



## **DISCUSSION OF PCR TESTING AND IMMUNOASSAY TESTING USING THE NANOMIX SYSTEM FOR THE DETECTION OF EBOLA VIRUS**

PCR testing is the current diagnostic standard deployed in Africa (and used by the CDC in the United States). PCR systems are very accurate in identifying infected subjects. However, they are expensive, require trained operators, and take hours from receipt of sample to test result. If the PCR system is not locally deployed, the transit time of samples to a lab and resultant time to diagnosis can grow to many hours or even a day or two. Time is a significant factor in successful quarantine and containment of infected individuals.

Rapid testing solutions are available from several sources for detection of Ebola. Rapid tests generally are done locally and results are available in a 10-20 minute window. Operation of rapid tests can usually be performed by local healthcare workers with minimal training. Most rapid tests are qualitative tests of Ebola, providing either a positive or negative test result. The Nanomix system is an automated system that provides a test result from whole blood in 10 minutes. The answers are quantitative, measuring the level of infection, and can include identification of differing infections. The proposed configuration of the Nanomix system would detect either Ebola or Lassa Fever from a single blood sample in the 10 minute timeframe. This is a very important capability as the clinical presentation of Ebola and Lassa Fever are the same. Only testing can differentiate the infection and result in appropriate segregation and treatment of Ebola versus Lassa patients. The proposed test would utilize reagents for both Ebola and Lassa that have been validated in Africa by Tulane University and the Viral Hemorrhagic Fever Consortium (VHFC). With further development, the Nanomix could be configured to test for Ebola, Lassa, and Malaria.

Feasibility testing of the Nanomix system was carried out by Tulane University and the VHFC in Sierra Leone in 2012/13. Development is needed to update the initial diagnostic panel for new reagents that have been developed and validated for both Ebola and Lassa Fever. A three month deployment timeframe is estimated to include the transfer of reagents to the Nanomix platform, validation of the Nanomix platform against existing targets, and the review of sample capture methods to assure efficient and safe operation. Validation data of the Ebola reagents is being gathered but initial data show that the rapid tests are very accurate in identifying infectious patients.

We compared the cost and capacity of PCR with the Nanomix solution (see attached summary). For the deployment of 100,000 tests, the cost of the PCR solution is estimated to be approximately \$26,000,000 while the Nanomix solution, including development, is \$10,000,000. In addition to the large cost difference, the Nanomix systems would be very widely deployed (250 test units versus 50 PCR units) covering more of the population, and have a daily capacity of 20,000 tests done in 10 minutes versus 5,000 tests per day done in hours or longer by PCR.

Both PCR and rapid testing are important for the detection and management of Ebola and other Hemorrhagic Fevers in the population. We recommend that rapid testing be used as the first line diagnostic test with reflex/confirmatory testing by PCR.

The final point to make is that an infrastructure of automated rapid testing that detects and differentiates Ebola, Lassa, and Malaria, complemented by the existing PCR solutions, would create a strong diagnostic infrastructure in the region that will aid in the current crisis as well as leaving behind a strong disease management capability for the future.

<b>PCR</b>		
<b>Assumptions</b>		
Instruments for Sample Handling and Detection		\$ 50,000
Cost per test (extraction, amplification, detection, reagents, tested in triplicate)		\$ 225
Lab staff cost per test		\$ 10
Daily capacity per system - # of tests		100
Time to result from patient sample		4 hours + transport time
<b>Cost of 100K Tests</b>		
Instruments	50	\$ 2,500,000
Tests	100,000	\$ 23,500,000
Daily test capacity	5,000	
<b>TOTAL</b>		<b>\$ 26,000,000</b>

<b>NANOMIX</b>		
<b>Assumptions</b>		
Instrument		\$ 10,000
Cost per test		\$ 35
Lab staff cost per test		\$ -
Daily capacity per system		80
Time to result from patient sample		10 minutes
<b>Cost of 100K Tests</b>		
Instruments	250	\$ 2,500,000
Tests	100,000	\$ 3,500,000
Daily test capacity	20,000	
<b>Dev Cost (3 months) - EUA Product Only</b>		
Staff		\$ 624,000
VHFC Staff		\$ 500,000
Sample capture engineering		\$ 300,000
Reagents, materials		\$ 600,000
Testing and validation (incl BSL4 access)		\$ 1,500,000
Equipment		\$ 500,000
<b>TOTAL</b>		<b>\$ 10,024,000</b>