



HEPAK^{PLUS} DOT (ORDER No. 4030)

HepAK plus Dot is used for the qualitative determination of IgG autoantibodies to M2, LKM1, LC1, SLA and F-actin in human serum and plasma for the differential diagnosis of autoimmune liver disease. The group of primary autoimmune liver disease (PAL) comprises autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC).

Benefits of test

- No need of sophisticated instruments.
- 80 min incubation
- High sensitivity by serum specific cut-off
- screening tool for labs with low number of samples
- confirmation of results obtained by IFA or ELISA through an alternative method

Evaluation of results

- The **positive dot control** must score positive in all cases. The coloration of the dot ensures that the test has been run correctly and the kit components are not degraded. If the positive control dot shows no coloration the results should not be interpreted.
- The **cut-off control** demonstrates the extent of non-specific antibody binding of the sample in the test. The coloration of the dot corresponds to the minimal intensity above which a sample is considered positive. It might be uncolored even if the test has been run in optimal conditions. The color intensity of the test dot depends on the titer of specific antibody binding in the sample. The patient sample is positive concerning a certain antibody if the test dot coloration is stronger (more intense) than the cut-off control.

Precision

Positive samples tested comprised different human sera positive for one specific antibody. Low positive samples were created by dilution of high positive sera with normal sera. The negative sample is a human serum demonstrating no corresponding autoantibodies.

- **Intraassay variance (n = 5)**
3 samples (1 high positive, 1 low positive and 1 negative) were tested in the same run in 5 replicates.

Sample	Colour intensity of specific Dot				
	M2	LKM1	LC1	SLA	f-Actin
highly positive	+4	+5	+5	+5	+3
low positive	+2	+2	+2	+3	+1
negative	0	0	0	0	0

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