selectra
PRO

ANTI-STREPTOLYSIN O

ASLO
ASLO-0250
R1 : 2 x 25 mL
R2 : 1 x 6 mL
Cal : 1 x 1 mL
ASLO-5025 R1 : 25 mL
ASLO-6006 R2 : 6 mL
ASLO-4001 Cal : 1 mL

CE

PIT-ASLO-EN-v8 (09/2024)

INTENDED USE
ANTI STREPTOLYSIN O is an *in vitro* diagnostic reagent intended for the quantitative determination of anti-streptolysin-O in human serum and plasma samples on analyzers or semi-automatic analyzers.
The calibrator is intended for the calibration of the reagent.
These *in vitro* diagnostic devices are for professional use only.

CLINICAL SIGNIFICANCE [1]
Streptolysin-O (SLO) is a toxin produced by ß-hemolytic streptococci of groups A, C and G.
Determination of SLO antibodies (ASLO or ASO) is used to help diagnose complications following a group A streptococcal infection such as rheumatic fever or acute glomerulonephritis.

LIMITATION OF USE
Confirmation of streptococcal infection requires two determinations separated by one to two weeks.[2]
The simultaneous determination of anti-streptodornase antibody is recommended to improve diagnostic specificity [1]
The quantitative assay of anti-streptolysin-O alone cannot be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE
Latex-enhanced immuno-turbidimetry – End Point.

When anti-streptolysin O antibodies are present in the sample, they combine with recombinant streptolysin O-coated latex beads. These complexes agglutinate leading to an increase of turbidity measured at 546 nm.

COMPOSITION
Reagent 1: R1
Buffer, pH 8.2
Preservative
Reagent 2: R2
Latex particles coated with recombinant streptolysin O, pH 8.2
Preservatives
Calibrator: Cal
Lyophilized calibrator prepared from human serum.
The value is lot-specific.

MATERIALS REQUIRED BUT NOT PROVIDED
- IRCT-0046 RHEUMATOLOGY CONTROL I
- IRCT-0047 RHEUMATOLOGY CONTROL II
- Normal saline solution (NaCl 9 g/L).
- Analyzers or semi-automatic analyzers.
- General Laboratory equipment (e.g. pipette).
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS
- The reagent **R1** is classified as hazardous :

WARNING : May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

- The reagent **R2** is classified as hazardous :

DANGER : May damage fertility. May damage the unborn child. Wear protective gloves/protective clothing/eye protection/face protection. Do not handle until all safety precautions have been read and understood. IF exposed or concerned: Get medical advice/attention.

Obtain Safety data sheet (SDS) before use for a proper handling.
- The reagent contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Each unit of human blood used in the manufacture of the calibrator was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2. The methods used were FDA-approved or CE compliant. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not interchange reagent vials from different kits.

STABILITY
Reagent / Calibrator:
Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
Reagent:
On board stability of reagent:
The on-board stability is specific for each analyzer. (Refer to § PERFORMANCE DATA).
Calibrator:
The calibrator should be immediately and tightly capped to prevent contamination and evaporation
Stability of calibrator after reconstitution:
Calibrator is stable for 1 month when stored at 2-8 °C or 3 months at -20°C.

PREPARATION
Reagent:
The device is ready to use. Before installing, homogenize the reagent bottles by successive inversions.
Calibrator:
Carefully open the bottle avoiding loss of lyophilizate.
Add exactly 1 mL of distilled or deionized water.
Carefully close the vial and dissolve the contents completely by occasional gentle stirring avoiding the formation of foam.
Keep at room temperature for 10 minutes before use.

PRODUCT DETERIORATION
Reagent:
- The reagent R1 is a clear liquid. R2 is a milky liquid.
- Any presence of particles or turbidity would be a sign of deterioration.
Calibrator:
- Calibrator should be clear after reconstitution. Cloudiness would indicate deterioration.
Reagent / Calibrator:
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the damages of packaging might have an effect on the product performances (leakages, pierced vial).

SAMPLES
Specimen required [3]
- Serum
- Plasma (Lithium heparin)
- Using any other specimen type should be validated by the laboratory.
Warnings and precautions
Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.
Storage and stability [3]
- 2 days at room temperature
- 8 days at 2-8°C
- 6 months at -20°C

REFERENCE VALUES [1,4]

Serum/plasma	IU/mL
Children	≤ 240
Adults	≤ 250

ASO levels are age-dependent and change with geographic location and with the local frequency of streptococcal infections.

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE
For use on Selectra Pro analyzers :
- Consult operator manual.
- **Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer.** Refer to Instructions For Use of ACID SOLUTION & SYSTEM CLEANING SOLUTION for adequate programming (See PIT-SOL).

