FDA obstructing approval of DNA based ‘germ tests’ that swiftly diagnose infections

The standard diagnostic technology for identifying microbes, decades old, is simply too slow and imprecise to help most patients. The good news is that scientists have developed far better technology….

…

First, there’s DNA sequencing, which has been growing steadily faster. Today’s automated sequencers can generate up to 400 billion bases…per day — 400,000 times faster than 15 years ago and 75,000 times more cheaply.

The second advance is in the scope of our genome databases. The very first bacterial genome was sequenced only 20 years ago, but already we have more than 30,000 bacterial genomes and 80,000 viruses, plus the genomes of hundreds of other pathogens (such as malaria) caused by microbes that are neither bacterial nor viral.

…

The trouble is, the FDA is proposing to make the process even more difficult. The agency recently announced that it wants to regulate DNA-sequencing diagnostic tests, something it has never done before. And getting FDA approval is much more onerous than getting a CLIA approval.

…

If the FDA will refrain from setting up unnecessary obstacles, scientists in both academia and industry can move ahead to develop CLIA-approved tests for DNA diagnostics.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: Make Way for Better Germ Tests