

Bulk Assay Supply Catalog



Living Immunoassay Excellence

Biokit is a privately owned biotechnological company that is part of Werfen. It was founded in 1973 and is aimed at the research, development, manufacture and worldwide distribution of clinical diagnostic reagents and systems.

Our knowledge and experience mainly involve *in vitro* diagnostic markers, based on antigen-antibody reactions, in the fields of infectious diseases and serum proteins, among others.

Biokit's mission is to become the partner of choice as a Centre of Excellence for Immunoassay by providing innovative OEM solutions (products & services) to major IVD players.



Innovation

Biokit ranks among the top centres of excellence for immunoassay development and manufacturing in the industry. Our focus on technological advances ensures that our portfolio continuously improves and evolves. Biokit's innovative nature is strengthened through close relationships with the most prestigious universities and biotechnology research centres around the world in order to offer the best quality and state-of-the-art products. As experts in Infectious Disease Serology, we offer a wide range of products implementing a variety of technologies, most notably, chemiluminescence.

Quality

Biokit is committed with the quality in all the activities, offering maximum quality standards in all the products and services. The Quality Assurance Department at Biokit is responsible for the Overall Quality of the Company. All processes are subject to strict controls, from the conception of and research into a new product, up to its final manufacturing and marketing. Compliance with various international standards is verified at all times. The quality systems of Biokit, S.A. have been registered by UL to the ISO 13485:2003 Standard (certificate number A12230).

Commitment

Customers and patients benefit from the efficiency of a team of more than 270 highly qualified and specialised professionals, who apply their enthusiasm, energy and dedication on a daily basis in order to provide hospitals, blood banks and IVD OEM partners with high quality systems and reagents.

Bulk Assay Supply

Biokit offers its high expertise in immunoassay research and manufacturing also in bulk format.

For more than 40 years, Biokit has produced a wide range of premium quality immunoassay reagents in the fields of infectious diseases and serum proteins, among others.

More than 80 companies in the IVD industry rely on the specialized OEM Services from Biokit.



Abbreviations

Ab	Antibody	K	Potassium
Ag	Antigen	Na	Sodium
ELISA	Enzyme-Linked ImmunoSorbent Assay	RBC	Red Blood Cells
FDA	Food and Drug Administration	RPR	Rapid Plasma Reagin
HBV	Hepatitis B Virus	HRP	Horseradish peroxidase
HCV	Hepatitis C Virus	DMSO	Dimethyl sulfoxide
IVD	In Vitro Diagnostics	WHO	World Health Organization
mAb	Monoclonal Antibody	TPHA	Treponema pallidum Hemmagglutination
Li	Lithium	ISO	International Organization for Standardization

Bulk Assay

Large Production Capacity

Biokit's knowledge and expertise mainly focus on *in vitro* diagnostic markers, based on antigen-antibody reactions.

- Top Center of Excellence for Immunoassay development and manufacturing in the IVD industry
- Extensive manufacturing scale-up capabilities
- State-of-the-Art equipment, expertise and skills

Biokit's world in numbers



Biokit offers:

- Reagent supply in bulk of Turbidimetric assays, ELISA and Rapid tests for the detection of serum proteins and infectious diseases.
- All the components required to perform the assay, including reagents, buffers, calibrators, controls, diluents, washing solutions and ELISA microplates, among others
- Biokit can fully adapt to your specific needs, from Bulk Reagents supply to Kit Assembly and packaging services.

Capabilities

Overview
35.000m ² facilities and 7.500m ² dedicated to production activities
Production under GMP's procedures & Lean manufacturing
5S methodology implemented in all the production areas
ISO 8 classified areas for production and filling
Positive and negative pressurized laboratories
Specific areas for CLIA, Latex, ELISA and Rapid tests
In process control
Final QC functional, physicochemical and packaging analysis
Production Equipment
More than 200 dedicated chromatographic columns
Affinity (Specific marker, GST, Ion Metal, Protein A, Protein G)
Ion exchange
Gel filtration
Centrifugation systems
Ultracentrifugation (up to 80.000 rpm)
High speed (up to 21.000 rpm)
Low speed (up to 6.000 rpm)
Automated high speed ELISA microplate filling machines (96 well plates)
Microtiter plates with breakable wells
2 Oyster Bay coating machines
Single well coating control by ultrasound sensor
Reagents production
Up to 1.000L per batch of CLIA reagents
Up to 160L per batch of microparticles
Up to 500L per batch of Buffers
Up to 300L per batch of Latex reagents
Up to 50.000 lyophilized vials/batch
Kits production
Up to 15.000 kits per batch
Filling and Packaging
10 High speed automated liquid filling lines
Labelling automated Vision Inspection System
Wide range of vials (more than 30 types of vials)
More than 8.000.000 vials filled per year
More than 1.200.000 kits packaged per year



