



**Stanton Territorial Hospital**

P.O. Box 10, 550 Byrne Road  
YELLOWKNIFE NT X1A 2N1

Document Number: MIC52201

Version No: 1.0

Page: 1 of 6

Distribution:  
Microbiology Test Manual

Effective: 19 May, 2017

Date Reviewed: 19 May, 2017

Next Review: 19 May, 2019

**Document Name:**

Streptococcus Grouping, MedicoDx kit

**Approved By:**

Jennifer G. Daley Bernier, A/Manager, Laboratory Services

Status: **APPROVED**

**PURPOSE:**

The MedicoDx Streptococcal-Select Grouping Kit provides a rapid method for the serological identification of groups A, B, C, D, F and G of the Lancefield groups of *Streptococci*.

A chemical extraction of the group specific carbohydrate antigens is performed using nitrous acid extraction reagents. Once the antigens are extracted, a neutralizing solution is added. Blue latex particles sensitized with purified group specific rabbit immunoglobulins are then mixed into the neutralized extract. The latex particles agglutinate strongly in the presence of the specific antigen and will not agglutinate when the antigen is absent.

**SAMPLE INFORMATION:**

<b>Source</b>	1-4 beta hemolytic colonies
<b>Storage</b>	All reagents are stored at 2-8°C

**PLEASE NOTE:**

- **Streptococcus pyogenes (Group A) from invasive sites is a critical result and needs to be phoned to ordering location and copied to HPU1. Refer to NWT Reportable Diseases.**
- **Any Streptococcus agalactiae (Group B) infections from neonates need to be copied to HPU1. Refer to NWT Reportable Diseases**
- **Any Streptococcus pyogenes (Group A) and Streptococcus agalactiae (Group B) from invasive sites must be sent to NML for International Circumpolar Surveillance (ICS) program. Refer to MIC10520.**

**NOTE:** This is a controlled document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

<b>Document Name: Streptococcus Grouping, MedicoDx kit</b>	<b>Document Number: MIC52201</b>	
	<b>Version No: 1.0</b>	<b>Page: 2 of 6</b>
	<b>Effective: 19 May, 2019</b>	

### **REAGENTS and/or MEDIA:**

- MedicoDx Streptococcal-Select Grouping Kit

### **SUPPLIES:**

- Glass test tubes
- Disposable plastic pipette
- Disposable reaction cards
- Wooden application sticks

### **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 where 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.

### **QUALITY CONTROL:**

- Quality Control is performed monthly using Polyvalent control as positive control and sterile saline as negative control.
- A TQC order is generated in the TQC system on the first Monday of the month.
- Each test should be tested with at least one extra grouping latex suspension as a negative control.

**NOTE:** This is a controlled document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

**QUALITY CONTROL PROCEDURE INSTRUCTIONS:**


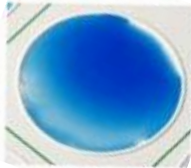
Step	Action
<b>Performing Streptococcal Grouping Quality Control</b>	
<b>1</b>	Add 2 drops of Extraction Reagent 1 to a test tube.
<b>2</b>	Add 1 drop of Polyvalent Positive Control to the tube. Mix by tapping for 5-10 seconds.
<b>3</b>	Add 2 drops of Extraction Reagent 2 to the tube. Mix by tapping for 5-10 seconds.
<b>4</b>	Add 2 drops of Extraction Reagent 3 to the tube. Mix by tapping for 5-10 seconds.
<b>5</b>	Using a pipette, place 1 drop of the mixture on separate circles of the test card for each latex reagent being control tested.
<b>6</b>	Dispense 1 drop of the appropriate blue latex suspension onto each circle.
<b>7</b>	Using a new stick for each circle, mix the latex and the extract over the complete area of the circle.
<b>8</b>	Gently rock the card, allowing the mixture to flow slowly over the entire test circle area.
<b>9</b>	At 1 minute, under normal lighting conditions, observe for agglutination.
<b>10</b>	Repeat steps 1-9, using saline in step #2 as a test of absence of auto agglutination.

**NOTE:** This is a controlled document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

**PROCEDURE INSTRUCTIONS:**

Step	Action
<b>Performing Streptococcal Grouping</b>	
1	Allow kit to come to room temperature before use.
2	Label one test tube for each specimen to be tested.
3	Add 2 drops of Extraction Reagent 1 to each tube.
4	Select 1-4 colonies using a wooden stick and suspend in the extraction reagent. If colonies are small, pick several colonies to be tested such that the Extraction Reagent 1 solution becomes turbid.
5	Add 2 drops of Extraction Reagent 2 to each tube. Mix by tapping for 5-10 seconds.
6	Add 2 drops of Extraction Reagent 3 to each tube. Mix by tapping for 5-10 seconds.
7	Dispense one drop of each blue latex suspension onto separate circles on the test card.
8	Using a pipette, place one drop of extract beside each drop of latex suspension.
9	Using a new stick for each circle, mix the latex and the extract over the complete area of the circle.
10	Gently rock the card, allowing the mixture to flow slowly over the entire test circle area
11	At 1 minute, under normal lighting conditions, observe for agglutination.

**INTERPRETATION OF RESULTS:**

IF	THEN
A significantly rapid, strong clumping of the latex particles to form an agglutination pattern with only one of the latex reagents indicates specific identification of the streptococcal isolate.	Positive for tested antigen 
No visible agglutination of the latex particles.	Negative for tested antigen 

**NOTE:** This is a controlled document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

Document Name: Streptococcus Grouping, MedicoDx kit	Document Number: MIC52201	
	Version No: 1.0	Page: 5 of 6
	Effective: 19 May, 2019	

### **PROCEDURE NOTES:**

- Do not use reagents after expiry date.
- Use safety precautions when handling, processing and discarding pathogenic organisms.
- Some reagents contain materials of animal origin and should be handled as potential carriers and transmitters of disease.
- A weak reaction with only one of the latex reagent should be repeated with a heavier inoculum.

### **LIMITATIONS:**

- False negative or false positive results can occur if insufficient amounts of culture or extraction reagents are used.
- 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.
- Some strains of Group D *Streptococcus* can cross-react with Group G latex. Confirm as Group D with a Vitek 2 GP card.
- *Enterococcus* can be differentiated from Group D *Streptococcus* with a Vitek 2 GP card.
- *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*.
- 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.

<b>NOTE:</b> This is a controlled document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.	
FILENAME: MIC52201StreptococcusGroupingMedicoDXKitPRO.doc	Print Date: 8/11/2017 3:21:00 PM

Document Name: Streptococcus Grouping, MedicoDx kit	Document Number: MIC52201	
	Version No: 1.0	Page: 6 of 6
	Effective: 19 May, 2019	

**REFERENCES:**

MedicoDx Streptococcal-Select Grouping Kit package insert, 2015 06

**REVISION HISTORY:**

REVISION	DATE	Description of Change	REQUESTED BY
1.0	19-May-2017	Initial Release	L. Steven
2.0	11-Aug-2017	Update limitations to reflect PYR testing and Group A streptococcus/Streptococcus pyogenes	L. Steven