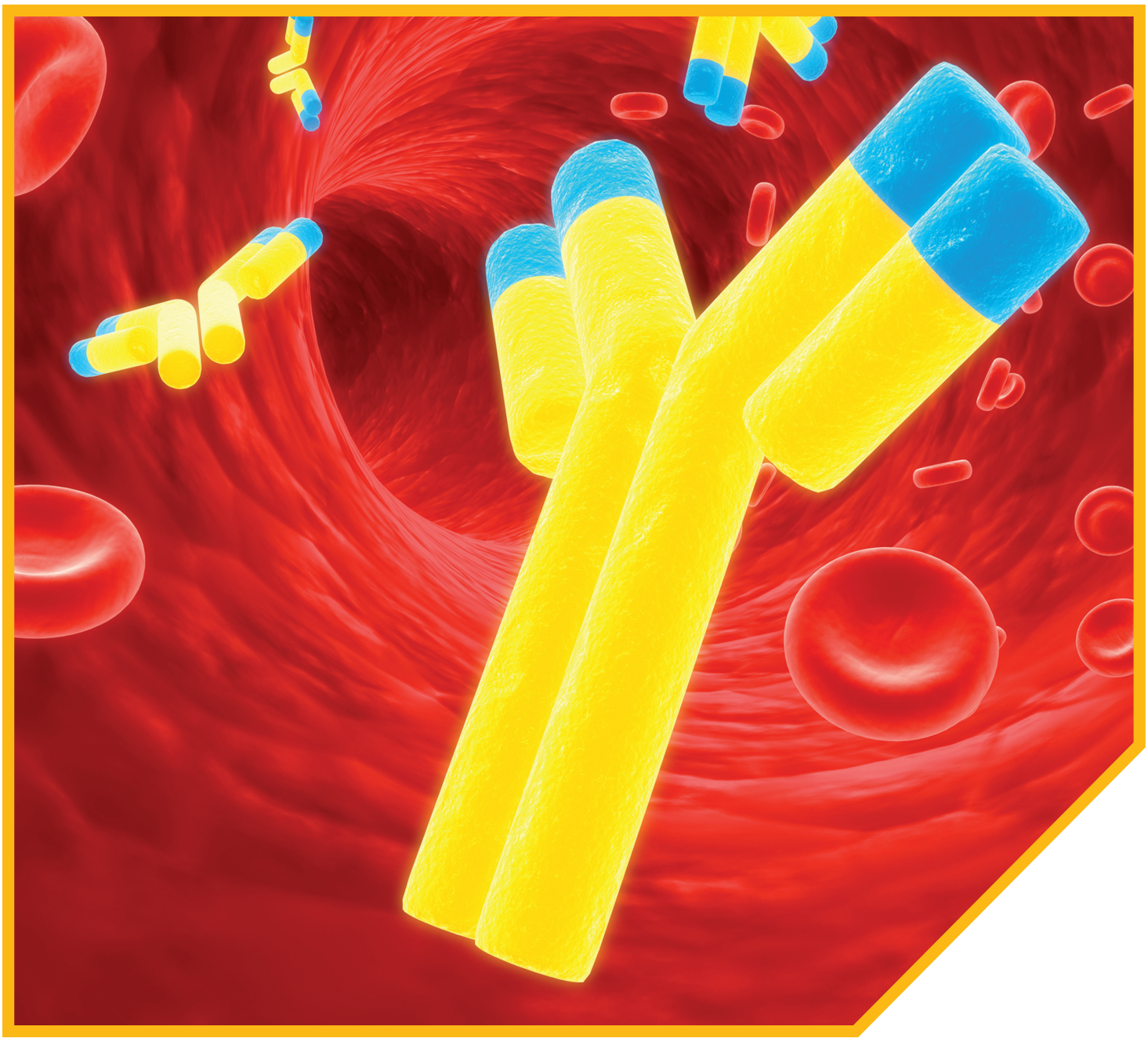


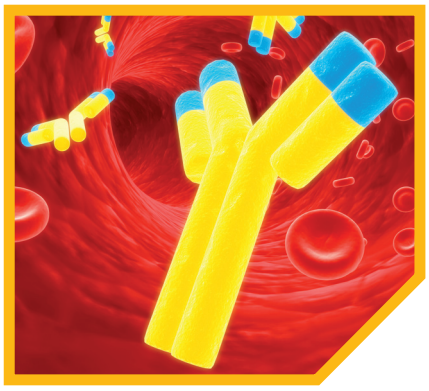
COMPLEMENT FACTOR H

ELISA DETECTION OF IgG ANTIBODIES

- Autoimmune hemolytic-uremic syndrome diagnostics
- Differential diagnostics of hemolytic-uremic syndrome

VIDIA

...the way to the correct results



ANTI-COMPLEMENT FACTOR H ANTIBODIES DETECTION

Differential diagnostics

- Hemolytic-uremic syndrome
- Autoimmune hemolytic-uremic syndrome
- DEAP HUS (deficiency of CFHR plasma proteins and factor H autoantibody positive HUS)

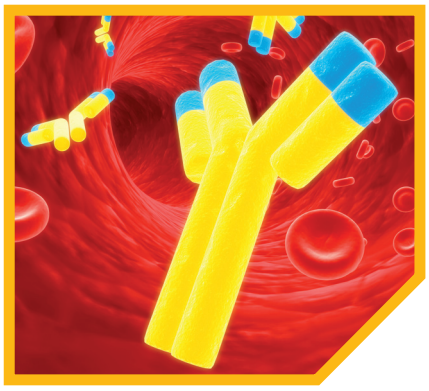
Factor H is a complement regulatory glycoprotein that is found in human plasma in concentrations about 500 µg/mL. Its main function is the regulation of complement activation. Inhibitory autoantibodies against complement factor H resulting from an immunopathological reaction dysregulate complement system.

