Elecsys® Cancer antigen 72-4 (CA 72-4) Electro-chemiluminescence immunoassay (ECLIA) for the quantitative determination of CA 72-4 in human serum and plasma

Indication
Tumor associated glycoprotein (TAG) 72 is a mucin-like protein of high molecular weight (200 - 400 kD). Elevated serum levels are preferentially found in gastric cancer patients, but can also be found in certain benign diseases like pneumonia, pancreatitis, liver cirrhosis and ovarian cysts. The most important advantage of CA 72-4 is its particularly high diagnostic specificity for benign diseases. CA 72-4 is a helpful tool in the management of patients with the following diseases:

Gastric cancer:
There is a correlation between the disease stage and the degree of CA 72-4 elevation. After surgery, CA 72-4 levels return to normal and remain within the normal range in cases where tumor tissue is no longer present. In 70% of relapse cases, CA 72-4 increases prior or concurrently with clinical diagnosis of the relapse. There are hints that preoperative CA 72-4 levels can be of prognostic value. The combination of CA 72-4, CA 19-9 and CEA has been shown to increase sensitivity in gastric cancer.

Ovarian carcinoma:
Combined use of CA 72-4 and CA 125 enhances diagnostic sensitivity.

Colorectal carcinoma:
There is a correlation with the clinical staging by Dukes. Diagnostic specificity of CA 72-4 to benign diseases of the colon is 98% and sensitivity of CA 72-4 can be enhanced by combining it with CEA. After complete resection of the tumor a marked drop in CA 72-4 occurs and it remains elevated when a residual tumor is present.

Test principle: one-step sandwich assay

The Elecsys CA 72-4 assay is based on the monoclonal B72.3 and CC49 antibodies, which are only available from Fujirebio Diagnostics, its licensees and its representatives.
**Elecsys technology**

ECL (ElectroChemiluminescence) is Roche's technology for immunoassay detection. Based on this technology and combined with well-designed, specific and sensitive immunoassays, Elecsys delivers reliable results. The development of ECL immunoassays is based on the use of a ruthenium-complex and tripropylamine (TPA). The chemiluminescence reaction for the detection of the reaction complex is initiated by applying a voltage to the sample solution resulting in a precisely controlled reaction. ECL technology can accommodate many immunoassay principles while providing superior performance.

**Elecsys® CA 72-4 assay characteristics:**

- **Testing time**: 18 min.
- **Test principle**: One-step sandwich assay
- **Traceability**: Standardized against the CA 72-4 enzymun test method. An IRP does not exist.
- **Sample material**: Serum, Na-heparin, Li-heparin, NH₄⁺-heparin and K₃-EDTA plasma.
- **Sample volume**: 30 µL
- **Detection limit**: 0.20 U/mL
- **Measuring range (low end defined by lower detection limit)**: 0.20 - 300 U/mL

**Repeatability**

- cobas e 601 / e 602 modules, E 170: 1.0 - 2.8 %
- Elecsys® 2010 and cobas e 411 analyzer: 1.8 - 2.4 %

**Intermediate precision**

- cobas e 601 / e 602 modules, E 170: 2.2 - 3.6 %
- Elecsys® 2010 and cobas e 411 analyzer: 2.9 - 4.9 %

**Expected values**

13 6.9 U/mL for healthy adults (for 95% of the results)

**Order information:**

### Material

- Elecsys CA 72-4
- Elecsys CA 72-4 CalSet
- PreciControl Tumormarker
- Diluent Universal

### Product configuration

- **100 tests**
- **4 x 1 mL**
- **2 x 3 mL each**
- **2 x 16 mL sample diluent or 2 x 36 mL sample diluent**

### Material number

- 11776258 122
- 11776274 122
- 11776452 122
- 11732277 122 or 03183971 122

**References:**


Not for distribution in the USA.

COBAS, COBAS E, LIFE NEEDS ANSWERS and ELECSYS are trademarks of Roche.

©2011 Roche

Roche Diagnostics Ltd.
CH-6343 Rotkreuz
Switzerland

www.cobas.com