

Hyaluronic Acid (HA) Test Kit

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Product #: 029-001
(96 well kit)

***Not FDA Cleared for Diagnostic Use in the
United States.***

*Performance characteristics have not been
established.*

- **Reagent complete kit,
convenient procedure**
- **96-well microplate format**
- **2 hour total incubation at room
temperature**
- **Accurate, precise results
reported in ng/mL**

Background

Hyaluronic Acid (HA), also called hyaluronate or hyaluronan, is a mucopolysaccharide widely distributed throughout the body. HA is produced mainly by fibroblasts and other specialized connective tissue cells. As a free molecule, HA can be found in the plasma and synovial fluid. HA is quickly removed from circulation by specific receptors present in sinusoidal cells (SEC) of the liver; the estimated half-life in plasma is 5-6 minutes. Increased plasma HA levels may result from one or more of the following factors:

- Decreased removal of HA from plasma, as a result of liver damage
- Increased production of HA by synovial cells or fibroblasts and release into circulation

The measurement of HA levels in the blood may be a useful tool for the assessment of the degree of liver fibrosis and cirrhosis in chronic liver disease.

Principle

The Corgenix HA Test kit is a sandwich protein binding assay in a microplate format. The assay uses microwells coated with a highly specific hyaluronic acid binding protein (HABP) from bovine cartilage to capture HA, and an enzyme-conjugated version of HABP to detect and measure HA in patient samples. Reference solutions (prepared from rooster comb HA) are used to calculate test results in ng/ml.

Procedure

Diluted samples and HA reference solutions are incubated in HABP-coated microwells, allowing the HA present in the samples to bind to the immobilized HABP. The wells are washed to remove unbound serum molecules, and HABP conjugated with horseradish peroxidase (HRP) is added to the wells, forming complexes with bound HA. Following a second washing step, a chromogenic substrate (TMB/H₂O₂) is added to develop a colored reaction. Stopping solution is added to the wells, and the intensity of the resulting color is measured in optical density (OD) units in a spectrophotometer at 450 nm. HA concentrations are calculated by comparing the absorbance of the sample against a reference curve prepared from the reagent blank and five HA reference solutions (50, 100, 200, 500, and 800ng/mL) included in the kit. Third-order polynomial regression, linear regression or hand plotting can be used to calculate results.

Clinical Relevance

Until now, the diagnosis of liver fibrosis and cirrhosis has been established mainly by histologic examination of liver biopsy samples. However, since the fibrotic changes are often distributed unevenly throughout the liver, liver biopsy has been associated with a sampling error of up to 24%. The risk of complications including bleeding and infection, the discomfort to

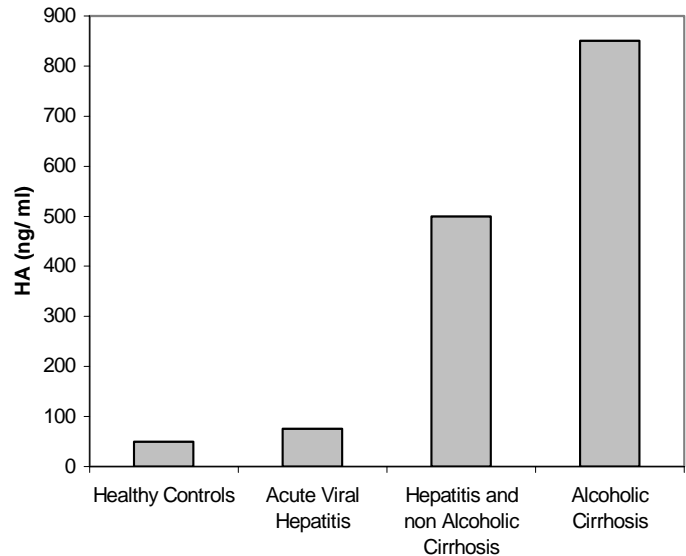
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patients and the high cost of hospitalization associated with this invasive procedure limit the use of liver biopsy as a routine screening procedure for cirrhosis. Serum HA levels have been correlated with the degree of fibrosis and cirrhosis in chronic liver disease and may be a non-invasive, less costly method to assess disease status in these patients. Unlike conventional liver function tests, HA levels reflect the function of sinusoidal endothelial cells (SEC) and may be an early marker of toxic liver damage. According to the literature:

- HA is an effective marker for fibrosis in chronic Hepatitis C patients with moderate to severe disease.
- Serum HA is elevated in patients with alcoholic liver disease and can be used to detect the progression from alcoholic fatty liver to cirrhosis.
- HA may also be used as an early marker of allograft rejection in liver transplant patients.

Clinical Performance

HA levels in normal and liver disease patients, as determined using the Corgenix HA Test Kit, are presented below:



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