

# Correcting the Record On DNA Tests



To Members of Congress:

Recent media reports have confused the public about the value and safety of genetic tests for patients.

Here are the facts. Sophisticated genetic tests are allowing earlier diagnosis and treatment tailored to the exact genetic profile of the individual patient—and lives are being saved. For example:

- ❖ Tests that read the DNA structure of the most common form of leukemia in children have helped boost the 10-year survival rate from four percent in the 1960's to more than 80 percent today.
- ❖ Diagnostic HIV tests that check the genetic code of the individual's virus and guide physicians have helped transform HIV from an almost certain death-sentence to a manageable chronic disease.
- ❖ The test for the "Her-2" gene has become critically important in better-targeting therapies for women with breast cancer.

All of these tests are performed in a laboratory regulated under the Clinical Laboratory Improvement Amendments by the Centers for Medicare and Medicaid Services, and genetic tests made by device manufacturers for general distribution are regulated by the Food and Drug Administration. In addition, laboratories are regulated by states, and most are additionally overseen by other accrediting bodies.

Government agencies have stepped-up enforcement against a few bad actors who are marketing "lifestyle," nutritional deficiency, and other tests directly to consumers online. But these aberrations should not confuse the public or policymakers. Genetic tests performed in certified laboratories are safe and are saving and improving lives daily.

For more information on the value of laboratory testing, go to [www.labresultsforlife.org](http://www.labresultsforlife.org) or call 202-637-9466.

