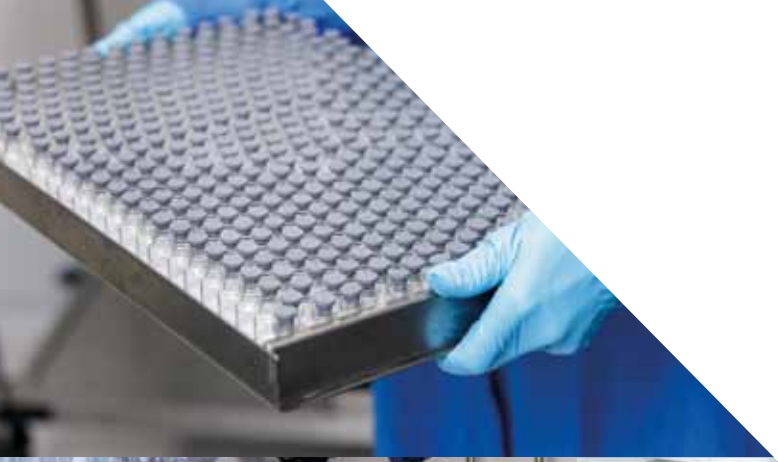
OEM



Bulk Assay Supply

Living Immunoassay Excellence

werfen

Werfen is a growing, family-owned, innovative company founded in 1966 in Barcelona, Spain.

Our OEM Technology Center has consolidated experience in research, development and manufacturing of customized assays and biomaterials.

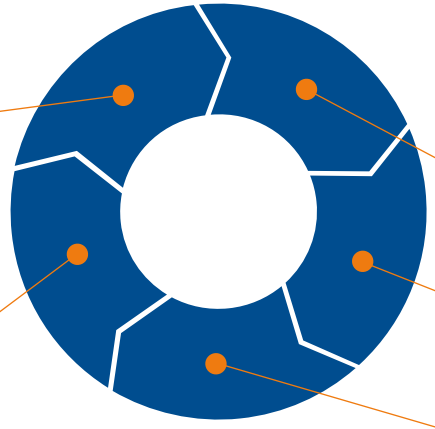
We offer end-to-end solutions for the IVD industry with the most innovative capabilities to enhance competitiveness and time-to-market.

Our mission is to become your partner of choice as a center of excellence in providing innovative end-to-end OEM solutions (products & services) to IVD companies.

Our know-how in turbidimetry technology is focused on their application in commercial IVD assays, which provides a low-risk, reliable and highly successful option for OEM partners to reduce time-to market in their developments and secure their operations.

To identify and incorporate the most **innovative** tools and technologies

Development adhering to validated quality procedures standards to ensure **traceability, reproducibility** and **robustness**



Most of the biomaterials and the entire manufacturing process are produced and performed at our facilities, allowing **complete control on the quality** of the final product.

> 100 references reached the IVD market

In-market product support to meet all the OEM partners' needs

Menu for Serum Proteins

Product Description	Method	Type of Assay	Preparation	Shelf Life (Reagent&Buffer)	
Inflammation makers					p. 4
Anti-Streptolysin O	Latex Reagent	Quantitative	Ready-to-use except calibrator	19 Months	
C-Reactive Protein	Latex Reagent	Quantitative	Ready-to-use	19 Months	
Rheumatoid Factor	Latex Reagent	Quantitative	Ready-to-use	19 Months	
Immunoglobulins					p. 7
IgE	Latex Reagent	Quantitative	Ready-to-use except calibrator	20 Months	
Other Serum Proteins					p. 9
Ferritin	Latex Reagent	Quantitative	Ready-to-use except calibrator	12 Months	
Myoglobin	Latex Reagent	Quantitative	Ready-to-use except calibrator	18 Months	
β-2 microglobulin	Latex Reagent	Quantitative	Ready-to-use except calibrator	24 Months	

We can also provide you all the necessary components for a chemiluminescent assay, reducing time-to-market and development risks.

Contact us to discuss your bulk reagent needs at oem@werfen.com

Anti-Streptolysin O

Clinical Significance

The group A ß-hemolytic streptococci produces various toxins that can act as antigens. One of these exotoxins is Streptolysin O (SLO). The affected organism produces specific antibodies against these exotoxins, among which concentration of anti-Streptolysin O (ASO) in the patient's serum will enable to establish the degree of infection due to the ß-hemolytic streptococcus.

Intended Use

The Anti-Streptolysin O (ASO) assay is intended for the quantitative determination of ASO in human samples using clinical chemistry analyzers.

