



New Device Clearance

N Latex Cystatin C Test Kit - K003503

This is a brief overview of information related to FDA's clearance to market this product.

Product Name: N Latex Cystatin C Test Kit

Manufacturer: Dade Behring, Incorporated

Address: Glasgow Business Community, PO Box 6101, Building 500, Newark, DE 19714

Clearance Date: March 13, 2001

What is it? A laboratory test that measures how well a person's kidneys are working. The test measures the amount of a substance called cystatin C in blood. Normally, the kidneys remove cystatin C from a person's blood. So if the test shows that the blood contains abnormally high amounts of cystatin C, this may mean that the kidneys are damaged.

How does it work? A laboratory instrument, the Dade Behring BN automated analyzer system is used to measure the amount of cystatin C in blood samples.

When is it used? This test is used when the doctor thinks a person may have kidney damage. For example, it could be used on people who have received liver transplants and are taking certain medications that can damage the kidneys.

What will it accomplish? This test tells doctors if a person's kidneys are damaged. Research results from a study of 500 persons showed that cystatin C is reliable in detecting damage to the kidneys and is easier to use than some other tests.

When should it not be used? This test can be used anytime doctors need to know if the kidneys are damaged. However, the test may not be reliable in children younger than a year old.

Additional information: Summary of Safety and Effectiveness Data and Labeling can be found at:
<http://www.fda.gov/cdrh/pdf/k003503.pdf>

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