In compliance with European Regulation 2017/746 (IVDR) and meeting the proficiency requirements outlined in Article 8 of the (EU) 2022/944 implementing regulations.

EVALUATED BY

Accreditation n°8-4247
Scope available
on www.cofrac.fr

About us

French laboratory accredited under ISO/IEC 17025:2017 for IVD-MD evaluation.

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Our partners

Analytical and Clinical Performance Evaluation Laboratory for in vitro diagnostic devices

Amarok Biotechnologies

ISO 17025:2017
Accredited

AMAROK BIOTECHNOLOGIES

Analytical and clinical performance evaluation of *in vitro* diagnostic medical devices (IVD-MDs)

Comprehensive testing of instruments and reagents in compliance with IVDR regulations, including stability, specificity, detection limits, interferences, and cross-reactions.

Ongoing performance monitoring and evaluation report updates (PER)

Performance evaluation is a continuous improvement process.
Support for post-market surveillance of IVD-MDs, ensuring continuous compliance and effectiveness.

Regulatory expertise, personalized consulting and support

Expert guidance on analytical parameters and regulatory requirements related to IVDR, facilitating the preparation of tailored regulatory documents.

Clinical sample access

Seamless access to high-quality biological samples through our strategic partnerships with biobanks and network laboratories.

Our area of expertise

Scientific Validity

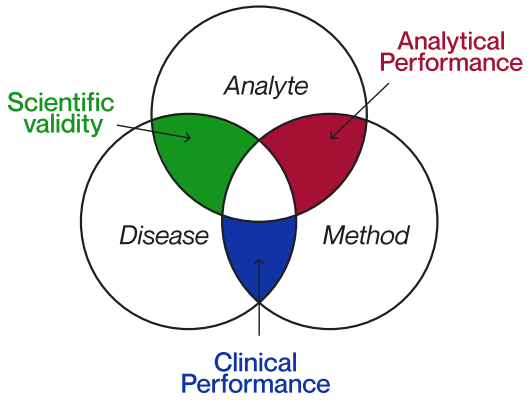
Association of an analyte with a clinical or a physiological state. Systematic review of the existing (peer-reviewed) literature relevant to the analyte.
If gaps are identified, additional data are needed by performing proof of concept, preclinical performance studies.

Analytical Performance

Ability to correctly detect or measure a particular analyte (specificity, sensitivity, reproducibility, stability, etc.).

Clinical Performance

Ability of the device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user.



Amarok Biotechnologies

More than 30 years of experience

Multidisciplinary Staff and Dedicated Laboratories

ISO 17025:2017 Accredited Laboratory

BIOSIGNIS
Clinical sample access

CLSI™ **CLSI member**

RAPS Euro Convergence **RAPS member**