Principle

The ASO plus reagent is a suspension of polystyrene latex particles of uniform size coated with recombinant SLO. When a sample containing ASO is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme

Reagent (SLO antigen - coated latex particles) | Sample (Anti - SLO Abs) | Agglutination

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
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**
ASO-CRP-RF Control I	Stable until the expiration date**
ASO-CRP-RF Control II	Stable until the expiration date**

Results: Results are expressed in IU/mL of anti-Streptolysin O based on the WHO International Standard.

Interferences: No significant interference from lipemia up to sample absorbance of 3.6/cm at 660 nm, triglycerides up to concentrations of 1282 mg/dL, bilirubin up to concentrations of 18 mg/dL, hemoglobin up to concentrations of 500 mg/dL and rheumatoid factor up to 400 IU/mL.

Linearity:

Without automatic rerun capability: 50 - 850 IU/mL
With automatic rerun capability: 50 – 4250 IU/mL

Precision:

ILab 600	Samples / Runs	Mean (IU/mL)	CV (%)	Mean (IU/mL)	CV (%)
Within run	3/10	183	3.7	335	4.3
Total	3/10	183	5.3	335	5.2

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
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

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

C-Reactive Protein

Clinical Significance

C-Reactive Protein (CRP) is frequently found in the sera of healthy adults in very low concentrations. However, during the inflammatory process, the titers of CRP can reach levels that are far above normal values. In these cases CRP titers increase of CRP occurs in a non-specific way in different kinds of tissular aggressions. For this reason a high CRP concentration in serum lacks diagnostic value when the patients'illness is not defined. Nevertheless, it is very useful for following-up and monitoring such illnesses, as well as for the differential diagnosis in certain cases.

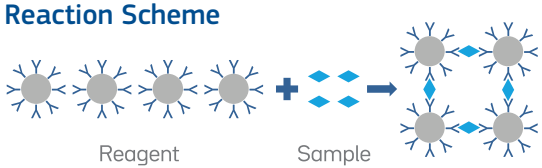
Intended Use

The CRP assay is intended for the quantitative determination of CRP inhuman samples using clinical chemistry analyzers.

Principle

The C-Reactive Protein (CRP) plus reagent is a suspension of polystyrene latex particles of uniform size coated with IgG anti-human CRP. When a sample containing CRP is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme



Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
Shelf life: 19 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**
ASO-CRP-RF Control I	Stable until the expiration date**
ASO-CRP-RF Control II	Stable until the expiration date**

Results: Results are expressed in mg/L of CRP based on the WHO International Standard (NIBSC 85/506)

Interferences: No significant interference from lipemia up to sample absorbance of 3.6 AU/cm at 660 nm, triglycerides up to concentrations of 340 mg/dL, bilirubin up to concentrations of 30 mg/dL and hemoglobin up to concentrations of 800 mg/dL.

Linearity:

Without automatic rerun capability: 5 / 100 mg/L
With automatic rerun capability: 5 / 600 mg/L

Precision:

ILab 600	Samples / Runs	Mean (mg/L)	CV (%)	Mean (mg/L)	CV (%)
Within run	5/6	18.0	2.5	71.4	0.8
Total	5/6	18.0	1.7	71.4	1.4

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
CRP plus Buffer	mL	300112209D	Ready to use
CRP plus Reagent	mL	300112209R	Ready to use
CRP plus Calibrator	mL	302112093S	Ready to use
ASO-CRP-RF Control I	mL	300112069C1	Ready to use
ASO-CRP-RF Control II	mL	300112070C2	Ready to use

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

Rheumatoid Factor

Clinical Significance

The sera of most rheumatoid arthritic patients react with human IgG and the IgG of other animals due to the presence of an immunoglobulin (in most cases of the IgM type) known as rheumatoid factor. During this reaction, which is of the antigen-antibody type, rheumatoid factor (RF) acts as an anti-IgG antibody. A positive latex test, indicating the existence of RF, is practically a decisive test for the diagnosis of rheumatoid arthritis in patients with inflammatory arthritis.

Intended Use

The Rheumatoid Factor (RF) assay is intended for the quantitative determination of RF in human samples using clinical chemistry analyzers.

Principle

The RF (II) reagent is a suspension of polystyrene latex particles of uniform size coated with human gammaglobulin. When a sample containing RF is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme

Reagent (Human IgG coated latex particles)

Sample (RF)

Agglutination

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
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**
ASO-CRP-RF Control I	Stable until the expiration date**
ASO-CRP-RF Control II	Stable until the expiration date**

Results: Results are expressed in IU/mL of RF based on the WHO International Standard.

Interferences: No significant interference from turbidity up to sample absorbance of 2.4 AU/cm at 660 nm, triglycerides up to concentrations of 1320 mg/dL, bilirubin up to concentrations of 19.6 mg/dL, and hemoglobin up to concentrations of 500 mg/dL.