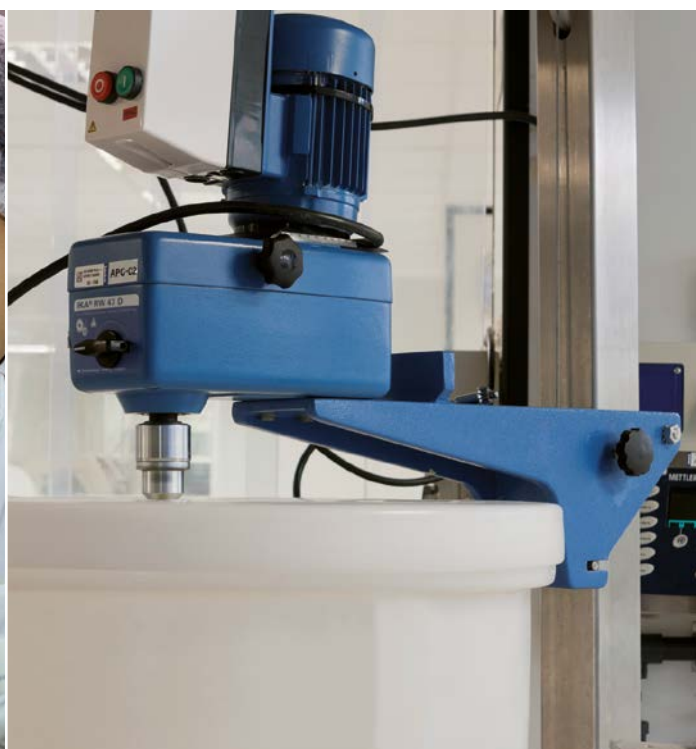
Bulk Assay Technologies

Turbidimetry

Turbidimetry is the process of measuring the loss of intensity of transmitted light due to the scattering effect of the particles suspended in it. Turbidimetric reagents give a quantitative result of concentration of the analyte through the increase in absorbance due to agglutination in antigen-antibody reactions.

Reagents can be based in latex or antiserum. The high level of expertise in latex manipulation gives our assays an excellent performance. Biokit turbidimetric assays include reagents, calibrators and controls.

Other assays not included in this catalog can be produced in bulk under demand. Please contact our OEM Department (OEM@biokit.com)

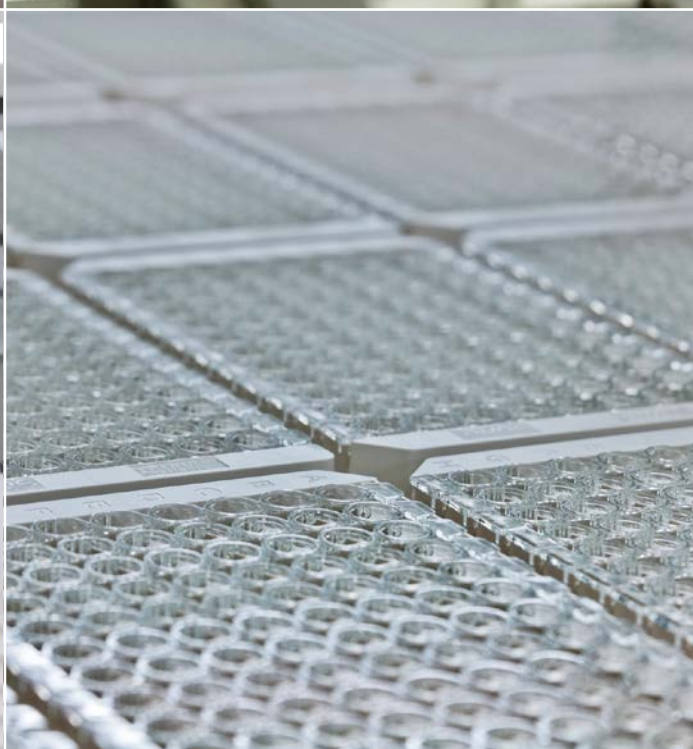
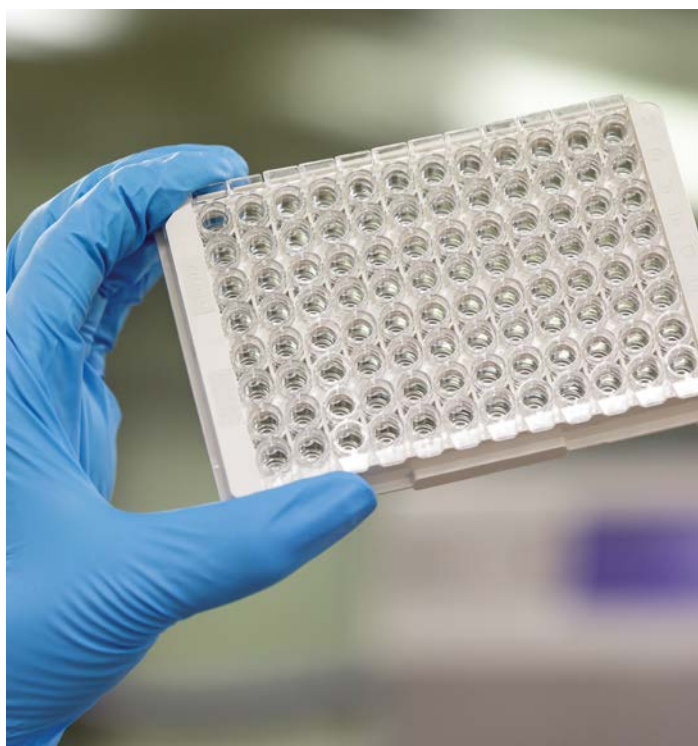


ELISA

Biokit's ELISA (Enzyme-Linked ImmunoSorbent Assay) reagents are based on horseradish peroxidase (HRP) enzyme conjugated to antibodies for the qualitative or quantitative detection of antibodies (IgG, IgM or total antibodies) or antigens for infectious diseases.