PROCEDURE
Manual Procedure

Wavelength :	*546 nm*
Optical path :	*1 cm*
Sample/ Reagent ratio :	*1:45*
Temperature:	*37 °C*

Calibrator and samples must be diluted 1:5 with NaCl 9 g/L solution before the following procedure.

Read against reagent blank.

	CALIBRATION	TEST
Reagent R1	1 000 µL	1 000 µL
Calibrator	25 µL	-
Sample	-	25 µL

Mix and wait 5 minutes and add :

Reagent R2	125 µL	125 µL

Mix, then read the absorbance immediately (A1), then 2 minutes after R2 addition (A2).

Automatic Procedure
These reagents may be used on several automatic analyzers. For Selectra Analyzers, validated applications are available on request. For Selectra TouchPro software, use the application included in the barcode available at the end of this insert.

Both calibrator and samples need to be pre-diluted 1:5 with saline solution NaCl 9 g/L before measurement. For users of Selectra Pro Series analyzers, predilution is performed automatically.

CALCULATION

$$\frac{\Delta A \text{ Sample}}{\Delta A \text{ Calibrator}} \times n$$ n = calibrator concentration

☛CALIBRATION

ANTI-STREPTOLYSIN O CALIBRATOR is traceable to the WHO's "1st International Standard for ASO".
The value, specific for each lot is indicated on the vial label and in the value sheet (PITV-ASLOCa) available on the website: www.vitalscientific.com.
The value is determined and validated by VitalScientific on VitalScientific Analyzers using ANTI-STREPTOLYSIN O reagent.
For users with Selectra TouchPro Software, use the value included in the barcode available at the end of the value sheet.

Calibration frequency : The calibration is specific for each analyzer. (Refer to § PERFORMANCE DATA).

QUALITY CONTROL

It is recommended that quality control sera such as RHEUMATOLOGY CONTROL I and RHEUMATOLOGY CONTROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra ProM, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range
20 - 1000 IU/mL.
Samples having greater concentrations should be diluted 1:5 with NaCl 9 g/L solution and re-assayed. This procedure extends the measuring range up to 2000 IU/mL.
Do not report results outside this extended range.

For users with Selectra TouchPro software, the «dilute» function performs the sample dilution automatically. Results take the dilution into account.

Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD = 9 IU/mL
LoQ = 20 IU/mL

- Hook effect
No hook effect up to 2000 IU/mL.

- Precision
Imprecision data has been obtained on 2 Selectra ProM analyzers over 20 days (2 runs per day, tests performed in duplicate).
Representative results are presented below.

		Mean	Within-run	Total
	n	IU/mL	CV (%)	
Level 1	80	103	4.9	8.2
Level 2	80	200	3.0	6.0
Level 3	80	429	1.6	4.1

☛- Correlation
A comparative study has been performed between ANTI STREPTOLYSIN O reagent on a Selectra ProM analyzer and a similar commercially available system on 55 human serum samples.
The sample concentrations ranged from 20 to 919 IU/mL.
The results are as follows :
Correlation coefficient : (r) = 0.989
Linear regression: y = 1.014x - 1 IU/mL.

- Limitations/Analytical interferences
- Studies have been performed to determine the level of interference from different compounds.
The following anti-streptolysin-O levels were tested: 100 IU/mL and 400 IU/mL..
No significant interference is defined by a recovery ≤±10% of the initial value.
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (504.6 µmol/L).
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL. (513.1 µmol/L)
Hemoglobin: No significant interference up to 500 mg/dL.
Triglycerides: No significant interference up to 3000 mg/dL (33.90 mmol/L).

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[5]

- Many other substances and drugs may interfere. Some of them are listed in reviews published by Young.[6-7]

- On board stability/Calibration frequency
On Board Stability: 56 days
Calibration frequency: 28 days
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

These performances have been obtained using Selectra ProM analyzer. Results may vary if a different instrument or a manual procedure is used.
☛The performances of applications not validated by VitalScientific are not warranted and must be defined by the user.

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

☛TECHNICAL ASSISTANCE

Contact your local distributor or VitalScientific (support@vitalscientific.com).

BIBLIOGRAPHY

1. Pasteur CERBA. Guide des examens spécialisés, 5th Edition, (2007).
2. Wu, A. H. B., Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds.), (2006), 1528.
3. Guder, W.G., *et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples.* (2002). WHO/DIL/LAB/99.1 Rev.2.
4. Kaplan, E.L., *et al*., Pediatrics, (1998), **101**, 86.
5. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
6. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
7. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

☛SYMBOLS

Symbols used on our documentation are defined on ISO-15223-1 standard, except for some presented in the symbols glossary available on the VitalScientific Website. (Symbols glossary).

ASLO

☛

- Special Programming instructions :
see § INSTALLATION AND USE

☛
VitalScientific
Zone Industrielle - 61500 SEES FRANCE
www.vitalscientific.com