Linearity:

Without automatic rerun capability: 10 – 200 IU/mL
With automatic rerun capability: 10 – 4000 IU/mL

There is no prozone effect for undiluted samples containing up to 5000 IU/mL.
Sample concentrations higher than 5000 IU/mL have not been tested.

Precision:

ILab 600	Samples / Runs	Mean (IU/mL)	CV (%)	Mean (IU/mL)	CV (%)	Mean (IU/mL)	CV (%)
Within run	2/40	15.3	2.5	49.9	2.1	130.6	2.5
Total	2/40	15.3	3.9	49.9	2.7	130.6	2.8

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
RF (II) Buffer	mL	300112333D	Ready to use
RF (II) Reagent	mL	300112333R	Ready to use
RF plus Calibrator	1 mL/vial	302112252S	Ready to use
ASO-CRP-RF Control I	mL	300112069C1	Ready to use
ASO-CRP-RF Control II	mL	300112070C2	Ready to use

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

Immunoglobulin E

Clinical Significance

Measurements of Immunoglobulin E (IgE) are useful to carry out on a routine basis for diagnosis postoperative monitoring and assessment of treatment of the atopy-associated diseases such as atopic asthma, rhinitis and dermatitis etc., as well as of the infectious diseases caused by parasites and of the IgE - myeloma. Furthermore it is used in confirmatory tests for the allergy-inducing specific agents (allergens).

Intended Use

The IgE assay is intended for the quantitative determination of Immunoglobulin E (IgE) in human samples using clinical chemistry analyzers.

Principle

The IgE reagent is a suspension of polystyrene latex particles of uniform size coated with anti-human IgE monoclonal antibody. When a sample containing IgE is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
Shelf life: 20 months (for Buffer and Reagent)

Stability:

IgE Buffer	20 days on-board stability
IgM Reagent (Latex)	20 days on-board stability
IgE Calibrators (5 calibration points)	Stable until the expiration date**
Fer/Myo/IgE Control I	15 days once reconstituted**
Fer/Myo/IgE Control II	15 days once reconstituted**

Results: Results are expressed in IU/mL of IgE based on the 2nd WHO International Standard (NIBSC 94/572).

Interferences: No significant interference from bilirubin up to concentrations of 14.7 mg/dL (250 µmol/L) and hemoglobin up to concentrations of 1600 mg/dL (0.96mmol/L).

Linearity:

Without automatic rerun capability: 30 – 1000 ng/dL
With automatic rerun capability: 30 – 10000 ng/dL

Precision:

ILab 600	Samples / Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	3/10	51.5	6.3	411	1.3
Total	2/10	51.5	9.6	411	2.2

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
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

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C


R-101

Ferritin

Clinical Significance

Ferritin is a large macromolecule consisting of a protein shell of 24 subunits and an iron core. Isoferritins differ in the proportion of basic "L" andacidic "H" subunits. The basic isoferritins are found in the liver, spleen and bone marrow. They are responsible for long-term iron storage. Acidic isoferritins are found mainly inmyocardium, placenta and tumour tissue and serve as intermediaries for the transfer of iron.

Clinically, low ferritin values can aid in the diagnosis of iron deficiency anaemia while elevated values are found in cases of iron overload due to haemolytic anaemia, multiple transfusions, tumour inflammation, and in patients with cell necrosis of the iron storage organs, such as in liver diseases.

Intended Use

The Ferritin assay is intended for the quantitative determination of ferritinin human samples using clinical chemistry analyzers.

Principle

The Ferritin reagent is a suspension of polystyrene latex particles of uniform size coated with rabbit IgG anti-human ferritin. When a sample containing ferritin is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme

Reagent (Anti - human Ferritin coated latex particles)

Sample (Ferritin)

Agglutination

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
Shelf life: 16 months (for Buffer and Reagent)
Stability:

Ferritin Buffer	30 days on-board stability
Ferritin Reagent (Latex)	30 days on-board stability
Ferritin Calibrators (2 calibration points)	Stable until the expiration date**
Fer/Myo/IgE Control I	15 days once reconstituted**
Fer/Myo/IgE Control II	15 days once reconstituted**

Results: Results are expressed in ng/mL of ferritin based on the 3rd WHO International Standard (NIBSC 94/572).

Interferences: Interference up to 10% is observed from lipemia, for samples with 1000 mg/dL of triglycerides. No significant interference from bilirubin up to concentrations of 20 mg/dL and hemoglobin up to concentrations of 500 mg/dL.