Such autoimmune dysregulation of complement is associated with a specific form of atypical hemolytic-uremic syndrome (AI-HUS). It is recommended testing anti-complement factor H autoantibodies in all cases of HUS at the onset of the disease. Approximately 30% of AI-HUS patients had diarrhoea as prodromal syndromes, which in turn are the typical sign in the classic form of HUS which is caused by Shigga toxin positive species of *E. coli*. Removal of anti-complement factor H antibodies from the bloodstream by plasmapheresis or the use of immune suppressive drugs to eliminate the antibody production is beneficial for the outcome of the disease.

Intended use and testing

ELISA-VIDITEST anti-complement factor H kit is intended for the detection of anti-complement factor H antibodies. The kit contains a standard with defined antibody concentration, which is diluted according to the instruction manual in order to prepare a calibration curve. The buffers are interchangeable between VIDIA ELISA kits.

- Samples: serum, plasma
- Quantitative determination in AU/ml
- 48 wells in the kit
- Incubations 60'/60'/20' at laboratory temperature
- CE IVD certified



COMPLEMENT FACTOR H

ELISA DETECTION OF IgG ANTIBODIES

Evaluation study

The evaluation study of ELISA-VIDITEST anti-complement factor H was performed in The Institute of Hematology and Blood Transfusion (Prague) and VIDIA spol. s r.o. with serum and plasma samples from The Institute of Hematology and Blood Transfusion.

Samples:

- Negative samples - serum and plasma samples from blood donors: 130 samples
- Samples clinically close to HUS:
  - Acquired thrombotic thrombocytopenic purpura (TPP) (acute stage): 20 samples
  - Atypical HUS (with CFH or MCP mutation): 8 samples
  - Inherited TPP: 5 samples
- DEAP HUS (deficiency of CFHR plasma proteins and factor H autoantibody positive HUS): 9 samples

Results:

Cut-off value for serum samples = 27 AU/mL

Cut-off value for plasma samples = 18 AU/mL

Diagnostic sensitivity

DEAP HUS samples: 9

Positive using anti-complement factor H test: 9

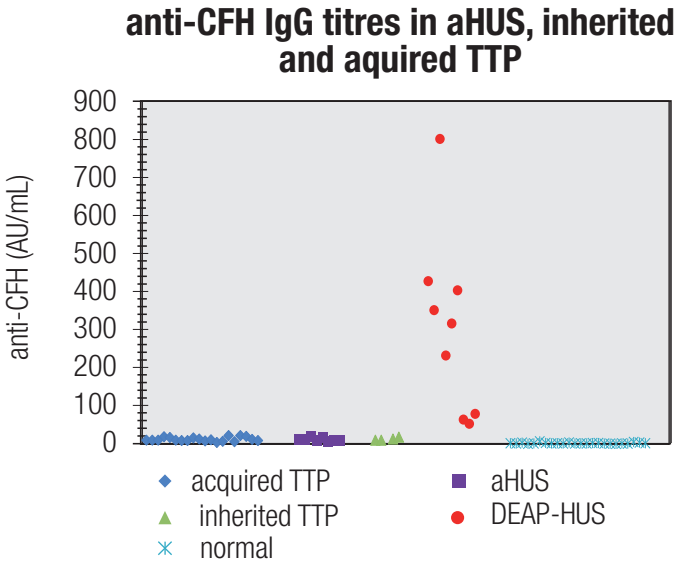
Diagnostic sensitivity: 9/9 = 100%

Diagnostic specificity

Blood donors samples: 130

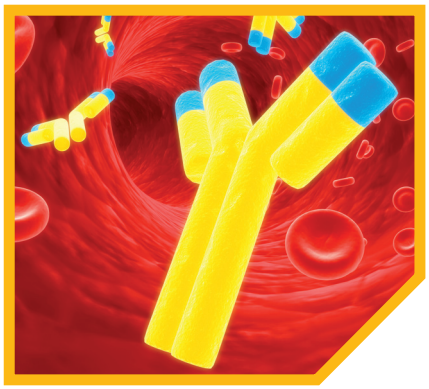
Negative using anti-complement factor H test: 128

Diagnostic specificity: 128/130 = 98.5%



All DEAP-HUS patients have high levels of anti-CHF antibodies.

The test was negative with samples previously characterised as negative and with samples clinically close to HUS. This study showed high sensitivity and specificity for the detection of anti-complement factor H autoantibodies and DEAP HUS diagnostics.



COMPLEMENT FACTOR H

ELISA DETECTION OF IgG ANTIBODIES

Advantages

- High sensitivity and specificity
- Quantitative evaluation
- First commercially available anti-complement factor H CE IVD certified kit
- Incubation at laboratory temperature

Ordering information

Catalogue number	Product	Wells	Sensitivity/specificity
ODZ-166	ELISA-VIDITEST anti-complement factor H	48	100% / 98,5%

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