ELISA is still the reference method used for diagnosis and monitoring patients in a high number of diseases and conditions, including blood screening. The high level of biomaterials purity and our expertise with ELISA reagents make Biokit the best choice.

Other assays not included in this catalog can be produced in bulk under demand. Please contact our OEM Department (OEM@biokit.com)



Bulk Assay Technologies

Rapid Test

Latex particle agglutination on slide

The latex reagents are based in a suspension of polystyrene latex particles of uniform size coated with native or recombinant proteins. Latex particles allow visual reading of the antigen-antibody reaction.

Biokit's products are characterized for their high-quality latex reagents which prevent the prozone effect, and for the high level of purity of both the native or recombinant proteins coated in the latex particles.

Flocculation

Flocculation reagents are based in the aggregation of materials that are in suspension. The RPR test is based in a suspension of cardiolipin and charcoal microparticles. When detecting a positive sample, the antigen-antibody complexes aggregate together with charcoal particles, allowing visual reading.

Its high level of expertise in RPR assays for Syphilis detection makes Biokit the perfect choice for Syphilis diagnosis.

Hemagglutination

Hemagglutination, or haemagglutination, is a specific form of agglutination that involves red blood cells that are sensitized with specific antigens. When the antigen-antibody reaction takes place, agglutination of red blood cells occurs.

Biokit's TPHA (*Treponema pallidum* Hemagglutination) reagents are composed by a solution of stabilized chicken erythrocytes sensitized with an antigen extract of *Treponema pallidum*.

Biokit's TPHA products have been evaluated in the most prestigious European Centers.

Other assays not included in this catalog can be produced in bulk under demand. Please contact our OEM Department (OEM@biokit.com)



Bulk Products

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		Assays			Approvals
Product Description	Page	Turbidimetric	ELISA	Rapid Test	CE*
Infectious Diseases					
Hepatitis B					
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Ferritin	15				
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* Approval related to Biokit own brand products



Turbidimetry

Product Description	Type of sample	Storage	Page
C-Reactive Protein	Serum	2 - 8 °C	12
Anti-Streptolysin O	Serum or Plasma	2 - 8 °C	12
Rheumatoid Factor	Serum or Plasma	2 - 8 °C	13
IgA	Serum or Plasma	2 - 8 °C	13
IgG	Serum or Plasma	2 - 8 °C	14
IgM	Serum or Plasma	2 - 8 °C	14
IgE	Serum or Plasma	2 - 8 °C	15
Ferritin	Serum or Plasma	2 - 8 °C	15
Myoglobin	Serum or Plasma	2 - 8 °C	16
β2-microglobulin	Serum or Plasma or Urine	2 - 8 °C	16



Turbidimetry

Product Description	Presentation	Reference	Preparation
C-Reactive Protein			
CRP plus Buffer	mL	300112209D	Ready to use
CRP plus Reagent	mL	300112209R	Ready to use
CRP plus Calibrator	mL	300112093S	Ready to use
ASO-CRP-RF Control I	mL	300112069C1	Ready to use
ASO-CRP-RF Control II	mL	300112070C2	Ready to use

Main features

Method.....	Turbidimetry (Latex based)	Results.....	Results are expressed in mg/L of CRP based on the WHO International Standard (NIBSC 85/506)
Type of Assay.....	Quantitative	Linearity*.....	5 - 100 mg/L without rerun 5 - 600 mg/L with rerun
Sample Type.....	Serum		
Shelf life.....	24 months (for Buffer and Reagent)		
Stability*.....	- CRP plus Buffer: 35 days on-board stability - CRP plus Reagent (Latex): 35 days on-board stability - CRP plus Calibrator (1 calibration point, Linear): stable until the expiration date (if stored between 2-8°C) - ASO-CRP-RF Control I: stable until the expiration date (if stored between 2-8°C) - ASO-CRP-RF Control II: stable until the expiration date (if stored between 2-8°C)		

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

Anti-Streptolysin O

ASO plus Buffer	mL	300112304D	Ready to use
ASO plus Reagent	mL	300112304R	Ready to use
ASO plus Calibrator	1 mL/vial	302112312S	Lyophilized
ASO-CRP-RF Control I	mL	300112069C1	Ready to use
ASO-CRP-RF Control II	mL	300112070C2	Ready to use

Main features

Method.....	Turbidimetry (Latex based)	Results.....	Results are expressed in IU/mL of anti-Streptolysin O based on the WHO International Standard
Type of Assay.....	Quantitative	Linearity*.....	50 - 850 IU/mL without rerun 50 - 4250 IU/mL with rerun
Sample Type.....	Serum or plasma (K2-EDTA, Li-Heparin)		
Shelf life.....	19 months (for Buffer and Reagent)		
Stability*.....	- ASO plus Buffer: 60 days on-board stability - ASO plus Reagent (Latex): 60 days on-board stability - ASO plus Calibrator (1 calibration point, Linear): 15 days once reconstituted (if stored between 2-8°C) - ASO-CRP-RF Control I: stable until the expiration date (if stored between 2-8°C) - ASO-CRP-RF Control II: stable until the expiration date (if stored between 2-8°C)		

