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Lieferung & Zahlungsart

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Zuschläge

- Mindermengenzuschlag
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ImmuGlo™
AMA, ASMA, AGPA Positive Pattern Controls

For *in vitro* Diagnostic Use

Product Codes #: 2210, 2211, 2212

INTENDED USE

For comparing the specificity and indirect immmunofluoresent staining intensity of anti-mitochondrial (AMA), anti-smooth muscle (ASMA), and anti gastric parietal cell (AGPA) antibody reactions on HEp-2 cell lines and/or rodent kidney and/or stomach substrate.

SUMMARY AND EXPLANATION

The detection by indirect immunofluorescence of AMA aids in the diagnosis of *primary biliary cirrhosis* and *chronic active hepatitis* and excludes *extra-hepatic biliary obstruction* and other liver diseases[1-3].

The detection of ASMA aids in the diagnosis of *chronic active hepatitis* and *acute viral hepatitis*[1, 2].

The detection of AGPA aids in the diagnosis of *pernicious anemia* and *chronic atrophic gastritis*[1, 2].

PRINCIPLES OF PROCEDURE

In the indirect immunofluorescence method patient and control sera are incubated on an appropriate substrate. Antibodies not bound to the antigen in the substrate are removed by rinsing. An incubation with fluorescein-labeled (FITC), anti-human IgG conjugate detects the binding to specific antibodies. Following a wash step the slides are ready to be cover-slipped. When observed under a fluorescence microscope equipped with appropriate filters, positive reactions appear as apple green fluorescence with a distinct staining pattern.

REAGENTS

Description: Human serum containing AMA or ASMA or AGPA and <0.1 % NaN_3 in a dropper vial.

Volume: Each control vial contains 0.5 ml.

Storage: Store at 2-8°C.

Instructions: Ready to use after equilibration to room temperature. Do not use if turbid or if precipitate is present.

Precautions: For *in vitro* Diagnostic Use. All human derived materials have been tested for HBsAg, HCV, HIV-1 and 2 and HTLV-I and found negative by FDA required tests. All human serum specimens and human derived products should be treated as potentially hazardous, regardless of their origin. Follow good laboratory practices in storing, dispensing and disposing of these materials.

WARNING - Sodium azide (NaN_3) may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal of liquids, flush with large volumes of water to prevent azide buildup. Sodium azide may be toxic if ingested. If ingested, report incident immediately to laboratory director or poison control center. Instructions should be followed exactly as they appear in this insert to ensure valid results. Do not interchange components with those from sources other than the same Product Code from IMMCO DIAGNOSTICS. Do not use beyond expiration date.

PROCEDURE

Materials Provided

Product Codes #: 2210, 2211, 2212

1x0.5 ml ImmuGlo™ AMA Positive Control (*#2210)*
1x0.5 ml ImmuGlo™ ASMA Positive Control, *(#2211)*
1x0.5 ml ImmuGlo™ AGPA Positive Control (*#2212)*

Materials Required but not Provided

ImmuGlo™ IFA Tests (HEp-2 Cells, *Product Codes #1102 or 1103* and/or rodent kidney/stomach substrate *Product Codes #1107, 1107-1& 1107-2 and/or 1134*) and other materials required for performing the assay as specified in product insert.

Optional Quality Control Reagent

ImmuGlo™ Optical Standard Slide, *Product Code 2550OS.*

Test Method

Invert dropper vial and apply one drop (approximately 50 µl) of one of the three positive control sera to a well. Apply one drop of Negative Control to another well and one drop of patient's serum to additional wells. Follow procedural steps described in package insert of test procedure.

RESULTS

Examine substrate under a fluorescence microscope at 200x or greater magnification for nuclear fluorescence and staining patterns. Compare patient's serum pattern and fluorescence intensities with the respective ANA Positive Controls and grade results as follows:

+4 Brilliant apple green fluorescence
+3 Bright apple green fluorescence
+2 Clearly distinguishable, positive fluorescence
+1 Lowest specific fluorescence that allows nuclei to be clearly differentiated from background

REFERENCES

1. Manns M, Gerken G, Kyriatsoulis A and Meyer zum Büschenfelde KH. Significant autoimmune markers of autoimmune liver disorders: current status. J Clin Lab Anal; 1:362-370, 1987.
2. Mackay IR. Autoimmunity and the liver. Clin Aspects Immunity; 2:8-17, 1988.
3. Berg PA and Bacon H. Serology of primary biliary cirrhosis. Springer Semin Immunopathol; 3:355-373, 1980.

Warranty Statement

These products are warranted to perform according to the labeling and procedure described herein. Results may be altered by any changes or modifications in the procedure. IMMCO Diagnostics Inc. disclaims any implied warranty, merchantability or fitness for any other purposes. In no event shall IMMCO Diagnostics Inc. be liable for any consequential damages arising out of the above express warranty.

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