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CLINICIANS' BIOSECURITY NEWS

ANALYSIS OF ADVANCES AND CHALLENGES IN CLINICAL BIOSECURITY

Rapid Ebola Test Now Available for Use in Hospitals

Eric Toner, MD, October 29, 2014

On Sunday, October 25, 2014, the Food and Drug Administration (FDA), acting with extraordinary speed to address an urgent situation, issued an Emergency Use Authorization (EUA) for the commercial Ebola assay manufactured by Biofire Defense, LLC, called FilmArray Biothreat-E.[1] This PCR-based test can confirm or rule out Ebola in symptomatic patients in approximately 1 hour, and the test can be done safely in many hospitals. This is a major step forward, because until now Ebola testing could be done only at the CDC or in a limited number of state laboratories that are part of the laboratory response network.

Why the Test Was Urgently Needed

Our national effort to promote hypervigilance about Ebola in emergency departments across the country has created an unintended hazard to some patients' health. Today, if someone who has been in one of the affected countries in the past 21 days presents to an ED with any of a variety of nonspecific symptoms, s/he is likely to be isolated and not be afforded regular diagnostic and therapeutic care until Ebola is ruled out. This can take many hours if the test has to be sent out to a reference laboratory.

This can be a critical problem if there is a brief window of opportunity for intervention, such as is the case with MI, stroke, or sepsis. In such cases, routine but essential blood tests will not be done in many hospitals unless they can be done at the bedside (many hospitals do not have bedside diagnostics like *iStat*, and there are no point-of-care versions of many essential tests), imaging studies will not be performed, and invasive therapeutic interventions will not be done for many hours.

Because of the exaggerated fear of Ebola, and "out of an abundance of caution," we are hearing anecdotes in which patients with illnesses that are not consistent with Ebola are being isolated and not given prompt treatment because of a travel history alone. Until now the principal purpose of Ebola testing has been to confirm the diagnosis in a patient with a high likelihood of being positive--in other words "ruling-in" a diagnosis. This is important, but the current situation also demands a "rule-out" capability in the relatively low-probability patient. In time-critical conditions, it is just as important to know that a patient does *not* have Ebola as it is to know s/he does.

Test Availability

According the manufacturer, 300 hospitals have the Biofire analyzer--which is FDA-cleared for the diagnosis of respiratory, gastrointestinal, and bloodborne pathogens--and, as of October 27, 2014, they reported having 800 Ebola test kits ready to ship.[2] Hospitals should seriously consider acquiring this test to better care for any

Ebola patients they might treat and, just as importantly, to be able to quickly rule out Ebola in patients with an unrelated and time-sensitive condition who also have an epidemiologic link to an affected region or person.

References

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