

INSTRUCTIONS FOR USE

FITC Anti-human Conjugates

	3ml	5ml	10ml
Anti-human IgG (H&L)	J500	-	-
Anti-human IgG (H&L) with Evans Blue	J501	J501-5	J501-10
Anti-human IgG (H&L) for Primate substrates with Evans Blue	J502	J502-5	-
Anti-human IgA	J527	-	-
Anti-human IgG	J528	-	-
Anti-human IgM	J529 (2ml)		
Anti-human IgG for ANCA	J501A (2.5ml)		

INTENDED USE

The Bio-Diagnostics FITC conjugates are intended for use in indirect immunofluorescent antibody (IFA) tests to detect autoantibodies in human serum.

SUMMARY AND EXPLANATION

Antibodies directed against human antibodies are conjugated with fluorescein isothiocyanate (FITC). These FITC conjugates are used during indirect immunofluorescent antibody (IFA) tests to bind to any human antibodies that have attached to the particular substrate. Depending on the type of FITC conjugate selected, human IgG, IgM or IgA antibodies can be detected. FITC conjugates directed against IgG (H&L) will also detect IgA and IgM classes through light chain binding.

PRINCIPLE OF THE TEST

Diluted human sera are incubated on tissue sections. The primary test reaction involves circulating antibodies present in the patient's serum, which attach to their homologous antigens.

A rinsing period is followed by a secondary reaction using a FITC anti-human globulin conjugate. The antigen surface is then thoroughly rinsed free of unbound conjugate and viewed under an appropriate fluorescent microscope to visually identify various morphological patterns of nuclear fluorescence. With a positive reaction, the nuclear pattern appears apple-green when viewed under a fluorescent microscope, whilst a negative reaction appears black or greenish-black.

WARNINGS AND PRECAUTIONS

1. The conjugate contains 0.1% sodium azide as a preservative. Although this is at a low concentration, these reagents should be considered toxic. They should not be ingested or allowed to come into contact with either the skin or the mucous membranes. Sodium azide may also cause the formation of potentially explosive lead or copper azides in sinks.
2. Do not use conjugate beyond its expiration date.
3. For in vitro diagnostic use.

MATERIALS PROVIDED / STORAGE & STABILITY

Anti-human IgG (H&L) - J500
Anti-human IgG (H&L) with Evans Blue- J501/J501-5
Anti-human IgG (H&L) for Primate substrates with Evans Blue - J502/J502-5
Anti-human IgG - J528
Anti-human IgG for ANCA – J501A
CONJ IgG
Anti-human IgA - J527
CONJ IgA
Anti-human IgM - J529
CONJ IgM

The conjugate must be stored at 2-8°C upon receipt. Check label for expiration date.

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

Substrate section slides as appropriate
 Negative and positive controls
 Mounting Medium (BioDiagnostics R005).
 Phosphate Buffered Saline (PBS) (BioDiagnostics R002).
 Test tubes and rack or microtitre system Disposable pipettes Coverslips
 Staining Dish and Slide Forceps Moisture Chamber Distilled Water
 Volumetric Flask (500 ml) Fluorescence Microscope Paper Towels – lint free

All reagents required are available from BioDiagnostics Ltd - see catalogue for details.

KEY FOR OTHER SYMBOLS

Used in this instruction leaflet and on accompanying product packaging:

	Manufacture	RFU	Ready for use
	Temperature limitation	IVD	In vitro diagnostic medical device

TEST INSTRUCTIONS

These conjugates are supplied ready to use for testing on Bio-Diagnostics slides. For use in other systems the user should perform a checkerboard titration to ensure an appropriate dilution.

QUALITY CONTROL

Positive and negative serum controls must be included in each day's testing to confirm reproducibility, sensitivity and specificity of the test procedure.

TEST LIMITATIONS

No diagnosis should be based upon a single serologic test result since various host factors must be taken into consideration.