SOLUBLE INTERLEUKIN-2-RECEPTOR ELISA.

The first IVDR sIL-2R ELISA providing trustworthy results for aiding in the sarcoidosis diagnosis

Sarcoidosis and sIL-2R: a deep dive.

sIL-2R levels can be used as physiological marker for the indication of inflammation in the body, in-vivo immune system activation and response activity. As such the measurement of sIL-2R levels can be applied as an aid in the diagnosis or monitoring of therapy of autoimmune diseases (e.g. sarcoidosis).

Why measure sIL-2R levels?

Measuring levels of sIL-2R in adults is considered as a good parameter to determine on-going immune response, which can be used to monitor immune mediated diseases[1].

This property is taken into account by several clinical guidelines. The German Society of Nephrology (Deutsche Gesellschaft für Nephrologie) together with the German Clinical Chemistry and Laboratory Society (Deutsche Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e. V. (DGKL)) recommend to measure sIL-2R together with other parameters in the diagnostic work-up of acute kidney failure to rule out a sarcoidosis origin[2]. Furthermore, the German Ophthalmologic Society (Deutsche Ophthalmologische Gesellschaft e.V.) and the Professional Association of Ophthalmologists in Germany (Berufsverband der Augenärzte Deutschlands e.V.) recommend in their clinical guidelines for optic neuritis (Optikusneuritis) also the measurement of sIL-2R to rule out a sarcoidotic background[3]. Another clinical guideline for the diagnostic of polyneuropathies from the German Society of Neurology (Deutsche Gesellschaft für Neurologie) also recommends to measure sIL-2R, if there is an indication of pulmonary involvement[4]. The guidelines refer to two additional publications[5,6] explaining how to use sIL-2R measurements. In particular, conditions that are characterized by excessive production of lymphocytes, termed lymphoproliferative disorders show high sIL-2R levels compared to healthy controls. But also granulomatous diseases, in which T-cell activation is a typical hallmark, show elevated sIL-2R levels.

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Comparison to similar devices.

Furthermore, the kit correlates very well with the previous sIL-2R ELISA (30166211) as shown in the linear regression graph of figure 1.

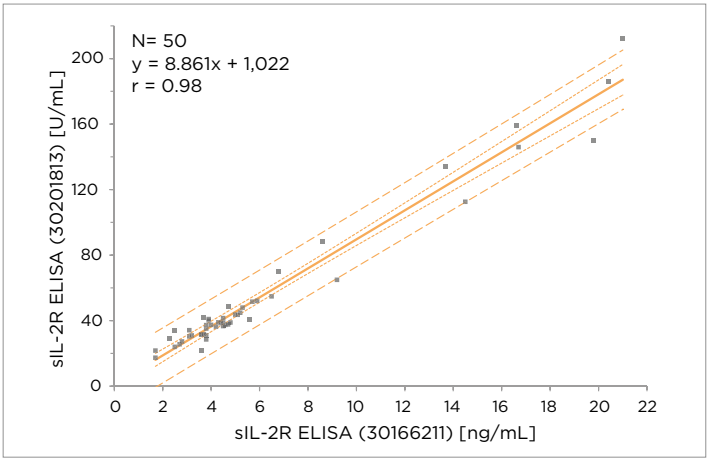

Figure 1: Linear regression curve to sIL-2R ELISA (30166211)

In a blinded external comparison study the correlation to a similar IVD device was examined. The results indicate an excellent comparability as shown with the linear regression graph (Fig. 2) and with the correlation coefficient of r=0.98.

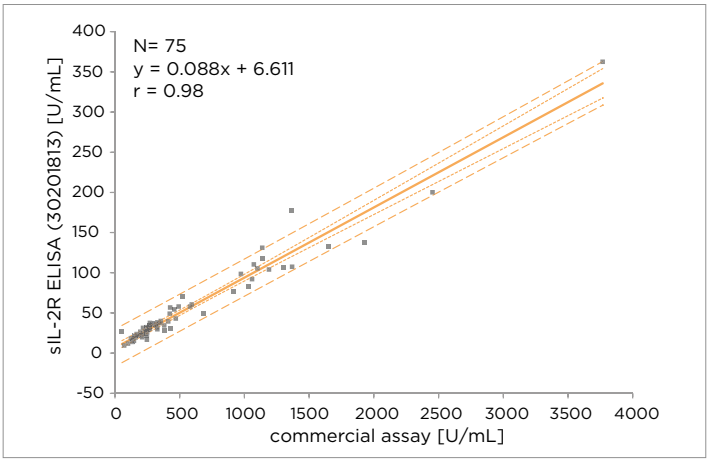

Figure 2: Linear regression to another commercial IVD assay

Features of the ELISA:

- Calibrated against non-WHO standard NIBSC 97/600
- Ready-to-use standard curve
- Internal kit controls – low & high
- Results reported in arbitrary U/mL
- First IVDR ELISA for soluble Interleukin-2 Receptor (based on Eudamed database search on Feb 23rd, 2024)

Your benefits:

- **Trustworthy results** – 95% specificity compared to established IVD solutions (N = 216 from 7 different labs)
- **Scalable solution** – manual assay that can be easily automated (e.g. ThunderBolt®, DSX®, Freedom EVOlyzer®)*

*The combined use of assays, process script and open system instrument (e.g. Freedom EVOlyzer, ThunderBolt®) has to be validated individually on site by each laboratory. Interchangeability is only valid within same lot numbers for the single components.

Product ordering information.

Description	Material number
sInterleukin-2-Receptor ELISA	30201813

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Literature:

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402916 V1.0, 2024-03