Linearity:

Without automatic rerun capability: 15 – 500 ng/mL
With automatic rerun capability: 15 – 5000 ng/mL

Precision:

ILab 600	Samples / Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	5/6	116.7	0.7	440.3	0.4
Total	5/6	116.7	1.1	440.3	1.0

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
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

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

Myoglobin

Clinical Significance

Myoglobin is an oxygen-binding protein of striated (cardiac and skeletal) muscle. Increases in serum myoglobin concentrations occur following trauma to either skeletal or cardiac muscle, as in crush injury or myocardial infarction. Myoglobin appears in the blood 2 to 4 hours after the onset of pain, and reaches maximum levels within 6 hours while the other cardiac markers show their maximum levels 20 to 24 hours after the onset of symptoms. Myoglobin is the biochemical marker of myocardial damage that most effectively fits the role as an "early" marker, whereas "definitive" markers are cardiac troponins.

Intended Use

The Myoglobin assay is intended for the quantitative of myoglobin in human samples using clinical chemistry analyzers.

Principle

The Myoglobin reagent is a suspension of polystyrene latex particles of uniform size coated with rabbit IgG anti-human myoglobin. When a sample containing myoglobin is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reaction Scheme

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
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**
Fer/Myo/IgE Control I	15 days once reconstituted**
Fer/Myo/IgE Control II	15 days once reconstituted**

Results: Results are expressed in ng/mL of myoglobin.

Interferences: Interference up to 10% is observed from lipemia, for samples with 1000 mg/dL of triglycerides. No significant interference from bilirubin up to concentrations of 20 mg/dL and hemoglobin up to concentrations of 500 mg/dL.

Linearity:

Without automatic rerun capability: 10 – 500 ng/mL
With automatic rerun capability: 10 – 5000 ng/mL

Precision:

ILab 600	Samples / Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	2/40	71.4	1.1	228.6	1.3
Total	2/40	71.4	1.9	228.62	2.3

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
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

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

β2-microglobulin

Clinical Significance

Serum levels of β2-microglobulin (β2m) are frequently elevated in patients with a variety of lymphoproliferative and inflammatory disorders reflecting an augmentation of synthesis. Abnormally high levels of β2m are also associated with renal dysfunction and reduced glomerular filtration reflecting a reduced urinary excretion. Acute rejection of renal transplant patients elevates serum β2m days before other markers like creatinine. In some renal disorders, β2m is also determined in urine being its concentration abnormally high in aminoglycoside or lithium toxicity, heavy metal poisoning and acute tubular necrosis. It also helps to differentiate infections of the upper urinary tract from those of the lower urinary tract.

Intended Use

The β2m assay is intended for the quantitative determination of β2m in human samples using clinical chemistry analyzers.

Principle

The β2m reagent is a suspension of polystyrene latex particles of uniform size coated with the IgG fraction of an anti-human β2m specific serum. When a sample containing β2m is mixed with the reagent, a clear agglutination occurs which can be measured by turbidimetry.

Reaction Scheme

Reagent (Anti - human β2m coated latex particles) | Sample (β2m) | Agglutination

Main Features*

Method: Turbidimetry
Type of Assay: Quantitative
Shelf life: 24 months (for Buffer and Reagent)
Stability:

β2m Buffer	28 days on-board stability
β2m Reagent (Latex)	28 days on-board stability
β2m Calibrators (5 calibration points)	Stable until the expiration date**
Proteins Control I	15 days once reconstituted**
Proteins Control II	15 days once reconstituted**

Results: Results are expressed in mg/L of β2m based on the WHO International Standard.

Interferences: No significant interference from lipemia up to a sample absorbance of 4.3/cm at 660 nm, bilirubin up to concentrations of 25 mg/dL, hemoglobin up to concentrations of 400 mg/dL and rheumatoid factor up to 750 IU/mL.

Linearity:

Without automatic rerun capability: 0.5 – 16 mg/L
With automatic rerun capability: 0.05 – 96 mg/L

High sensitivity application for urine samples: Very low concentrations of β2m can be quantified in urine samples using the rerun capability of the instrument, when possible.

Precision:

ILab 600	Samples / Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	4/10	0.77	2.0	6.02	2.7
Total	4/10	0.77	2.9	6.02	3.7

Applications

Instrument Specific Applications are available for a wide range of Clinical Chemistry analyzers. Contact us to enquire about your specific analyzer.

OEM Ordering References

Description	Presentation	Reference	Preparation
β2m Buffer	mL	300112307D	Ready to use
β2m Reagent	mL	300112307R	Ready to use
β2m Calibrator	mL	300112192S1	Ready to use
Proteins Control I	1 mL/vial	300112122C1	Lyophilized
Proteins Control II	1 mL/vial	300112122C2	Lyophilized

Please contact us for further information about the regarding availability.

* Stability, Linearity and Interferences studies performed using an ILab 600 / 650 analyzer (Instrumentation Laboratory).
**If stored at 2-8°C

Living Immunoassay Excellence

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