PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC81000 – GeneXpert Dx System	Policy Number: 29-09-V1
Program Name: Laboratory Services	
Applicable Domain: Epidemic/Pandemic	
Additional Domain(s): Lab, DI and Pharmacy Services	
Effective Date: 19/01/2021	Next Review Date: 19/01/2023
Issuing Authority: Director of Health Services	Date Approved: 19/01/2021
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:
The GeneXpert Dx System automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR).

PURPOSE/RATIONALE:
This standard operating procedure describes the GeneXpert Dx System and its components.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists processing specimens using the GeneXpert Dx System.

SAMPLE INFORMATION:
- Refer to assay specific GeneXpert procedures for sample information

REAGENTS and/or MEDIA:
- Refer to assay specific GeneXpert procedures for reagent information

SUPPLIES:
- Refer to assay specific GeneXpert procedures for supply information

EQUIPMENT
- GeneXpert Dx System

ENVIRONMENTAL CONTROLS:

- Operating temperature: 15°C to 30°C
- Relative humidity: 10% to 95%, non-condensing

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potential infectious materials or cultures.

- Ensure that appropriate hang hygiene practices be used.
- Lab gown must be worn when performing activities with potential pathogens.
- Gloves must be worn when direct skin contact with infected materials is unavoidable.
- Eye protection must be used when there is a known or potential risk of exposure of splashes.
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC).
- The use of needles, syringes and other sharp objects should be strictly limited.

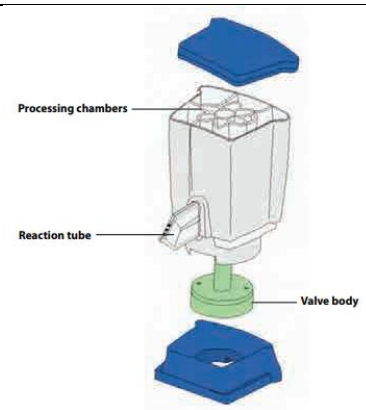
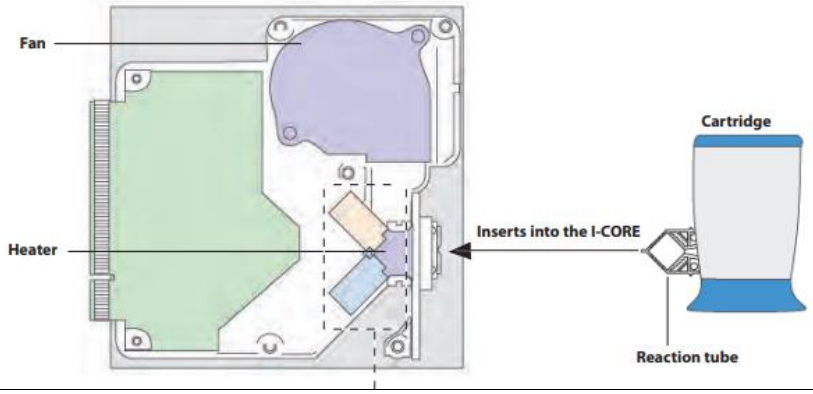
All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:

- Refer to assay specific GeneXpert procedures for quality control information

PROCEDURE INSTRUCTIONS:

Step	Action
System Components	
1	**GeneXpert Instrument:** • The GeneXpert GX-IV System is composed of 4 modules • The GeneXpert GX-XVI System is composed of 16 modules • A cartridge loading and unloading mechanism assures the proper movement of the cartridge in the instrument • The system is designed to perform a self-test before each test starts to verify that the system is functioning properly • Because the system allows you to control the modules independently, you can process different samples using different assay definitions in the same system at the same time
2	**GeneXpert Cartridges:** • The disposable, single use GeneXpert Dx cartridge holds the samples and reagents that you want to process in the GeneXpert Dx System • Each cartridge consists of the processing chambers, valve body and reaction tube • The cartridge is designed to keep the reagent contained within the cartridge. It is a closed system vessel:

	
3	**I-CORE Module:** • The I-CORE (Intelligent Cooling/Heating Optical Reaction) module is the hardware component within each instrument module that performs PCR amplification and fluorescence detection • As the cartridge is loaded onto the instrument, the reaction tube is inserted into the I-CORE module • The sample and reagent mixture are pushed from the cartridge into the reaction tube • During the amplification process, the I-CORE heater heats up and the fan cools down the reaction tube contents. The optical blocks excite the dye molecules and detect the fluorescence emitted: 
4	**Heating and Cooling Mechanisms:** • Within the I-CORE, the heater consists of two ceramic plates that have high thermal conductivity to assure temperature uniformity and rapid heat transfer • Resistive heater elements are deposited on the ceramic plates and a thermistor attached directly to each plate monitors its temperature • A high efficiency fan cools the reaction tube contents by moving ambient air across the heater plates • During thermocycling, the instrument firmware controls the temperature inside the instrument module • The firmware incorporates a control loop to ensure rapid heating of the plates while minimizing the temperature overshoot around the desired target temperature

5	**Optical System:** • Within the I-CORE, the optical system consists of two blocks: ➢ Six-color excitor module-Contains high intensity light-emitting diodes (LEDs) to excite the reporter dye molecules ➢ Six-color detector module-Contains silicon photodetectors and filters to detect the six spectra bands • The optical blocks are positioned within the I-CORE such that their apertures mate with the optical windows of the reaction tube, allowing excitation and emission detection of the reaction mixture. • By using probes labeled with different fluorescent reporter dyes, up to six targets can be detected simultaneously in a single reaction tube • The emission spectra of fluorescent dyes can overlap and a particular dye could produce signal in more than one channel. To compensate for the spectra, overlap, the system uses appropriate calibration and data analyses algorithms to determine the concentrations of each reporter dye
6	**System Calibration:** • The thermal reaction chamber thermistors are calibrated to ± 1.0°C using NIS traceable standards • During the manufacturing process, the temperature of the heating system is measured at two temperatures: 60°C and 95°C • Calibration coefficients that correct for small errors in the raw thermistor readings for the heaters are stored in the memory of each I-CORE module
7	**GeneXpert Software:** • The GeneXpert Dx System software is installed on the supplied laptop and can accommodate a variety of applications: ➢ Administrative tasks – Configure the system to accommodate your organization's preferences, define system users and set up permissions, import and delete *in vitro* diagnostic assay definitions, general external control trend reports and manage the test data in the database ➢ Test tasks – Create and start an *in vitro* diagnostic test, stop a test in progress, monitor a test in progress, view the test results, edit test information and generate test reports ➢ Maintenance tasks – Perform various maintenance tasks including plunger and valve maintenance controls for cleaning the module plungers and valves, performing a self-test manually for troubleshooting, checking the calibration and test counts and commands for opening a module door

INTERPRETATION OF RESULTS:

- Refer to assay specific GeneXpert procedures for the interpretation of results

REPORTING INSTRUCTIONS:

- Refer to assay specific GeneXpert procedures for the reporting of results

REFERENCES:

1. Cepheid GeneXpert. *Dx System User Manual*. 301-0045, Rev.C, June 2012

APPROVAL:

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Date

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	27 May 20	Initial Release	L. Steven