

# GBS PNA FISH®



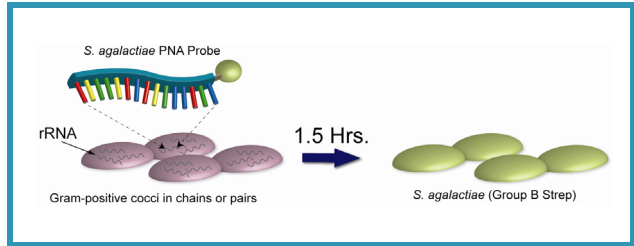
Rapid identification of *Streptococcus agalactiae* (aka Group B Strep – GBS) from turbid Lim broth

For in vitro diagnostic use.

## GBS PNA FISH (KT010)



## Technology Overview



## Description

GBS PNA FISH is a qualitative nucleic acid hybridization assay intended for identification of *Streptococcus agalactiae* from turbid growth in Lim broth obtained from vaginal and rectal swabs of pregnant women between 35 and 37 weeks gestation.

Conventional identification methods using Lim broth and culture methods can take 3 to 4 days and may miss some true positives due non-β-hemolytic strains and overgrowth of normal flora that can hide *S. agalactiae* colonies.

GBS PNA FISH combines the high sensitivity of Lim broth with the fast identification results and ease-of-use of PNA FISH molecular tests to provide accurate results 2 to 3 days earlier than conventional culture methods. The test ensures timely detection of Group B Strep colonization to help prevent as many infections in newborns as possible.

## Features and Benefits

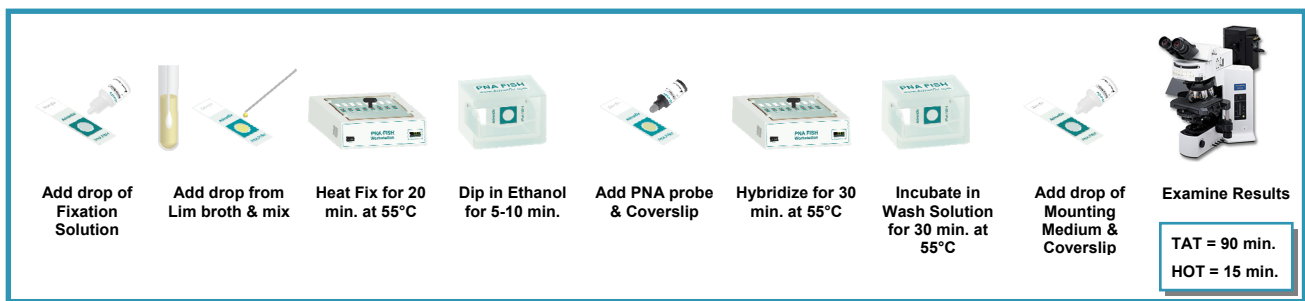
### Features

- Employs high sensitivity and selective growth of traditional Lim broth
- *S. agalactiae* (Group B Strep) identification by 16S rRNA detection using PNA molecular probes
- Results in just 90 min. from turbid Lim broth

### Benefits

- Identification of both β-hemolytic and non-β-hemolytic *S. agalactiae* as well as identification in samples containing growth of normal flora
- Shown to detect more positive Group B Strep results than conventional culture methods<sup>1</sup>
- Provides results 2 to 3 days earlier than conventional culture methods<sup>1</sup>

## GBS PNA FISH Protocol<sup>2</sup>



1. Montague et al. J Clin Microbiol. 2008 Oct;46(10):3470-2.

2. Please see package insert for complete instructions for use.

# GBS PNA FISH® – Clinical Trials Data<sup>3</sup>

The performance of GBS PNA FISH was evaluated against 5 different identification methods (Comparator) on 636 Lim broth cultures obtained from vaginal and rectal swabs at three clinical trial sites in the United States (FL, PA and OH)

## Summary

Study	Positive Agreement	Negative Agreement
A-1	98.0% (48/49) 95% CI (89.2-100)	86.8% (164/189) 95% CI (81.1-91.3)
A-2	98.4% (61/62) 95% CI (91.3-100)	93.2% (164/176) 95% CI (88.4-96.4)
B	89.2% (33/37) 95% CI (74.6-97.0)	98.1% (157/160) 95% CI (94.6-99.6)
C-1	98.4% (63/64) 95% CI (91.6-100)	100% (137/137) 95% CI (97.8-100)
C-2	100% (62/62) 95% CI (95.3-100)	99.3% (138/139) 95% CI (96.1-100)

## Study Site A1

SBA and Streptocard™ Enzyme Latex Test

	Comparator Method	
	Positive	Negative
GBS PNA FISH +	48	25
GBS PNA FISH -	1	164
<b>Agreement</b>	98.0% (48/49) 95% CI (89.2-100)	86.8% (164/189) 95% CI (81.1-91.3)

## Study Site A2

Group A Selective Streptococcus agar with 5% Sheep Blood to SBA and BBL™ Streptocard™ Acid Latex Test

	Comparator Method	
	Positive	Negative
GBS PNA FISH +	61	12
GBS PNA FISH -	1	164
<b>Agreement</b>	98.4% (61/62) 95% CI (91.3-100)	93.2% (164/176) 95% CI (88.4-96.4)

## Study Site B

SBA to PathoDx® Strep Grouping Assay

	Comparator Method	
	Positive	Negative
GBS PNA FISH +	33	3
GBS PNA FISH -	4	157
<b>Agreement</b>	89.2% (33/37) 95% CI (74.6-97.0)	98.1% (157/160) 95% CI (94.6-99.6)

## Study Site C1

SmartCycler® Smart GBS® Assay

	Comparator Method	
	Positive	Negative
GBS PNA FISH +	63	0
GBS PNA FISH -	1	137
<b>Agreement</b>	98.4% (63/64) 95% CI (91.6-100)	100% (137/137) 95% CI (97.8-100)

## Study Site C2

SBA to Remel® Streptex Test

	Comparator Method	
	Positive	Negative
GBS PNA FISH +	62	1
GBS PNA FISH -	0	138
<b>Agreement</b>	100% (62/62) 95% CI (95.3-100)	99.3% (138/139) 95% CI (96.1-100)

3. Sites A and C each performed two different comparator methods.