35 months

NEW

READY-TO-USE BULK

Grouping

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-A DIAGAST BULK	9113D10	70111	IgM	22 months
ANTI-B DIAGAST BULK	9621A8	70211	IgM	22 months
ANTI-A,B DIAGAST BULK	152D12 + 9113D10	70311	IgM	22 months
ANTI-H DIAGAST BULK	10934C11	70510	IgM	
ANTI-D IGM DIAGAST BULK	P3x61	71111	IgM	16 months
ANTI-D IGM DIAGAST BULK	HM10	80449	IgM	11 months
ANTI-D IGG DIAGAST BULK	P3x290	71151	IgG	11 months
ANTI-D IGG DIAGAST BULK	HM16	71171	IgG	11 months
ANTI-D TOTEM DIAGAST BULK	P3x61+P3x21223B10+P3x290+P3x35	71101	2 IgM+2 IgG	16 months
NEGATIVE CTRL DIAGAST BULK		79011		22 months

Phenotyping

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-C DIAGAST BULK	P3x25513G8	80415	IgM	17 months
ANTI-C DIAGAST BULK	P3x25513G8 + MS24	80448	IgM	17 months
ANTI-E DIAGAST BULK	906	80410	IgM	17 months
ANTI-c DIAGAST BULK	951	80441	IgM	17 months
ANTI-e DIAGAST BULK	P3GD512 + MS63	80423	IgG	22 months
ANTI-Kell DIAGAST BULK	601	80412	IgG	22 months
ANTI-Kell DIAGAST BULK	MS56	80419	IgM	22 months
ANTI-CDE DIAGAST BULK	P3x25513G8 + P3x61 + P3x234	80464	IgM	17 months

Diluent

Product Name	Reference	Expiry date
DILUTION BUFFER (X5)	80555	35 months

Rare Sera

Product Name	Cell Line(s)	Reference	Type	Expiry date
ANTI-Fya (FY1) DIAGAST BULK	DG-FYA-02	80442	IgG	11 months
ANTI-Fyb (FY2) DIAGAST BULK	SpA264Lbg1	80450	IgM	<i>In progress</i>
ANTI-M (MNS1) DIAGAST BULK	2514E6	80432	IgM	11 months
ANTI-N (MNS2) DIAGAST BULK	1422C7	80433	IgM	11 months
ANTI-Jka (JK1) DIAGAST BULK	P3HT7	80434	IgM	22 months
ANTI-Jkb (JK2)DIAGAST BULK	P3.143	80435	IgM	22 months
ANTI-k (KEL2) DIAGAST BULK	P3A1180L67	80452	IgG	<i>In progress</i>
ANTI-Lea (LE1) DIAGAST BULK	13643B9	80436	IgM	11 months
ANTI-Leb (LE2) DIAGAST BULK	GX336	80437	IgM	22 months
ANTI-S (MNS3) DIAGAST BULK	P3S13JS123	80438	IgG	15 months
ANTI-s (MNS4) DIAGAST BULK	P3YAN3	80443	IgG	15 months
ANTI-P1 DIAGAST BULK	650	80444	IgM	11 months

Antiglobulins

Product Name	Cell Line(s)	Reference	Expiry date
Maestria (polyspecific IgG + C3d)	18833 + 18896 + 12011D10	80420	17 months
Antiglobulin monoclonal anti-C3d	12011D10	80421	14 months
Maestria IgG (mono specific IgG)	18833 + 18896	80422	14 months

Bromelin

Product Name	Reference	Expiry date
BROMELINE 100 mL	69023	

Other Reagents

Product Name	Reference	Expiry date
A and B Substances	69723	

NEW

NEW

Submission Tracking No. (STN)	FDA Product Name	Cell Line(s)	Reference	Specificity
BL125209	Anti-s (Monoclonal)(IgG)(FFMU)	P3YAN3	80439	Anti-s (MNS4)
BL125210	Anti-P ₁ (Murine Monoclonal)(IgM)(FFMU)	650	80440	Anti-P1
BL125211	Anti-Fya (Monoclonal)(IgG)(FFMU)	DG-FYA-02	80430	Anti-Fya (FY1)
BL125236	Anti-C (Human Monoclonal)(FFMU)	P3X25513G8	80408	Anti-C (RH2)
BL125435	Anti-B (Murine Monoclonal)(FFMU)	9621A8	70905	Anti-B (AB01)
BL125442	Anti-D (Human Monoclonal)(IgM)(FFMU)	P3X61	70906	Anti-D (RH1)
BL125443	Anti-E (Human Monoclonal)(FFMU)	906	70913	Anti-E (RH3)
BL125439	Anti-Human Globulin, Anti-IgG (Rabbit Polyclonal)(FFMU)	Non Applicable	70919	Anti-IgG

Biological Products submitted for Approval – In progress

BL125500	Anti-Jk ^a (Monoclonal)(IgM)(FFMU)	P3HT7	70917	Anti-Jka (JK1)
BL125501	Anti-Jk ^b (Monoclonal)(IgM)(FFMU)	P3.143	70918	Anti-Jkb (JK2)
BL125202	Anti-S (Monoclonal)(IgG)(FFMU)	P3S13JS123	70921	Anti-S (MNS3)

List of FDA Licensed Establishments available on the website:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149969.pdf>