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

Product Description	Presentation	Reference	Preparation
Rheumatoid Factor			
RF(II) Buffer	mL	300112333D	Ready to use
RF(II) Reagent	mL	300112333R	Ready to use
RF plus Calibrator	mL	300112252S	Ready to use
ASO-CRP-RF Control I	mL	300112069C1	Ready to use
ASO-CRP-RF Control II	mL	300112070C2	Ready to use

Main features

Method.....	Turbidimetry (Latex based)	Results	Results are expressed in IU/mL of RF based on the WHO International Standard
Type of Assay.....	Quantitative	Linearity*.....	10 - 200 IU/mL without rerun 10- 4000 IU/mL with rerun
Sample Type.....	Serum or plasma (K2-EDTA, Li-Heparin, Li-Heparin PST, Na-Heparin and Na-Citrate)		
Shelf life.....	16 months (for Buffer and Reagent)		
Stability*.....	- RF (II) Buffer: 42 days on-board stability - RF (II) Reagent (Latex): 42 days on-board stability - RF plus standard (6 calibration points by serial dilutions): stable until the expiration date (if stored between 2-8°C) - ASO-CRP-RF Control I: stable until the expiration date (if stored between 2-8°C) - ASO-CRP-RF Control II: stable until the expiration date (if stored between 2-8°C)		* Stability and Linearity studies were performed using an ILab600/650 analyzer (Instrumentation Laboratory).

IgA

IgA/IgG/IgM Buffer	mL	300112268D	Ready to use
IgA Reagent	mL	300112268R	Ready to use
PROTEINS Calibrator 1	mL	300112128S1	Ready to use
PROTEINS Calibrator 2	mL	300112128S2	Ready to use
PROTEINS Calibrator 3	mL	300112128S3	Ready to use
PROTEINS Calibrator 4	mL	300112128S4	Ready to use
PROTEINS Calibrator 5	mL	300112128S5	Ready to use
PROTEINS Control I	1 mL/vial	300112122C1	Lyophilized
PROTEINS Control II	1 mL/vial	300112122C2	Lyophilized

Main features

Method.....	Turbidimetry (Antiserum Reagent)	Results	Results are expressed in mg/dL or g/L of IgA based on the International Reference Material ERM-DA470k/IFCC
Type of Assay.....	Quantitative	Linearity*.....	30 - 900 mg/dL without rerun 6 - 9000 mg/dL with rerun
Sample Type.....	Serum or plasma (EDTA)		
Shelf life.....	20 months (for Buffer and Reagent)		
Stability*.....	- IgA/IgG/IgM Buffer: 30 days on-board stability - IgA Reagent (Antiserum): 30 days on-board stability - PROTEINS Calibrators (5 calibration points): stable until the expiration date (if stored between 2-8°C) - PROTEINS Control I: 15 days once reconstituted (if stored between 2-8°C) - PROTEINS Control II: 15 days once reconstituted (if stored between 2-8°C)		* Stability and Linearity studies were performed using an ILab600/650 analyzer (Instrumentation Laboratory).

Turbidimetry

Product Description	Presentation	Reference	Preparation
IgG			
IgA/IgG/IgM Buffer	mL	300112268D	Ready to use
IgG Reagent	mL	300112269R	Ready to use
PROTEINS Calibrator 1	mL	300112128S1	Ready to use
PROTEINS Calibrator 2	mL	300112128S2	Ready to use
PROTEINS Calibrator 3	mL	300112128S3	Ready to use
PROTEINS Calibrator 4	mL	300112128S4	Ready to use
PROTEINS Calibrator 5	mL	300112128S5	Ready to use
PROTEINS Control I	1 mL/vial	300112122C1	Lyophilized
PROTEINS Control II	1 mL/vial	300112122C2	Lyophilized

Main features

Method	Turbidimetry (Antiserum reagent)	Results	Results are expressed in mg/dL or g/L of IgG based on the International Reference Material ERM-DA470k/IFCC
Type of Assay	Quantitative	Linearity*	350-4100 mg/dL without rerun 70-41000 mg/dL with rerun
Sample Type	Serum or plasma (EDTA)		
Shelf life	20 months (for Buffer and Reagent)		
Stability*	- IgA/IgG/IgM Buffer: 30 days on-board stability - IgA Reagent (Antiserum): 30 days on-board stability - PROTEINS Calibrators (5 calibration points): stable until the expiration date (if stored between 2-8°C) - PROTEINS Control I: 15 days once reconstituted (if stored between 2-8°C) - PROTEINS Control II: 15 days once reconstituted (if stored between 2-8°C)		

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

IgM

IgA/IgG/IgM Buffer	mL	300112268D	Ready to use
IgM Reagent	mL	300112270R	Ready to use
PROTEINS Calibrator 1	mL	300112128S1	Ready to use
PROTEINS Calibrator 2	mL	300112128S2	Ready to use
PROTEINS Calibrator 3	mL	300112128S3	Ready to use
PROTEINS Calibrator 4	mL	300112128S4	Ready to use
PROTEINS Calibrator 5	mL	300112128S5	Ready to use
PROTEINS Control I	1 mL/vial	300112122C1	Lyophilized
PROTEINS Control II	1 mL/vial	300112122C2	Lyophilized

