PURPOSE: The Streptococcus latex test is used to serologically identify beta-hemolytic *Streptococci* belonging to Lancefield groups A, B, C, D, F and G.

SAMPLE INFORMATION:

Type	One to four, well-isolated colonies that are: • Gram-positive cocci • Beta-hemolytic • Catalase negative • From a 18 to 24 hour culture

REAGENTS and/or MEDIA:

Type	PROLEX STREPTOCOCCAL GROUPING LATEX KIT
Stability and Storage Requirements	• Store at 2°C to 8°C. • Do not freeze.

NOTE:

- ***Streptococcus pyogenes* (Group A) from invasive sites is a critical result and needs to be phoned to ordering location and phoned and copied to HPU1. Refer to NWT Reportable Diseases.**
- ***Streptococcus agalactiae* (Group B) from invasive sites in neonates need to be copied to HPU1. Refer to NWT Reportable Diseases**

SUPPLIES:

- Glass test tubes
- Disposable loops
- Wooden sticks
- Sterile pipettes
- Disposable test cards

SPECIAL SAFETY PRECAUTIONS:

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

- 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 to 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. Universal precautions 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:

- Quality control is performed weekly:
  - Positive: Polyvalent positive control
  - Negative: Sterile saline
- A TQC order is automatically generated on Wednesdays to record the QC results.
- Each test should be tested with at least one extra grouping latex suspension as a negative control.

QUALITY CONTROL PROCEDURE INSTRUCTIONS:

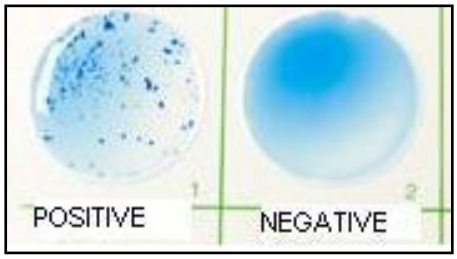
Step	Action
Performing Streptococcus latex test quality control	
1	Remove the test kit from the refrigerator 10 minutes prior to use and allow the reagents to reach room temperature.
2	Add 2 drops of Extraction Reagent 1 to a test tube.
3	Add 1 drop of Polyvalent Positive Control to the tube. Mix by tapping for 5 to 10 seconds.
4	Add 2 drops of Extraction Reagent 2 to the tube. Mix by tapping for 5 to 10 seconds.
5	Add 2 drops of Extraction Reagent 3 to the tube. Mix by tapping for 5 to 10 seconds.
6	Using a sterile pipette, place 1 drop of the mixture on separate circles of the test card for each latex reagent being control tested.
7	Re-suspend the latex reagents by inverting the dropper bottle several times. Dispense 1 drop of the appropriate blue latex suspension onto each circle.
8	Using a new stick for each circle, mix the latex and the extract over the complete area of the circle.
9	Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
10	At 1 minute, under normal lighting conditions, observe for agglutination.
11	Repeat steps 1-9, using saline in step #3 as a test of absence of auto agglutination.

TEST PROCEDURE INSTRUCTIONS:

Step	Action
Performing the Streptococcus latex test	
1	Remove the test kit from the refrigerator 10 minutes prior to use and allow the reagents to reach room temperature.
2	Label one test tube for each specimen to be tested.
3	Add 2 drops of Extraction Reagent 1 to each tube.
4	Select 1 to 4 colonies using a wooden stick or disposable loop and suspend in the extraction reagent. If colonies are small, emulsify enough well isolated colonies so that the extraction reagent becomes turbid.
5	Add 2 drops of Extraction Reagent 2 to each tube. Mix by tapping for 5 to 10 seconds.
6	Add 2 drops of Extraction Reagent 3 to each tube. Mix by tapping for 5 to 10 seconds.
7	Re-suspend the latex reagent by inverting the dropper bottle several times.
8	Dispense one drop of each latex suspension to be tested onto separate circles on the test card.
9	Using a sterile pipette, place one drop of extract beside each drop of latex suspension.
10	Using a new stick for each circle, mix the latex and the extract over the complete area of the circle.
11	Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
12	At 1 minute, under normal lighting conditions, observe for agglutination.

INTERPRETATION OF RESULTS:

IF	THEN
Strong agglutination within 1 minute	**Streptococcus latex test = Positive**
No visible agglutination within 20 seconds	**Streptococcus latex test = Negative**



LIMITATIONS/PRECAUTIONS:

1. False negative or false positive results can occur if insufficient amounts of culture or extraction reagents are used.
2. The kit is intended for use in identification of beta-hemolytic *Streptococcus* only. If alpha or non-hemolytic *Streptococci* are tested, the identification should be confirmed with a Vitek 2 GP card.
3. False positive reactions have been known to occur with organisms from unrelated genera, e.g. *Escherichia coli*, *Klebiella* or *Pseudomonas*.
4. Some strains of Group D *Streptococcus* can cross-react with Group G latex. Confirm as Group D with a Vitek 2 GP card.
5. *Enterococcus* can be differentiated from Group D *Streptococcus* with a Vitek 2 GP card.
6. *Listeria monocytogenes* may cross-react with Group B and/or G latex. Perform the catalase test and Gram-stain to differentiate *Listeria* (catalase +, Gram-positive bacilli) from *Streptococcus*.
7. *Streptococcus* isolates from sterile sites that are positive with group A latex must have a PYR test performed. Do not report Group A *Streptococcus* that is PYR negative as *Streptococcus pyogenes*. Report as *Streptococcus* species and refer organism to DynaLIFE for further identification.
8. Some reagents contain a small amount of sodium azide. Sodium azide can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used if the reagents are flushed down the sink.
9. The extraction reagents contain a mildly caustic agent. In case of skin contact, immediately wash the area with soap and copious amounts of water. If the reagent comes into contact with an eye, flush with water for at least 15 minutes.

REFERENCES:

- PRO-LAB, PROLEX STAPH LATEX KIT package insert, 2015 06
- Clinical Microbiology Procedures Handbook, 4th edition, ASM Press, 2016

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	8 APR 19	Initial Release	L. Steven