



Health Technology Review	
Technology Ref.:	HTA24018
Technology Name/Version/Model:	Elecsys IL-6 (Interleukin-6) 09015604190 - 09015612190
Approvals by International Bodies:	CE Mark
Company name:	Germany
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<b>Short Description of the Technology:</b>	<ul style="list-style-type: none"> <li>• Immunoassay for the in vitro quantitative determination of Interleukin-6 (IL-6) in serum and plasma. This assay can be used to aid in the management of critically ill patients as early indicator for acute inflammation.</li> <li>• IL-6 production is rapidly induced in the course of acute inflammatory reactions associated with injury, trauma, stress, infection, brain death, neoplasia, and other situations.</li> <li>• IL-6 concentrations in trauma patients may predict later complications from additional surgical stress or indicate missed injuries or complications. Sequential measurements of IL-6 in serum or plasma of patients admitted to the ICU (intensive care unit) showed to be useful in evaluating the severity of SIRS (systemic inflammatory response syndrome), sepsis and septic shock and to predict the outcome of these patients.</li> <li>• IL-6 is also useful as an early alarm marker for the detection of neonatal sepsis. IL-6 also plays a role in chronic inflammation e.g. rheumatoid arthritis</li> <li>• Levels of interleukin 6 correlate with disease severity and survival prognosis.<sup>30</sup></li> <li>• The level of IL-6 in healthy people is extremely low, generally not exceeding 7 pg/mL, but it increases rapidly in the serum of patients with sepsis within 2 hours of infection onset Higher levels of IL-6 are associated with sepsis diagnosis, severity of organ dysfunction, and mortality.</li> <li>• When it comes to compare between CRP as standard of care, Interleukin 6 and even Procalcitonin play a complementary role .First one to become elevated is Interleukin 6 to provides the best opportunity to recognize the disease very early on, aiding in early-stage diagnosis, and also ensuring the best outcomes of the patients following the correct antibiotic and/or hemodynamic treatments. Procalcitonin and CRP elevated only at the later point of the infection</li> </ul>
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**Health Technology Assessment Team Recommendation:**

**Approve**

**Summary of Review:**

Immunoassay for the in vitro quantitative determination of nterleukin-6 (IL-6) in serum and plasma. This assay can be used to aid in the management of critically ill patients as early indicator for acute inflammation.

Advantages	Disadvantages
IL-6 has been included on the UAE National Guidelines for CoVid -19 laboratory testing.	Interleukin-6 is also suspected to cause increased susceptibility to diabetes mellitus, as well as to the systemic form of juvenile rheumatoid arthritis.
Ilecsys IL-6 immunoassay has become the first interleukin-6 (IL-6) test to have a certified claim for use in diagnosis of neonatal sepsis, in countries accepting the CE Mark.	
IL6 help diagnose sepsis earlier in the ED / ICU and in postoperative patients.	
IL-6 has been included on the UAE National Guidelines for CoVid -19 laboratory testing.	

We recommend an **approval this technology** for Market entry with the following conditions:

1. Elecsys IL-6 (Interleukin-6) 09015604190 - 09015612190.
2. The technology to be performed by Medical lab Technologist.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

**Moreover**, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

## Technology Image



### Population, setting and intended user for Technology “IL-6”

- **Population/ Intended User;**
  - management of critically ill patients as an early indicator for acute inflammation
  - diagnosis of sepsis in neonates with suspected or confirmed bacterial infection
  - Early detection of acute inflammatory reactions associated with injury, trauma, stress, infection, brain death, neoplasia, and other situations.
  - Evaluating of the severity of SIRS (systemic inflammatory response syndrome), sepsis and septic shock to predict the outcome of the patients.
- **To be performed by:**
  - By Medical lab technologist
- **Clinical Setting:**
  - Hospitals, clinical, laboratories.
- **Condition of use:**
  - Patients suspected to have sepsis at different age groups.
  - Neonates at risk of developing sepsis.
  - Trauma patients
- **Exclusion criteria:**
  - Non