Main features

Method	Turbidimetry (Antiserum reagent)	Results	Results are expressed in mg/dL or g/L of IgM based on the International Reference Material ERM-DA470k/IFCC
Type of Assay	Quantitative	Linearity*	30 - 400 mg/dL without rerun 10 - 4000 mg/dL with rerun
Sample Type	Serum or plasma (EDTA)		
Shelf life	20 months (for Buffer and Reagent)		
Stability*	- IgA/IgG/IgM Buffer: 30 days on-board stability - IgA Reagent (Antiserum): 30 days on-board stability - PROTEINS Calibrators (5 calibration points): stable until the expiration date (if stored between 2-8°C) - PROTEINS Control I: 15 days once reconstituted (if stored between 2-8°C) - PROTEINS Control II: 15 days once reconstituted (if stored between 2-8°C)		

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

Product Description	Presentation	Reference	Preparation
IgE			
IgE Buffer	mL	300112238D	Ready to use
IgE Reagent	mL	300112238R	Ready to use
IgE Calibrator 1	mL	300112240S1	Ready to use
IgE Calibrator 2	mL	300112240S2	Ready to use
IgE Calibrator 3	mL	300112240S3	Ready to use
IgE Calibrator 4	mL	300112240S4	Ready to use
IgE Calibrator 5	mL	300112240S5	Ready to use
FER/MYO/IgE Control I	3 mL/vial	300112222C1	Lyophilized
FER/MYO/IgE Control II	3 mL/vial	300112222C2	Lyophilized

Main features

Method.....	Turbidimetry (Latex based)
Type of Assay.....	Quantitative
Sample Type.....	Serum or plasma (EDTA, heparin, citrate)
Shelf life.....	20 months (for Buffer and Reagent)
Stability*.....	- IgE Buffer: 20 days on-board stability - IgE Reagent (Latex): 20 days on-board stability - IgE Calibrators (5 calibration points): stable until the expiration date (if stored between 2-8°C) - FER/MYO/IgE Control I: 15 days once reconstituted (if stored between 2-8°C) - FER/MYO/IgE Control II: 15 days once reconstituted (if stored between 2-8°C)

Results.....	Results are expressed in IU/mL of IgE based on the 2 nd WHO International Reference Preparation (NIBSC 75/502)
Linearity*.....	30 - 1000 IU/mL without rerun 10 -10000 IU/mL with rerun

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

Ferritin

FERRITIN Buffer	mL	300112271D	Ready to use
FERRITIN Reagent	mL	300112271R	Ready to use
FERRITIN Calibrator 1	mL	300112223S1	Ready to use
FERRITIN Calibrator 2	mL	300112223S2	Ready to use
FERRITIN Calibrator 3	mL	300112223S3	Ready to use
FERRITIN Calibrator 4	mL	300112223S4	Ready to use
FER/MYO/IgE Control I	3 mL/vial	300112222C1	Lyophilized
FER/MYO/IgE Control II	3 mL/vial	300112222C2	Lyophilized

Main features

Method.....	Turbidimetry (Latex based)
Type of Assay.....	Quantitative
Sample Type.....	Serum or plasma (EDTA)
Shelf life.....	12 months (for Buffer and Reagent)
Stability*.....	- FERRITIN Buffer: 30 days on-board stability - FERRITIN Reagent (Latex): 30 days on-board stability - FERRITIN Calibrators (4 calibration points): stable until the expiration date (if stored between 2-8°C) - FER/MYO/IgE Control I: 15 days once reconstituted (if stored between 2-8°C) - FER/MYO/IgE Control II: 15 days once reconstituted (if stored between 2-8°C)

Results.....	Results are expressed in ng/mL of ferritin based on the 3 rd WHO International Standard (NIBSC 94/572)
Linearity*.....	15 - 500 ng/mL without rerun 15 - 5000 ng/mL withrerun

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

Turbidimetry

Product Description	Presentation	Reference	Preparation
Myoglobin			
MYOGLOBIN Buffer	mL	300112329D	Ready to use
MYOGLOBIN Reagent	mL	300112329R	Ready to use
MYOGLOBIN Calibrator 1	1 mL/vial	300112330S1	Ready to use
MYOGLOBIN Calibrator 2	1 mL/vial	300112330S2	Ready to use
MYOGLOBIN Calibrator 3	1 mL/vial	300112330S3	Ready to use
MYOGLOBIN Calibrator 4	1 mL/vial	300112330S4	Ready to use
MYOGLOBIN Calibrator 5	1 mL/vial	300112330S5	Ready to use
FER/MYO/IgE Control I	3 mL/vial	300112222C1	Lyophilized
FER/MYO/IgE Control II	3 mL/vial	300112222C2	Lyophilized

Main features

Method.....	Turbidimetry (Latex based)
Type of Assay.....	Quantitative
Sample Type.....	Serum or plasma (EDTA, Li-Heparin)
Shelf life.....	18 months (for Buffer and Reagent)
Stability*.....	• MYOGLOBIN Buffer: 60 days on-board stability • MYOGLOBIN Reagent (Latex): 60 days on-board stability • MYOGLOBIN Calibrators (5 calibration points): stable until the expiration date (if stored between 2-8°C) • FER/MYO/IgE Control I: 15 days once reconstituted (if stored between 2-8°C) • FER/MYO/IgE Control II: 15 days once reconstituted (if stored between 2-8°C)

