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New technology for testing multiple blood borne pathogens

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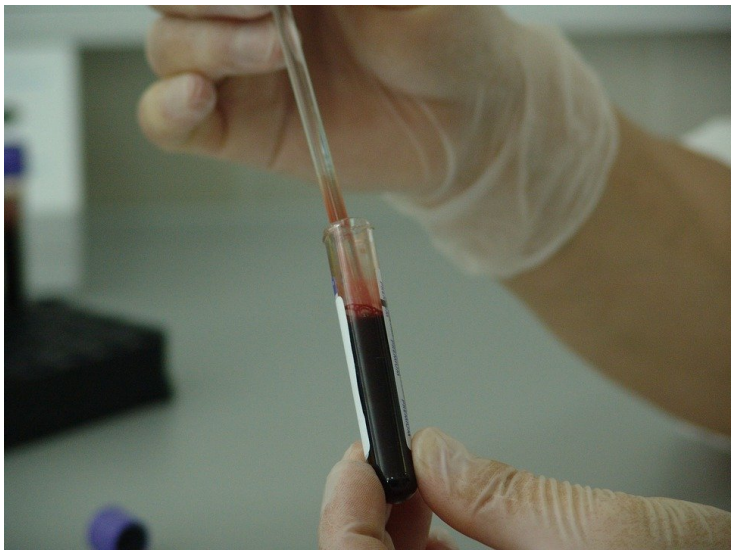

The new open array system, designed at the Center for Biologics Evaluation and Research within the FDA in the US, offers simultaneous detection of multiple viruses, bacteria, and protozoan pathogens in human blood samples. Investigators determined that this system is a promising tool for flexible, fast, and accurate blood screening.

Some highly virulent pathogens may have a low prevalence rate and/or be restricted seasonally or geographically. However, the impact of transfusion-transmitted infection of such agents can have fatal consequences, particularly in highly vulnerable populations such as newborns, the elderly, or immunocompromised individuals. The cost effectiveness of a multiple agent test means that more testing could be done, resulting in safer blood.

To design this device, the first step required choosing regions on each of the pathogen genomes to target and short pieces of DNA to accomplish that targeting. These short pieces, called primers and probes, which achieve the PCR, were loaded into the OpenArray device. The next critical step was laboratory growth of the 30 pathogens and mixing each one of them with normal volunteers' whole blood or plasma to mimic the blood from an infected individual. Once performance of the device was adjusted to maximum ability to detect these infectious agents in the mock clinical samples, it was tested with 92 donor samples obtained from a blood donor testing center with known pathogen content, as determined by FDA-licensed tests. Ninety-five percent of virus-positive samples were correctly identified.

Currently, this OpenArray Platform is for research use only and is not cleared or approved for clinical use.