

Euro Diagnostica Functional Complement ELISAs

Complement System

– A hot topic in Drug Development and Clinical Research

The complement system is an important part of the innate immune system. It consists of three different activation pathways - classical, alternative and lectin/MBL - and is regulated by complex protein cascades involving more than 35 proteins. The complement system cooperates closely with the adaptive immune system and cross-talks with the coagulation system.

Having an important role in the fight against infections, and in the development of autoimmune and other diseases, the complement system is a matter of extensive research and topic of innovative and interesting new treatment regimens (1).

Your advantages using Wieslab® functional complement assays*

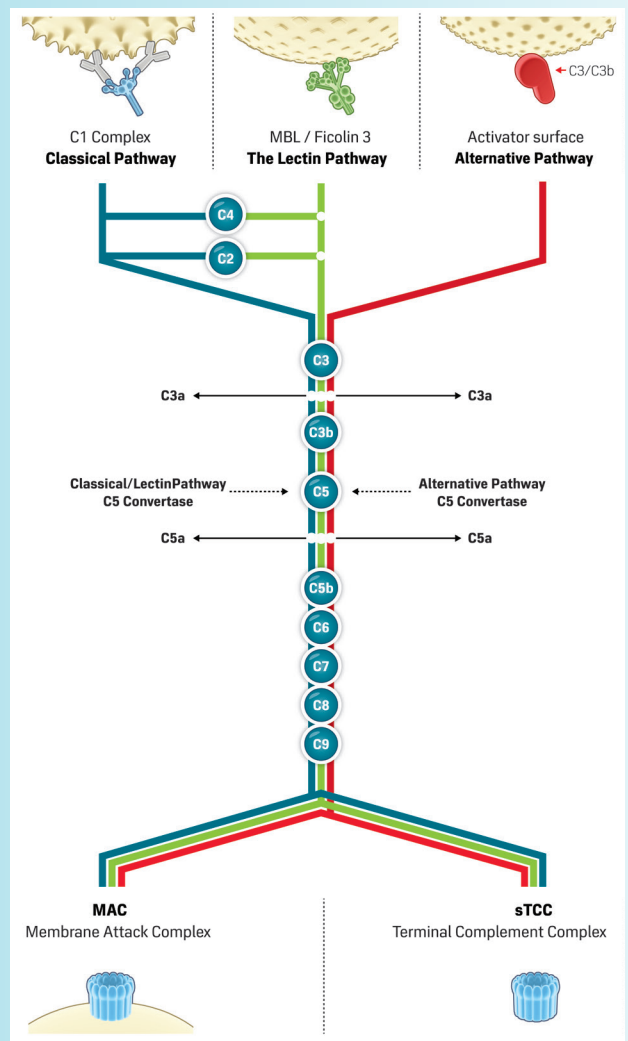
The Euro Diagnostica complement function assay solution is an ELISA based platform under the Wieslab brand (previously called Wielisa). The assays enable determination of specific activity of all three pathways separately without interference from the others (2).

- ELISA – well established technology, similar assay procedure for all three pathways
- Robust, standardised assays, commercially available since 2005
- Reflect the true physiological *in vivo* situation
- Fast & reliable - results within 3 hours
- Flexible - assay adaptations possible for individual research protocols, some species cross-reactions (pigs (3), monkeys)
- Automation: high-throughput option, validated protocols available (Dynex DS2, DSX)
- Very good agreement with haemolytic assays (CH50, APH50)
- Well established assays, several papers supporting good performance
- CE-marked for IVD (in vitro diagnostic) use for all three pathways, also available for Research Use (RUO)**

Our assay solution provides a complete picture of complement function.

* Data and details available in the Instructions for Use

** RUO = for Research Use Only, i.e. the results obtained should not be used for patient management or in treatment decisions.



Lab Services via Wieslab

Our in-house laboratory services are performed in compliance with GLP, GCP and ISO 17025, ensuring that regulatory requirements are met. A comprehensive menu of markers for complement function and activation (C3d and sTCC) is available, as well as test packages for assessment of complement deficiencies and complement function.

Expert Consultation and Bioanalytical Services

Expert study consultation and tailored bioanalytical services are also available. For more information please visit our website or contact us directly.

For further information please visit our dedicated complement website www.complementsystem.se

Examples of Research Use

- Applications in Drug Development and Clinical Research

Drug development - potency of complement-targeted therapies

- The Euro Diagnostica complement assays are recognised for their ability to assess the efficacy of complement targeted therapies, whether the aim is to inhibit or enhance complement functionality in research settings (4-8).