Results.....	Results are expressed in ng/mL of myoglobin
Linearity*.....	10 - 500 ng/mL without rerun 10 - 5000 ng/mL with rerun

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

β2-microglobulin

β2m Buffer	mL	300112307D	Ready to use
β2m Reagent	mL	300112307R	Ready to use
β2m Calibrator	mL	300112192S	Ready to use
PROTEINS Control I	1 mL/vial	300112122C1	Lyophilized
PROTEINS Control II	1 mL/vial	300112122C2	Lyophilized

Main features

Method.....	Turbidimetry (Latex based)
Type of Assay.....	Quantitative
Sample Type.....	Serum, plasma (EDTA, Na-Heparin) or urine
Shelf life.....	24 months (for Buffer and Reagent)
Stability*.....	• β2-microglobulin Buffer: 28 days on-board stability • β2-microglobulin Reagent (Latex): 28 days on-board stability • β2-microglobulin Calibrator (1 calibration point, Linear): stable until the expiration date (if stored between 2-8°C) • Proteins Control I: 15 days once reconstituted (if stored between 2-8°C) • Proteins Control II: 15 days once reconstituted (if stored between 2-8°C)

Results.....	Results are expressed in mg/L of β2-microglobulin based on the WHO International Standard
Linearity*.....	0.5 - 16 mg/L without rerun 0.05 - 96 mg/L with rerun

* Stability and Linearity studies were performed using an iLab600/650 analyzer (Instrumentation Laboratory).

ELISA

Product Description	Type of sample	Storage	Page
HBsAg	Serum or Plasma	2 - 8 °C	18
HCV	Serum or Plasma	2 - 8 °C	18
Syphilis	Serum or Plasma	2 - 8 °C	19
Chagas	Serum or Plasma	2 - 8 °C	19



Product Description	Presentation*	Reference	Preparation
HBsAg			
Plate ELISA HBsAg	unit	300111158R	Ready to use
Concentrated Conjugate ELISA HBsAg 51x	0.4 mL/vial	300111158C	Concentrated
Conjugate Diluent ELISA HBsAg	16 mL/vial	300111158D	Ready to use
Positive Control ELISA HBsAg	1.7 mL/vial	300111158P	Ready to use
Negative Control ELISA HBsAg	5 mL/vial	300111158N	Ready to use
Wash Solution ELISA	50 mL/vial	300111158L	Concentrated
TMB-DMSO ELISA	1.5 mL/vial	300111158T	Concentrated
Substrate Buffer ELISA	14 mL/vial	300111158S	Ready to use
Stop Solution ELISA	12mL/vial	300111158B	Ready to use

* Presentation can be adapted to specific needs.

Main features

Method.....	EIA Sandwich
Type of Assay.....	Qualitative
Sample Type.....	Serum or plasma (EDTA, Citrate)
Sample size.....	100 µL
Shelf life.....	14 months
Stability.....	• Plate ELISA HBsAg: 3 months after opening plastic bag • Diluted conjugate: 7 days (if stored between 2-8 °C) • Diluted wash solution: 14 days (if stored between 2-8 °C) • Diluted substrate: 8 hours • All other components are stable until expiration date

Composition.....	• Microplate: Polyclonal Antibodies against HBsAg (ad+ay subtypes) • Conjugate: Polyclonal Antibodies against HBsAg (ad+ay subtypes), labelled with HRP
Performance.....	• Analytical sensitivity • 0.100 U/mL for ad and ay subtypes, based on Paul Ehrlich Institute Standard (PEI-Germany, ref. 87) • 0.125 IU/mL for adw2 subtype, genotype A, based on the 2nd WHO International Standard (NIBSC code: 00/588) • Sensitivity: 100% (n=416) • Specificity: 99.94% (n=4,871)

HCV

Plate ELISA HCV	unit	300111115R	Ready to use
Concentrated Conjugate ELISA HCV 51x	0.4 mL/vial	300111115C	Concentrated
Conjugate Diluent ELISA HCV	15 mL/vial	300111115D	Ready to use
High Positive Control ELISA HCV	2 mL/vial	300111115H	Ready to use
Low Positive Control ELISA HCV	7 mL/vial	300111115M	Ready to use
Negative Control ELISA HCV	5 mL/vial	300111115N	Ready to use
Sample Diluent ELISA HCV	30 mL/vial	300111115A	Ready to use
Wash Solution ELISA	50 mL/vial	300111158L	Concentrated
TMB-DMSO ELISA	1.5 mL/vial	300111102T	Concentrated
Substrate Buffer ELISA	14 mL/vial	300111158S	Ready to use
Stop Solution ELISA	12mL/vial	300111158B	Ready to use

* Presentation can be adapted to specific needs.

