Elecsys® Cancer antigen 19-9 (CA 19-9)

Electro-chemiluminescence immunoassay (ECLIAXA) for the quantitative determination of CA 19-9 in human serum and plasma

**Indication**

CA 19-9 is a mucin which corresponds to the sialylated Lewis (Le)a blood group antigen with a molecular weight of approx. 10 kD. Individuals with a Le*a–b– phenotype are unable to synthesize CA 19-9. Approximately 5% of the population is Le*a–b– and therefore do not express this mucin which must be taken into account when interpreting the findings.

**CA 19-9 is a helpful tool in the management of patients with pancreatic cancer (PC):**

- CA 19-9 is the most clinically useful serum marker to enhance the diagnostic accuracy of PC. Elevated serum levels are observed in approximately three-quarters of all patients with PC. Although false-positive findings can occur in other benign and malignant gastrointestinal diseases, the overall sensitivity and specificity of CA 19-9 is approximately 80% and 90% respectively for detecting PC.
- Serial CA 19-9 measurements are performed for the clinical course and prognosis and for monitoring patients as an indicator for therapeutic response. It has been reported that persistent elevation or rise in serum CA 19-9 levels after treatment are indicative of poor response and prognosis. A decrease in CA 19-9 levels is associated with favorable prognosis and good response to treatment.
- Considering the fact that different drugs are now available for the treatment of PC, a rapid move from first to second line therapy could be useful for the patient. It is necessary to detect as soon as possible a worse prognosis and pre-clinical signs of progressive disease as some data have recently reported response to second line therapy.
- Further evidence for prolonged survival of PC patients by efficacy oriented sequential polychemotherapy was demonstrated based on serial determinations of CA 19-9 and the carcinoembryonic antigen (CEA).

**Test principle: one-step sandwich assay**

CA 19-9 values measured are defined by the use of the monoclonal antibody 1116-NS-19-9, a monoclonal antibody generated against a colon carcinoma cell line.
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 19-9 assay characteristics:

- **Testing time**: 18 min.
- **Test principle**: One-step sandwich assay
- **Traceability**: Standardized against the CA 19-9 enzymun test method. An IRP does not exist.
- **Sample material**: Serum, Li-, Na- and NH₄⁺-heparin and K₃-EDTA plasma
- **Sample volume**: 10 µL
- **Detection limit**: 0.60 U/mL
- **Measuring range (low end defined by lower detection limit)**: 0.60 - 1000 U/mL
- **Repeatability**
  - cobas e 601 / e 602 modules, E 170: 1.2 - 2.5%
  - Elecsys® 2010 and cobas e 411 analyzer: 2.9 - 4.4%
- **Intermediate precision**
  - cobas e 601 / e 602 modules, E 170: 1.9 - 2.7%
  - Elecsys® 2010 and cobas e 411 analyzer: 2.9 - 4.8%
- **Expected values**
  - 27 U/mL for healthy adults (95th percentile)

Order information:

<table>
<thead>
<tr>
<th>Material</th>
<th>Product configuration</th>
<th>Material number</th>
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<tbody>
<tr>
<td>Elecsys® CA 19-9</td>
<td>100 tests</td>
<td>11776193 122</td>
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<tr>
<td>Elecsys® CA 19-9 CalSet</td>
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<td>11776215 122</td>
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<tr>
<td>PreciControl Tumormarker</td>
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<td>Diluent Universal</td>
<td>2 x 16 mL sample diluent or 2 x 36 mL sample diluent</td>
<td>11732277 122 or 03183971 122</td>
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References:

10. Results from the multicenter evaluation. Data on file at Roche.

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