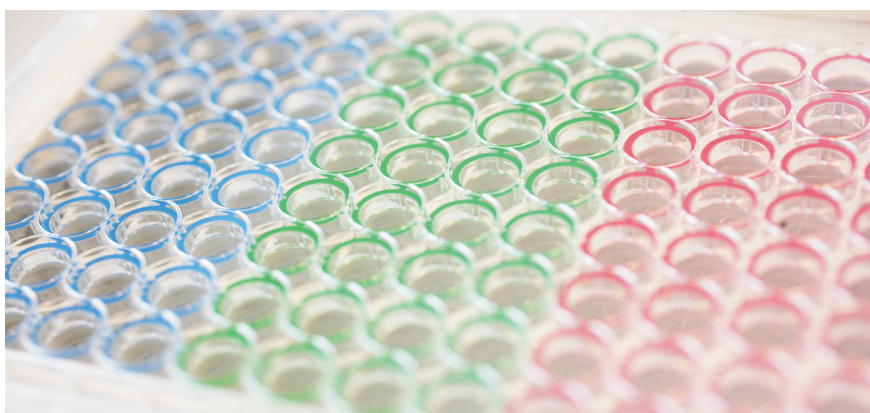
Clinical studies - monitoring of complement function/activity

- Assessment of complement function is also valuable in the development and optimisation of treatment regimens for complement related diseases. Examples are studies evaluating new treatment concepts for diseases involving the complement system, and algorithms for drugs modulating the complement system directly (5, 9-11).

Off-target complement reactions

- During some circumstances complement activation can be devastating and cause severe reactions such as off-target reactions to a drug candidate, antibody dependent complement activation (ACA), or contribute to graft rejection after transplantation (12-13).

“Wieslab® Complement System Screen is a multifunctional ELISA kit for reliably detecting complement deficiencies of all three pathways selectively, but also for assessing complement activation in research applications”. Conclusion from Würzner *et al* (6).



Product info

COMPL 300 ¹ / COMPL 300 RUO ²	Complement System Screen	96 wells break-apart
COMPL CP310 ¹ / COMPL CP310 RUO ²	Complement System Classical Pathway	96 wells break-apart
COMPL MP320 ¹ / COMPL MP320 RUO ²	Complement System MBL (Lectin Pathway)	96 wells break-apart
COMPL AP330 ¹ / COMPL AP330 RUO ²	Complement System Alternative Pathway	96 wells break-apart
COMPL F3 RUO ²	Complement System Ficolin-3 (Lectin Pathway)	96 wells break-apart

All devices are CE-marked for IVD use unless otherwise noted.

- Please contact your local representative for availability in your country, not available in US.
- For research use only, contact your local representative for research use availability in your country.

Bibliography

- Ricklin D and Lambris JD. Complement in Immune and Inflammatory Disorders: Therapeutic Interventions. J Immunol 2013; 190: 3839-3847
- Seelen MA et al. Functional analysis of the classical, alternative, and MBL pathways of the complement system: standardization and validation of a simple ELISA. J Immunol Meth 2005; 296: 187-198
- Salvesen B and Molnes TE. Pathway-specific complement activity in pigs evaluated with a human functional complement assay. Mol Imm 2009;6:1620-1625
- Hill A et al. A Subcutaneously Administered Investigational RNAi Therapeutic (ALN-CC5) Targeting Complement C5 for Treatment of PNH and Complement-Mediated Diseases: Interim Phase 1 Study Results. Abstract 2413; 58th ASH Annual Meeting 2015
- Jore MM et al. Structural basis for therapeutic inhibition of complement C5. Nature Structural & Molecular Biology 2016; doi:10.1038/nsmb.3196
- Würzner R et al. Assessment of complement activity by ELISA. Abstract #41 16th Biennial Meeting of the European Society for Immunodeficiencies, ESID 2014
- Kocsis A. Selective Inhibition of the Lectin Pathway of Complement with Phage Display Selected Peptides against Mannose-Binding Lectin-Associated Serine Protease (MASP)-1 and -2: Significant Contribution of MASP-1 to Lectin Pathway Activation. J of Immunol 2010;185: 4169-4178
- Kadam A P and Sahu A Identification of Complin, a Novel Complement Inhibitor that Targets Complement Proteins Factor B and C2. J of Immunol 2010;184: 7116-24
- Volokhina E B et al. Sensitive, reliable and easy-performed laboratory monitoring of eculizumab therapy in atypical hemolytic uremic syndrome. Clin Immunol 2015; 160: 237-43
- Heinen S et al. Monitoring and modeling treatment of atypical hemolytic uremic syndrome. Molecular Immunology 2013; 54:84- 88
- Hallenstensen RF et al. Eculizumab treatment during pregnancy does not affect the complement system activity of the newborn. Immunobiology 2015; 220:452-459
- Castellano G et al. Therapeutic Targeting of Classical and Lectin Pathways of Complement Protects from Ischemia-Reperfusion-Induced Renal Damage. Am J Pathol 2010; 176:1648-1659
- Brennan FR et al. Safety and immunotoxicity assessment of immunomodulatory monoclonal antibodies. mAbs 2010; 2:3, 233-255

Euro Diagnostica AB

Mail address:
P.O. Box 50117
SE - 202 11 Malmö
Sweden

Visiting address:
Lundavägen 151
Malmö
Sweden

T +46 40 53 76 60
F +46 40 43 28 90
E info@eurodiagnostica.com
W www.eurodiagnostica.com

Doc No: E-201-GB01, June 2016