Main features

Method.....	EIA Indirect
Type of Assay.....	Qualitative
Sample Type.....	Serum or plasma (EDTA)
Sample size.....	10 µL (Dilution 1:20)
Shelf life.....	12 months
Stability.....	• Plate ELISA HCV: 2 months after opening plastic bag • Diluted conjugate: 14 days (if stored between 2-8 °C) • Diluted wash solution: 14 days (if stored between 2-8 °C) • Diluted substrate: 8 hours • All other components are stable until expiration date

Composition.....	• Microplate: recombinant antigens Core, NS3, NS4 and NS5 from Hepatitis C Virus • Conjugate: anti-Human IgG labelled with HRP
Performance.....	• Sensitivity: 100% (n=723) • Specificity: 99.8% (n=6,206)

Product Description	Presentation*	Reference	Preparation
Syphilis			
Plate ELISA Syphilis	unit	300111148R	Ready to use
Concentrated Conjugate ELISA Syphilis 51x	0.4 mL/vial	300111148C	Concentrated
Conjugate Diluent ELISA Syphilis	15 mL/vial	300111148D	Ready to use
High Positive Control ELISA Syphilis	2 mL/vial	300111148H	Ready to use
Low Positive Control ELISA Syphilis	2 mL/vial	300111148M	Ready to use
Negative Control ELISA Syphilis	2 mL/vial	300111148N	Ready to use
Sample Diluent ELISA Syphilis	30 mL/vial	300111148A	Ready to use
Wash Solution ELISA	50 mL/vial	300111158L	Concentrated
TMB-DMSO Colour ELISA	1.5 mL/vial	300111158T	Concentrated
Substrate Buffer ELISA	14 mL/vial	300111158S	Ready to use
Stop Solution ELISA	12mL/vial	300111158B	Ready to use

* Presentation can be adapted to specific needs.

Main features

Method.....	EIA Sandwich
Type of Assay.....	Qualitative
Sample Type.....	Serum or plasma (EDTA, ACD, Li-Heparin, Na-Heparin, Na-Citrate, K-Oxalate, CPD and CPDA)
Sample size.....	50 µL (Dilution 1:2)
Shelf life.....	18 months
Stability.....	• Plate ELISA Syphilis: 3 months after opening plastic bag • Diluted conjugate: 30 days (if stored between 2-8 °C) • Diluted wash solution: 14 days (if stored between 2-8 °C) • Diluted substrate: 8 hours • All other components are stable until expiration date

Composition.....	• Microplate: <i>Treponema pallidum</i> recombinant antigens p15, p17 and p47 • Conjugate: <i>Treponema pallidum</i> recombinant antigens p15, p17 and p47 labelled with HRP
Performance.....	• Analytical sensitivity: 0.030 IU/mL based on the 1st WHO International Standard (HS, 1958, NIBSC) • Sensitivity: 100% (n=184) • Specificity: 99.8% (n=2,883)

Chagas

Plate ELISA Chagas	unit	300111236R	Ready to use
Concentrated Conjugate ELISA Chagas 51x	0.35 mL/vial	300111236C	Concentrated
Conjugate Diluent ELISA Chagas	15 mL/vial	300111236D	Ready to use
Positive Control ELISA Chagas	2 mL/vial	300111236P	Ready to use
Negative Control ELISA Chagas	3 mL/vial	300111236N	Ready to use
Sample Diluent ELISA Chagas	30 mL/vial	300111236A	Ready to use
Wash Solution ELISA	50 mL/vial	300111158L	Concentrated
TMB-DMSO ELISA	1.5 mL/vial	300111102T	Concentrated
Substrate Buffer ELISA	14 mL/vial	300111158S	Ready to use
Stop Solution ELISA	12mL/vial	300111158B	Ready to use

* Presentation can be adapted to specific needs.

Main features

Method.....	EIA Indirect
Type of Assay.....	Qualitative
Sample Type.....	Serum or plasma (EDTA)
Sample size.....	10 µL (Dilution 1:20)
Shelf life.....	13 months
Stability.....	• Plate ELISA Chagas: 3 months after opening plastic bag • Diluted conjugate: 1 day • Diluted wash solution: 15 days (if stored between 2-8 °C)

Composition.....	• Diluted substrate: 8 hours • All other components are stable until expiration date • Microplate: recombinant antigen representing 4 immunodominant epitopes • Conjugate: anti-human IgG and anti-human IgM labeled with HRP
Performance.....	• Sensitivity: 100% (n=115) • Specificity: 99.5% (n=8,402)

Rapid Test

Product Description	Type of sample	Storage	Page
C-Reactive Protein	Serum	2 - 8 °C	21
Anti-Streptolysin O	Serum	2 - 8 °C	21
Rheumatoid Factor	Serum	2 - 8 °C	21
RPR	Serum or Plasma	2 - 8 °C	22
TPHA	Serum or Plasma	2 - 8 °C	22
Mononucleosis	Serum or Plasma	2 - 8 °C	22
Toxoplasma	Serum	2 - 8 °C	23
Rubella	Serum	2 - 8 °C	23



Product Description	Presentation	Reference	Preparation
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C-Reactive Protein

LATEX CRP Reagent	mL	300117049R	Ready to use
LATEX CRP Positive Control	mL	300117049P	Ready to use
LATEX CRP Negative Control	mL	300117049N	Ready to use

Main features

Method..... Latex agglutination
 Type of Assay..... Qualitative or semiquantitative
 Sample Type..... Serum
 Sample size..... 50 µL
 Shelf life..... 24 months
 Stability..... All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent..... Suspension of polystyrene latex particles coated with rabbit IgG anti-human CRP
 Performance..... • Agreement with diluted samples: 98,5% (n=204)

ASO

LATEX ASO Reagent	mL	300117007R	Ready to use
LATEX ASO Positive Control	mL	300117007P	Ready to use
LATEX ASO Negative Control	mL	300117007N	Ready to use

