



Bulk Assay Supply

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

Our Immunoassay 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.

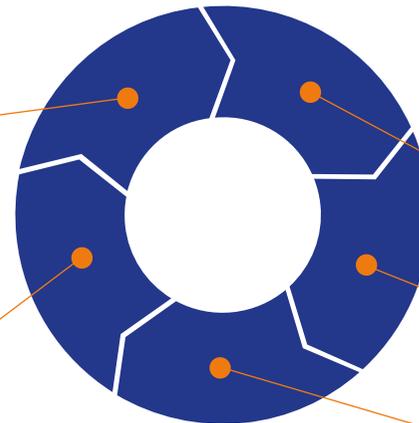
Our mission is to become your partner of choice as a center of excellence in providing innovative end-to-end solutions (products & services) to IVD companies.

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 our 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 our 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 | |
| Other Serum Proteins | | | | | p. 6 |
| 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 immunoassay@werfen.com.

Anti-Streptolysin O

Clinical Significance

The group A β -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 β -hemolytic streptococcus.

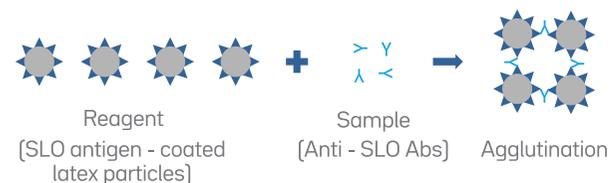
Intended Use

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



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.

Product Range

| Description | Presentation | Preparation |
|-----------------------|--------------|--------------|
| ASO plus Buffer | mL | Ready to use |
| ASO plus Reagent | mL | Ready to use |
| ASO plus Calibrator | 1 mL/vial | Lyophilized |
| ASO-CRP-RF Control I | mL | Ready to use |
| ASO-CRP-RF Control II | mL | Ready to use |

For further information about the regarding availability please contact immunoassay@werfen.com.

* Stability, Linearity and Interferences studies performed using an 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.

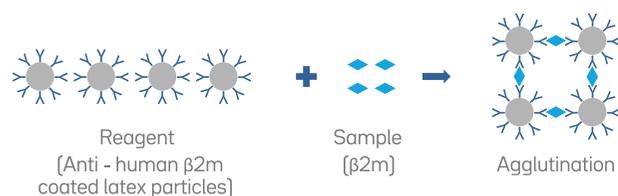
Intended Use

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



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.

Product Range

| Description | Presentation | Preparation |
|---------------------|--------------|--------------|
| β2m Buffer | mL | Ready to use |
| β2m Reagent | mL | Ready to use |
| β2m Calibrator | mL | Ready to use |
| Proteins Control I | 1 mL/vial | Lyophilized |
| Proteins Control II | 1 mL/vial | Lyophilized |

For further information about the regarding availability please contact immunoassay@werfen.com.

* Stability, Linearity and Interferences studies performed using an 650 analyzer [Instrumentation Laboratory].

**If stored at 2-8°C



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