



Respiratory Pathogen Panel Specifications

Supplier shall provide one (1) complete system/platform, reagents and consumables to perform respiratory viral panel testing to the State of Tennessee. This will be a five (5) year contract.

Definitions:

ELC: Federal grant program intended to enhance laboratory capacity

FDA: Food and Drug Administration

Instrument: Refers to the (manual, semi-automated, fully automated) analyzer that performs and interprets the test results.

LIMS: Laboratory Information Management System – Laboratory Services uses StarLIMS v.11

Software: Refers to any firmware or analytical processing programming that allows for the operations and calculations of an instrument to produce reportable results.

Accession number: Refers to the unique identifier that is assigned to each sample by the State of Tennessee’s Laboratory Information Management System (LIMS).

I. TEST KITS

1. Assays shall have the ability to operate on the instrument/system platform provided.
2. Assays shall have a turnaround time that is no more than seven and a half (7.5) hours.
3. These FDA cleared assays shall have the ability to detect the following viruses from a single nasal/nasopharyngeal swab:

Influenza A	Respiratory Syncytial Virus (RSV) A	Human Metapneumovirus (hMPV)
Influenza A H1	Respiratory Syncytial Virus (RSV) B	Human Rhinovirus (HRV) /Enterovirus (EV)
Influenza A H3	Parainfluenza Virus (PIV) 1	Adenovirus
Influenza A 2009 H1N1	Parainfluenza Virus (PIV) 2	Coronavirus OC43
Influenza B	Parainfluenza Virus (PIV) 3	Coronavirus NL63
Human Bocavirus	Parainfluenza Virus (PIV) 4	Coronavirus 229E
<i>Chlamydomphila pneumoniae</i>	<i>Mycoplasma pneumoniae</i>	Coronavirus HKU1

4. Assays shall add the SARS-CoV-2 analyte to the panel before December 31st, 2020.

II. INSTRUMENTATION

1. The State expects using approximately seven hundred (700) tests per year. Please supply pricing costs per kit in a reagent rental agreement that includes all reagents, accessories, instrumentation, software(s), maintenance, repair, technical support, training (if required), and shipping costs.
2. The Supplier shall be able to provide reagent rental which encompasses fully functional analytical instrument at no additional charge to the State.
3. Instrument shall remain the property of the manufacturer.



4. Instrument processing software shall be capable of organizing accession numbers numerically for data analysis.
5. The instrument shall feature an onboard (or connectable accessory) barcode reader that permits a user to efficiently assign specimens to the run and relevant test selection (routinely less than fifteen (15) seconds per specimen entry) in absence of a connection to the LIMS (e.g. manual entry).
6. Instrument shall include all operating software and any data processing software required for fully functional analysis. Supplier is responsible for updating and servicing all instrument related software, updates should be deployed as soon as possible and no later than two (2) weeks post release.

III. MAINTENANCE, TECHNICAL SUPPORT AND INSTALLATION

1. Supplier shall be responsible for all maintenance and all associated costs of leased instruments and accessories.
2. Instrument shall be maintained according to the original manufacturer's maintenance standard. Instrument shall remain state of the art.
3. Software shall remain most current, up-to-date version.
4. Supplier shall provide on-site technical support Monday-Friday from 8:00 AM to 4:30 PM CT.
5. Supplier shall provide a toll-free phone number for technical support that is available seven (7) days per week (including holidays) 8:00 AM-4:30 PM CT.
6. Supplier shall respond within twenty-four (24) hours of notification for on-site service and within one (1) hour of notification for telephone technical support, or by the next business day with respect to holidays and weekends.
7. Supplier shall provide electronic (e.g. PDF) operation manual for each instrument and a digital copy of the product insert for the reagent kits.
8. Supplier shall provide training for a minimum of two (2) lab personnel for a minimum of four (4) hours (if requested).
 - No travel or per diem charges will be paid by the State of Tennessee.
 - Training will be included at no additional charge to the State of Tennessee, Department of Health, Laboratory Services. Training shall take place and provided within standard business hours Monday-Friday from 8:00 AM to 4:30 PM CT.

All services offered in this contract shall be provided to the following location:

**TN Department of Health, Division of Laboratory Services
630 Hart Lane
Nashville, TN 37216**