Main features

Method..... Latex agglutination
 Type of Assay..... Qualitative or semiquantitative
 Sample Type..... Serum
 Sample size..... 50 µL
 Shelf life..... 16 months
 Stability..... All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent..... Suspension of polystyrene latex particles coated with recombinant Streptolysin-O
 Performance..... • Sensitivity: 96.7% (n=170)
 • Specificity: 95.4% (n=170)

RF

LATEX RF Reagent	mL	300117034R	Ready to use
LATEX RF Positive Control	mL	300117034P	Ready to use
LATEX RF Negative Control	mL	300117034N	Ready to use

Main features

Method..... Latex agglutination
 Type of Assay..... Qualitative or semiquantitative
 Sample Type..... Serum
 Sample size..... 50 µL
 Shelf life..... 19 months
 Stability..... All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent..... Suspension of polystyrene latex particles coated with human IgG
 Performance..... • Agreement with diluted samples: 91,7% (n=192)
 • Agreement with undiluted samples: 96% (n=223)

Rapid Test

Product Description	Presentation	Reference	Preparation
RPR			
RPR Reagent	mL	300115511R	Ready to use
RPR Positive Control	mL	300115511P	Ready to use
RPR Negative Control	mL	300115511N	Ready to use

Main features

Method.....	Charcoal flocculation
Type of Assay.....	Qualitative or semiquantitative
Sample Type.....	Serum or plasma (EDTA)
Sample size.....	50 µL
Shelf life.....	19 months
Stability.....	All the reagents are stable until expiration date (if stored between 2-8 °C)

Performance.....	• Serum samples • Sensitivity: 92.3% (n=52) • Specificity: 99.3% (n=453) • Plasma samples • Sensitivity: 100% (n=174) • Specificity: 99.4% (n=174)
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TPHA

TPHA Antigen Reagent	mL	300115700R	Ready to use
TPHA Positive Control	mL	300115700P	Ready to use
TPHA Negative Control	mL	300115700N	Ready to use
TPHA Control Reagent	mL	300115700C	Ready to use
TPHA Diluent Solution	mL	300115700D	Ready to use

Main features

Method.....	Hemagglutination
Type of Assay.....	Qualitative or semiquantitative
Sample Type.....	Serum or plasma (EDTA)
Sample size.....	25 µL
Shelf life.....	18 months
Stability.....	All the reagents are stable until expiration date (if stored between 2-8 °C)

Performance.....	• Sensitivity: 99.6% • Specificity: 97.8%
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Mononucleosis

LATEX Mononucleosis Reagent	mL	300111001R	Ready to use
LATEX Mononucleosis Positive Control	mL	300111001P	Ready to use
LATEX Mononucleosis Negative Control	mL	300111001N	Ready to use

Main features

Method.....	Latex agglutination
Type of Assay.....	Qualitative or semiquantitative
Sample Type.....	Serum or plasma (EDTA)
Sample size.....	50 µL
Shelf life.....	24 months
Stability.....	All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent.....	Suspension of polystyrene latex particles coated with Paul-Bunnell antigen
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Performance.....	• Compared with hemagglutination tests against Paul-Bunnell antigen • Sensitivity: 93% • Specificity: 94% • Comparison with Epstein-Barr antigen method • Sensitivity: 99% • Specificity: 93%
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Product Description	Presentation	Reference	Preparation
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Toxoplasma

Toxocell Latex Reagent	mL	300114525R	Ready to use
Toxocell Latex Positive Control	mL	300114525P	Ready to use
Toxocell Latex Negative Control	mL	300114525N	Ready to use

Main features

Method.....	Latex agglutination
Type of Assay.....	Qualitative or semiquantitative
Sample Type.....	Serum
Sample size.....	50 µL
Shelf life.....	16 months
Stability.....	All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent..... Suspension of polystyrene latex particles coated soluble *Toxoplasma gondii* antigen

Performance.....

- **General population**
- **Sensitivity:** 100%
- **Specificity:** 84.2%
- **Pregnant population**
- **Sensitivity:** 100%
- **Specificity:** 98.1%

Rubella

Rubella Latex Reagent	mL	300114001R	Ready to use
Rubella Latex Positive Control	mL	300114001P	Ready to use
Rubella Latex Negative Control	mL	300114001N	Ready to use

Main features

Method.....	Latex agglutination
Type of Assay.....	Qualitative or semiquantitative
Sample Type.....	Serum
Sample size.....	50 µL
Shelf life.....	20 months
Stability.....	All the reagents are stable until expiration date (if stored between 2-8 °C)

Composition latex reagent..... Suspension of polystyrene latex particles coated with inactivated Rubella Virus antigen

Performance.....

- **Sensitivity:** 100%
- **Specificity:** 98.1%

Living Immunoassay Excellence.

Biokit is a biotechnological company aimed at the research, development, manufacture and worldwide distribution of clinical diagnostic reagents and systems.

Biokit's mission is to become the partner of choice as a Centre of Excellence for Immunoassay by providing innovative OEM solutions (products & services) to major IVD players.

Biokit is strongly founded on three major values:

Innovation at all the company levels, always focused on science and technological advances to ensure that our portfolio continuously improves and evolves.

Quality in all processes, from the conception of and research on a new product, up to its final manufacturing and marketing.

Commitment to patients and healthcare professionals, improving quality of care and facilitating disease diagnosis.



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