selectra MACH

ANTI-STREPTOLYSIN O

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

CE

PIMAC-ASLO-EN-V2 (12/2021)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of anti-streptolysin-O in human serum and plasma samples on Selectra Mach Series 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 can not 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
Proclin 950 0.1% (w/w)
Reagent 2: R2
Latex particles coated with recombinant streptolysin O, pH 8.2
Proclin 950 0.1% (w/w)
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)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- The reagents R1 and R2 are classified as hazardous :

Obtain Safety data sheet (SDS) before use for a proper handling.
- 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 : 8 weeks.
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 contamination or damage (e.g. particle matter).
- Damage to the device container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimen[3]
- Serum
- Plasma (Lithium heparin)
- Using any other specimen type should be validated by the laboratory.
Warnings and precautions
According to Good Laboratory Practice, sampling should be performed prior to the administration of drugs.
Storage and stability [3]
- Samples with presence of fibrin should be centrifuged before testing.
- 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

Consult Selectra Mach 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 for WASH SOLUTION A & WASH SOLUTION B for adequate programming (See PIMAC-WASH).

☛PROCEDURE

For importing the test parameters, an import file is available on request.
Please contact your local distributor for details.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

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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.elitechgroup.com
The value is determined and validated by ELITech Clinical Systems SAS on ELITech Clinical Systems Analyzers using ELITech Clinical Systems ANTI-STREPTOLYSIN O reagent.

Calibration frequency : 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as RHEUMATOLOGY CONTROL I and RHEUMATOLOGY CONTROL II should 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 Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

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

- Hook effect

No hook effect up to 2000 IU/mL.

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

LoD : 10 IU/mL
LoQ : 20 IU/mL

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented in the following table.

		Mean	Within-run	Total
	n	IU/mL	CV (%)	
Level 1	80	97	2.5	6.0
Level 2	80	195	1.7	4.4
Level 3	80	418	1.0	4.5

- Correlation

A comparative study has been performed between ANTI-STREPTOLYSIN O reagent on a Selectra Mach5 analyzer and a similar commercially available system on 72 human serum samples.
The sample concentrations ranged from 21 to 943 IU/mL.
The results are as follows :
Correlation coefficient : (r) = 0.998
Linear regression: y = 0.985 x + 0 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.
A no significant interference is defined by a recovery ≤± 10% of the initial value.
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L).
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Hemoglobin: No significant interference up to 500 mg/dL
Triglycerides: No significant interference up to 3000 mg/dL. (33.9 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 plublished by Young.[6-7]

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.

BIBLIOGRAPHY

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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 are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent R1
R2	Reagent R2
CAL	Calibrator
RCNS X mL	Reconstitute with x mL
1 mL	Add exactly 1 mL of distilled or deionised water
10 min 25°C 15°C	Keep at room temperature for 10 minutes before use
X months meses mois monat x°C x	These products are stable X months at X°C after the first opening
	These products should be immediately and tightly capped to prevent contamination and evaporation
☛	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE:

Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

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