selectra MACH

PREALBUMIN IP

IPAL
IPAL-0400
R1 : 2 x 25 mL
R2 : 1 x 5 mL

CE

PIMAC-IPAL-EN-V2 (01/2022)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of prealbumin in human serum samples on Selectra Mach Series analyzers.

This *in vitro* diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE [1]

Prealbumin or transthyretin is a plasma protein synthesized by the liver. It transports thyroid hormones and vitamin A in blood.
Because of its short half-life (2 days) and its limited body pool, prealbumin is a sensitive marker of change in the liver protein synthesis function. Prealbumin concentration decreases in case of protein intake deficiency (malnutrition), reduced protein synthesis in the liver or during inflammation. Increased prealbumin levels occur in case of increased protein anabolism (anabolic treatments or in Hodgkin's disease).
In clinical practice, prealbumin is indicated, in the absence of inflammation, for the assessment of nutritional status and for the monitoring of nutritional therapy.

LIMITATION OF USE

The quantitative assay of prealbumin 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

Immuno-turbidimetry - End Point.

The formation of Prealbumin / anti-Prealbumin antibody complexes is started by the addition of the antiserum to the sample in presence of an accelerator. These complexes agglutinate leading to an increase of turbidity measured at 340 nm.

COMPOSITION

Reagent 1: R1
Buffer, pH 7.43
Accelerator
Sodium azide < 0.1 % (w/w)
Reagent 2: R2
Buffer, pH 7.43
Polyclonal anti-human Prealbumin antibody (goat)
Sodium azide < 0.1 % (w/w)

MATERIALS REQUIRED BUT NOT PROVIDED

- IPRO-0043 PROTEIN IP CALIBRATOR SET
- CONT-0060 ELITROL I
- 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

- Consult Safety Data Sheet (SDS) for a proper handling.
- The reagents contain 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.
- 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

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 4 weeks.

PREPARATION

The device is ready to use.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent 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

Specimens required [2]
- Serum
- 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 [2-3]
- Do not keep at room temperature
- 3 days at 2-8°C
- 6 months at -20°C

REFERENCE VALUES [4]

Serum	mg/dL	mg/L
Adults	20 - 40	200 - 400

Interpretation of serum prealbumin concentrations in the evaluation of nutritional status must take into account the inflammatory status of the patient.

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.

CALIBRATION

Calibrators from PROTEIN IP CALIBRATOR SET are traceable to ERM-DA470k/IFCC reference material.
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 ELITROL I 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)).

ELITechGroup
EMPOWERING IVD

PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

5.0-80.0 mg/dL (50 – 800 mg/L)

The exact range depends on the calibrator used.

Do not report results outside the measuring range.

- Hook effect

No hook effect up to 240.0 mg/dL (2 400 mg/L)

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

LoD: 1.2 mg/dL (12 mg/L)
LoQ: 5.0 mg/dL (50 mg/L)

- 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 below.

		Mean		Within-run	Total
	n	mg/dL	mg/L	CV (%)	
Level 1	80	10.2	102	2.2	7.8
Level 2	80	17.7	177	3.5	5.9
Level 3	80	33.5	335	2.0	5.2

- Correlation

A comparative study has been performed between PREALBUMIN IP reagent on a Selectra Mach5 analyzer and a similar commercially available system on 67 human serum samples.
The sample concentrations ranged from 5.8 to 82.8 mg/dL (58 to 828 mg/L).
The results are as follows :
Correlation coefficient : (r) = 0.990
Linear regression: y = 0.969 x + 3.3 mg/dL (33 mg/L).

- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following prealbumin levels were tested: 10 mg/dL and 20 mg/dL.
No significant interference is defined by a recovery ≤± 2.5 mg/dL of the initial value at prealbumin concentration of 10 mg/dL and ≤± 12.5 % of initial value at prealbumin concentration of 20 mg/dL.
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L).
Hemoglobin: No significant interference up to 500 mg/dL.
Turbidity: No significant interference up to 614 mg/dL of triglycerides equivalent (6.9 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

1. Alcock, N.W., Human Nutrition. Clinical Chemistry: Theory, Analysis, Correlation, 5th Ed., Kaplan, L.A, Pesce, A.J., (Mosby Inc. eds), (2010), 790 and appendix.
2. 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.
3. Wu, A. H. B., Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds.), (2006), 1070.
4. Dati, F., Eur. J. Clin. Chem. Biochem., (1996), **34**, 517.
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 1
R2	Reagent 2
☞	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE:

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

ELITech Clinical Systems SAS
Zone Industrielle - 61500 SEES FRANCE
www.elitechgroup.com