SOLE SOURCE DETERMINATION

The Purchasing Division has been requested to approve a sole source purchase for the commodity or service described below. Pursuant to West Virginia Code 5A-3-10c, the Purchasing Division is attempting to determine whether the commodity or service is a sole source procurement. If you believe your company meets the required experience and qualification criteria stated below, please e-mail the Purchasing Division at team@wvadmin.gov to express your interest in the project. Please forward any and all information that will support your company's compliance with required qualification and eligibility criteria along with any other pertinent information relative to this project to the Purchasing Division no later than 12/18/2007.

Requisition Number: LBS80429
Department/Agency: WVDHHR/Bureau for Public Health/Office of Laboratory Services

Detailed Description of Project: Purchase of reagents for use with a semiautomatic processing system to perform Neonatal Screening for mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.

Proposed Sole Source Vendor: Third Wave Technologies, Inc.
502 S. Rosa Rd.
Madison, WI 53719

Specific Eligibility Criteria: Vendor must be able to provide all of the CFTR Mutation Panels listed in the requested specifications.

Vendor must be able to provide the specific microfluidics testing technology as requested in the specifications.

Vendor must be able to provide a semiautomatic processing system, at no cost, to perform Neonatal Screening for mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene for the Office of Laboratory Services.

Specific Qualification Criteria: Bidders must be able to provide all of the CFTR Mutation Panels listed in the requested specifications and they must provide the semiautomatic processing system, at no cost, to perform Neonatal Screening for mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene as listed in the requested specifications.

1. EQUIPMENT SUMMARY:

To provide a semi-automated processing system to perform neonatal screening for mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene for use in the Newborn Screening Section of the Office of Laboratory Services (OLS) at no cost per the following specifications:

INSTRUMENT / EQUIPMENT SPECIFICATIONS:

1. Equipment must be the following, ***or equivalent***:

Third Wave Technologies Part #	**Description**
12-231	Thermal Cycler (96-well)
12-236	Thermocentrifuge
12-237	Thermocentrifuge Rotor
12-231	Thermal Cycler
12-067	Tecan Genios FL Reader
12-167	Centrifuge (Non-refrigerated Tabletop)
12-168	Rotor (750 mL Swing-Out)
12-172	Buckets (Microplate)
12-173	Buckets w/Clips
12-170	Inplex™ Sealer
12-206	Hybridization Oven w/12-Microplate Carousel

2. All equipment needed for dried blood spot specimen preparation and DNA extraction must be supplied by the vendor. However, reagents necessary for DNA extraction do not have to be provided by the vendor and will be purchased separately by OLS.
3. All equipment needed for testing, including but not limited to thermal cyclers, hybridization ovens, centrifuges and plate readers, must be supplied by the vendor.
4. Vendor must supply computer, monitor, laser printer, software, cables, communication ports, and any other components necessary for operation.
5. Computer operating system software must be Windows 2000, XP or VISTA.
6. Computer must have CD-R/RW capability to allow data backup.
7. The system software must provide electronic file storage and retrieval capabilities, as well as a printed data record.
8. Test results must be accessible in a Microsoft Office Excel spreadsheet.

COMPUTER INTERFACE SPECIFICATIONS:

1. Computer must have Fast Ethernet 100BT or greater connectivity and have the ability be joined to the WVDHHR network domain to allow automatic data transfer to a designated folder to allow data merging into LIMS.

2. Vendor must allow the computer to be interfaced with the WVDHHR network domain, and must allow any necessary software (Symantec Antivirus, etc.) to be installed onto the PC.
3. Vendor must allow all WVDHHR network security and management configurations required by established policy to maintain network security and restrict access as necessary.

EQUIPMENT OWNERSHIP / MAINTENANCE / TECHNICAL ASSISTANCE REQUIREMENTS:

1. Vendor must remain the owner and retain the title of the equipment.
2. All instrumentation provided by the vendor shall be maintained at vendor's expense during the term of this contract.
3. One annual preventative service visit at the Office of Laboratory Services shall be provided at no additional charge.
4. Vendor must provide a company representative for technical service, repairs, maintenance, etc. Subcontracting of these services shall not be acceptable to the State of West Virginia.
5. Vendor must provide technical telephone assistance 8:00 am – 5:00 pm EST Monday through Friday.
6. Replacement part(s) and/or on-site service must be provided within 24 hours, if equipment problems can not be resolved via telephone by the end of the work day in which the problem has been reported.

TRAINING / INSTALLATION REQUIREMENTS:

1. Delivery of the equipment must be within 30 days of the approved purchase order.
2. Vendor must provide a company representative for installation and training. Subcontracting of these services shall not be acceptable to the State of West Virginia.
3. Training of personnel must be provided at the Office of Laboratory Services within two weeks after delivery date.

2. TEST / REAGENT KITS SUMMARY:

To purchase test / reagent kits, compatible with furnished system, to perform neonatal screening for mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene for use in the Newborn Screening Section of the Office of Laboratory Services per the following specifications:

ESTIMATED ANNUAL VOLUME:

The expected annual volume is 1700 tests. The estimated number of tests provided is for bidding purpose only and the vendor will be required to provide the quantity of test kits needed, be it more or less.

TEST METHOD AND REAGENT KIT REQUIREMENTS:

1. Analyte Specific Reagents (ASR) or FDA approved test kits are acceptable.
2. Must identify, at a minimum, the mutations of the CFTR gene listed in Table 1 below.
3. Must provide automatic reflex testing for R117H positive results for the intervening sequence mutations IVS8-5T/7T/9T.
4. Must have a minimum shelf life of 90 days.
5. Must use a limited 14 or 16 cycle polymerase chain reaction (PCR).
6. Must use a maximum of 1 thermal cycler reaction and no more than 1 post thermal cycler reaction including, but not limited to a hybridization reaction.
7. Turnaround time for the test method, including DNA extraction, must not exceed 5 hours.
8. DNA extracted from a one-eighth inch (1/8") neonatal dried blood spot specimen must be acceptable for the test method.
9. Must use a microfluidics card format in which the reaction chambers are spaced in a 384-well format.
10. Vendor must provide a list of at least 5 other state newborn screening laboratories using their reagent kits.

Table 1

CFTR Mutation Panel			
ΔF508	ΔI507	R117H	1717-1G>A
R553X	621+1G>T	R334W	2789+5G>A
R1162X	G85E	3849+10kbC>T	W1282X
2184delA	1898+1G>A	G551D	A455E
3120+1G>A	G542X	R347P	711+1G>T
3659delC	N1303K	R560T	E60X
Q493X	D1270N	Y122X	F508C
3849+4A>G	I148T	V520F	3876delA
1078delT	3905insT	S549N	Y1092X C>A
2183AA>G	IVS8-5T	R347H	S549R A>C
Y1092X C>G	IVS8-7T	394delTT	S549R T>G
D1152H	IVS8-9T		

DELIVERY / SHIPPING REQUIREMENTS:

1. To be F.O.B. Destination, unless vendor states otherwise in submitted quotation.
2. Reagent kits must be shipped no more than 3 days after receiving the order, at vendor's expense.