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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	***Direct*igen® Meningitis Combo Test** ***Direct*igen® *Neisseria meningitidis* Test**
Common Name/Description:	Latex agglutination antigen detection kit
Classification Name:	Antisera, All groups; N.meningitidis
PREDICATE DEVICE:	Phadebact® *S.pneumoniae* and *H.influenzae* co-agglutination tests; Phadebact® Streptococcus Test (A,B,C,G) and Strep A Test, Strep B Test, Strep D Test, and Strep F Test; Bacto Antisera for *N.meningitidis* groups A,B,C,D,X,Y,Z,Z', and W135.

DEVICE DESCRIPTION:

INTENDED USE: The ***Direct*igen®** Meningitis Test Kits are a presumptive latex agglutination test for the direct qualitative detection of antigens to *H. influenzae* type b, *S. pneumoniae,* group B *Streptococcus, N. meningitidis* groups A, B, C, Y or W135 and *E. coli* K1 in cerebrospinal fluid (CSF), serum, urine, or blood culture media. Visible agglutination occurs when a sample containing any of these bacterial antigens is reacted with its respective antibody-coated latex beads. This 510(k) was submitted to add colony confirmation and serotyping claims to the Intended Use Statement.

KIT DESCRIPTION: Specific antibodies are bound to the surface of latex beads. In the presence of specific antigens, latex particle aggregation becomes large enough to allow visualization of positive agglutination These specific soluble polysaccharide antigens accumulate in CSF, serum, urine or blood as a result of infection by *H. influenzae* type b, *S. pneumoniae,* group B *Streptococcus, N. meningitidis* groups A, B, C, Y or W135 and *E. coli* K1.

PERFORMANCE DATA:

Clinical Correlation: Two external studies were conducted to enable the addition of a claim for the ***Direct*igen®** Meningitis Test Kits by providing colony confirmation and serogrouping capabilities from suspected colony growth for *S.pneumoniae, H. influenzae* type b, group B *Streptococcus, N. meningitidis* groups A, B, C, Y, or W135.

Conclusion: The ***Direct*igen®** Meningitis Test Kits demonstrated acceptable performance for all latex reagents for serologic identification of each respective pathogen from culture plates.

Suspected Organism	# Tested	Relative Sensitivity (95% Confidence Interval)	Relative Specificity (95% Confidence Interval)	% Uninterpretable Initial Testing
H. influenzae type b	112	100% (92-100)	98.5% (92-100)[2]	3.6%
S. pneumoniae	124	93% (84-98)	79% (66-88)[1]	0%
Group B *Streptococcus*	129	100% (95-100)	90.5% (80-96)[1]	0%
Neisseria meningitidis Group A/Y	106	100% (83-100)	100% (96-100)[2]	10.4%
Neisseria meningitidis Group C/W135	94	96% (82-100)	98.5% (92-100)[2]	11.7%
Neisseria meningitidis Group B	106	85% (55-98)	100% (96-100)[2]	4.7%

1- Refer to Limitations of the Procedure
2 - Results after repeat testing with 1:10 dilution

Based on the clinical trial data, a footnote has been added to the data summary table referring the user to the Limitations of the Procedure regarding the possibility of cross-reactivity with some strains of *S. viridans* group with the *S. pneumoniae* latex reagent. Additional tests may be needed to differentiate *S. viridans* from *S. pneumoniae*. In addition, certain bacterial isolates obtained from blood culture plates which are morphologically similar to, but gram stain inconsistent with the suspect colony, may exhibit non-specific agglutination and/or false positive reactions (ie. beta-hemolytic nonpathogenic Neisseria species with the Group B Strep latex). Therefore, a gram stain result should be performed prior to use with the colony confirmation procedure.