PURPOSE

Group A Streptococcus, or Strep pyogenes, is a bacterium commonly found in the human throat or on skin. S. pyogenes causes a wide variety of diseases in humans, the most common being acute pharyngitis or strep throat. Acute pharyngitis is one of the most frequent illnesses for which physicians are consulted. It is important to determine if the pharyngitis is caused by Group A strep or Non Group A strep. Group A pharyngitis requires appropriate antimicrobial therapy to prevent rheumatic fever and suppurative complications, and to minimize the spread of the illness.

POLICY

The Illumigene Group A Streptococcus assay is a qualitative in vitro diagnostic test for the detection of Streptococcus pyogenes (Group A β-hemolytic Strep) in throat swabs. The Illumigene Group A Strep assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect a target segment of the Strep pyogenes genome. The Sensitivity and Specificity of this molecular amplification method of testing for Group A Strep is 98% meaning a backup culture for negative screens is no longer necessary.

MATERIALS

* Illumipro-10 Reader
* 95° Heat Block w/ tracing thermometer
* Meridian Group A Strep Kits
* 50 µl Pipette with *filtered* sterile tips
* Orange sample splash protector

SAMPLE : Throat swab sample (Liquid Amies *without* charcoal **or** Liquid Stuarts Media) good for 48 hours at room temperature or 7 days 2-8° C.

PROCEDURE

Sample prep

1. Sample collection- Throat sample collection should be performed in accordance with published guidelines for collection of clinical specimens for culture of Group A Strep using the above swabs.
2. Separate double swabs and remove one swab for Illumigene testing. Note: PCR testing is very sensitive. Change gloves prior to testing and disinfect work area with fresh 10% bleach solution before and after setting up specimens.
3. Using an orange splash guard square, Insert swab into Specimen diluent in the Sample Preparation apparatus (Blue top tube included in kit) and break off. Recap and vortex for 10 seconds.

Specimen is stable up to 2 hours at this step.

1. Remove cap and squeeze 5-10 drops into the heat treatment tube (small conical tube).
2. Turn tracing thermometer on. It will begin to trace minimum and maximum temperature when turned on.
3. Heat the Illumigene Heat treatment tube at 95° C (+/- 5°) for 10 minutes (+/- 2 min). Remove after 10 minutes and vortex for 10 seconds. Record heat treatment time on **Specimen log sheet.**

Specimen is stable for 1 hour at this step.

1. Press the MIN/MAX button on the traceable thermometer and record the min and max temperature on the **Specimen log sheet** for that run. Then turn thermometer OFF.
2. Remove a test device from the foil pouch and transfer 50 µl of the heat treated sample into each well using a new pipette tip with each transfer. Close and fasten latch.
3. Gently flick or tap test device to remove trapped air bubbles from the bottom. Examine to ensure no bubbles in tube.

Loading Test Device into Illumipro

1. Print and record System check for Instrument run. Select 4 “SERVICE”, then Print system check. Record on **Specimen log sheet**.
2. Allow instrument to warm to 63° C. The instrument will display asterisks **\*while warming**, and **--- dashes when ready to run**. (This takes approximately 10 minutes.)
3. From the main menu Press 1 “Block A” or 2 “Block B”. Select “Group A Strep” assay and follow prompts for checking for used test devices and removing. **Note:** to open lid press on the outer corner over the latch and lift.
4. Insert test devices into Illumipro reader matching up sample with well # on specimen log sheet. Close lid and Press RUN.
5. Press 1 “Edit Sample IDs”. Select correct well and barcode sample ID or manually enter using keyboard.
6. When testing is complete, Press 1 or 2 for corresponding Block A or B and results will automatically print for that incubator.

NOTE: Incubators A and B are separate and can have simultaneous runs performed on them. Once a run is initiated, lid cannot be opened until testing is complete on the block in use.

INSTRUMENT MAINTENANCE

**Daily:**

1. Using a KimWipe with 10% bleach, wipe foam strip on inside upper lid and top of wells, avoiding the latch, followed by 70% alcohol to rid the bleach residue. **Do NOT** use canned air on instrument.
2. Turn instrument off, wait 30 seconds and turn back on.

**Monthly:**

Run an Optical Verification Test when “!!!!” is displayed. Press 4 for “Service” then follow prompts for running Standard.

NOTE: Insert Standard with Serial # towards you. In the event of a failure, clean the standard with a KimWipe or lens paper and repeat. Be careful with Standard, it is fragile and made of glass.

CONTROLS

**Internal:** The right side of each test cartridge contains a staph aureus specific primer and DNA for the internal positive. If this internal control does not work, the assay will result as invalid and no results will print. These internal control reactions ensure amplification is not inhibited, reagents are performing as intended and that sample processing was performed appropriately.

**External:** A positive and negative control shall be run with each new lot/shipment or every 30 days, whichever is more frequent.

**Positive -** Add 50 µl of positive Group A strep control to the Blue top Sample Prep apparatus and continue setting up in the same manner as a patient.

**Negative -** Use a plain Blue top Sample Prep apparatus with nothing added and continue setting up in the same manner as a patient.

RELATED DOCUMENTS: Specimen Log sheet

Monthly maintenance form

REFERENCES: Illumigene DNA Amplification Assay for Streptococcus pyogenes package insert REF # 280150

Illumipro-10 Operator’s manual 113687-001 Rev B 07/2010