CLAIMS

A composition for determining the presence or absence of Group B Streptococcus (GBS) in a sample, said composition comprising:

an amplification oligomer combination comprising first and second *CFB*-specific amplification oligomers capable of amplifying a target region of a GBS *CFB* target nucleic acid, wherein the first and second *CFB*-specific amplification oligomers comprise, respectively, first (A) and second (B) *CFB*-specific target-hybridizing sequences

(A) SEQ ID NO:16, or an RNA equivalent or DNA/RNA chimeric thereof, and

(B) SEQ ID NO:17, or an RNA equivalent or DNA/RNA chimeric thereof.

2. The composition of claim 1, wherein said composition further comprises a *CFB*-specific detection probe oligomer comprising a *CFB*-specific detection probe target-hybridizing sequence that is from about 5 to about 35 nucleotides in length and is configured to hybridize to a target sequence contained within a *CFB* amplicon amplifiable by the first and second *CFB*-specific amplification oligomers,

wherein the *CFB*-specific detection probe oligomer further comprises a detectable label wherein the detectable label is a fluorescent or chemiluminescent label, or wherein the detectable label is a fluorescent label and the *CFB*-specific detection probe oligomer further comprises a non-fluorescent quencher.

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3. The composition of claim 2, wherein the *CFB*-specific detection probe target-hybridizing sequence is SEQ ID NO:24, or an RNA equivalent or DNA/RNA chimeric thereof.

~~(A) SEQ ID NO:16, or an RNA equivalent or DNA/RNA chimeric thereof, and~~

(B) SEQ ID NO:17, or an RNA equivalent or ~~DNA/~~RNA chimeric thereof.

~~wherein the detection probe~~ oligomer further comprises a detectable label, ~~wherein the detectable label is a fluorescent or chemiluminescent label.~~

4 A kit for determining the presence or absence of Group B Streptococcus (GBS) in a sample, said kit comprising the amplification oligomer combination of claim and the detection probe oligomer of claim 2 or 3.

5. A method for determining the presence or absence of Group B Streptococcus (GBS) in a sample, said method comprising:

(1) contacting a sample suspected of containing GBS with the composition of any one of claims 1-3 or the kit of claim 4,

(2) performing an *in vitro* nucleic acid amplification reaction, wherein any GBS *CFB* target nucleic acid, if present in the sample, is used as a template for generating an amplicon corresponding to the *CFB* target region; and

(3) detecting the presence or absence of the amplicon, thereby determining the presence or absence of GBS in the sample.

6. The method of claim 5, wherein the detecting step comprises contacting the *in vitro* nucleic acid amplification reaction with a *CFB*-specific detection probe oligomer comprising a *CFB*-specific detection probe target-hybridizing sequence that is from about 15 to about 35 nucleotides in length and is configured to hybridize to a target sequence contained within a *CFB* amplicon amplifiable by the first and second *CFB*-specific amplification oligomers

wherein the *CFB*-specific detection probe oligomer further comprises a detectable label, wherein the detectable label is a fluorescent or chemiluminescent label, or wherein the detectable label is a fluorescent label and the *CFB*-specific detection probe oligomer further comprises a non-fluorescent quencher.

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7. The method of claim 6, wherein the *CFB*-specific detection probe target-hybridizing sequence is SEQ ID NO:24, or an RNA equivalent or DNA/RNA chimeric thereof.

8. The method of any one of claims 5-7, wherein the detecting step is performed in real time.

9. The method of any one of claims 5-8, wherein the *in vitro* nucleic acid amplification reaction is a PCR amplification reaction.

10. An aqueous formulation for the amplification of Group B Streptococcus (GBS) nucleic acid, wherein the aqueous formulation comprises:

a composition as in any one of claims 1-3, and

an organic buffer,

11. The aqueous formulation of claim 10, wherein the aqueous formulation further comprising a DNA polymerase enzyme, and/or a reverse transcriptase enzyme, and/or a and/or a bulking agent selected from the group consisting of trehalose, raffinose, and a combination thereof.

12. The aqueous formulation of claim 10 or 11, wherein the formulation contains inorganic salt at a concentration of 4 mM or less.

13. The aqueous formulation of any one of claims 10-12, wherein the aqueous formulation further comprises a surfactant, a non-linear surfactant, a polyethylene glycol mono [4-(1,1,3,3-tetramethylbutyl) phenyl] ether, a polysorbate 20, or a combination thereof.

14. A dried formulation for the amplification of Group B Streptococcus (GBS) nucleic acid, wherein the dried formulation is a lyophilized formulation of the aqueous formulation of any one of claims 10-13.

15. A combination for the detection of Group B Streptococcus (GBS) nucleic acid comprising:

an aqueous formulation comprising the amplification oligomer combination of claim 1 and an organic buffer;

an aqueous formulation comprising the detection probe oligomer of claim 2 or 3 and an organic buffer.

16. The combination of claim 15, wherein the aqueous formulation comprising the amplification oligomer combination of claim 1 and/or the aqueous formulation comprising the detection probe oligomer of claim 2 or 3 further comprises one of more of:

(a) a surfactant, a non-linear surfactant, a polyethylene glycol mono [4-(1,1,3,3-tetramethylbutyl) phenyl] ether, a polysorbate 20, and a combination thereof;

(b) a DNA polymerase enzyme;

(c) a reverse transcriptase enzyme; and

(d) a bulking agent selected from the group consisting of trehalose, raffinose, and a combination thereof.

17. The combination of claim 15 or 16, wherein the aqueous formulation comprising the amplification oligomer combination of claim 1 and/or the aqueous formulation comprising the detection probe oligomer of claim 2 or 3 contains inorganic salt at a concentration of 4 mM or less.

18. A combination for the detection of Group B Streptococcus (GBS) nucleic acid, wherein the combination comprises dried formulations consisting of lyophilized formulations of the aqueous formulations of any one of claims 15-17.

19. A reaction mixture for the amplification and/or detection of Group B Streptococcus (GBS) nucleic acid, wherein the reaction mixture is formed by reconstitution of the dried formulation according to claim 14 with water or an organic buffer.

20. The reaction mixture of claim 19, wherein the reaction mixture contains an inorganic salt, preferably an inorganic salt selected from the group consisting of magnesium, potassium, and sodium, wherein the concentration of the inorganic salt is 4 mM or less.

21. A combination of reaction mixtures for the detection of Group B Streptococcus (GBS) nucleic acid, wherein the reaction mixtures are formed by reconstitution of the dried formulations according to claim 18 with water or an organic buffer.

22. The combination of reaction mixtures of claim 21, wherein at least one of the reaction mixtures contain an inorganic salt, preferably an inorganic salt selected from the group consisting of magnesium, potassium, and sodium, wherein the concentration of the inorganic salt is 4 mM or less.

23. The composition of any one of claims 1-3, or the kit of claim 4, further comprising an amplification oligomer combination capable of amplifying a target region of a GBS *SIP* target nucleic acid selected from the group consisting of

(a) SEQ ID NO:3, or an RNA equivalent or DNA/RNA chimeric thereof, and SEQ ID NO:4, or an RNA equivalent or DNA/RNA chimeric thereof; or

(b) SEQ ID NO:7, or an RNA equivalent or DNA/RNA chimeric thereof, and SEQ ID NO:8, or an RNA equivalent or DNA/RNA chimeric thereof.

24. The composition or kit of claim 23, wherein the composition or kit further contains a *SIP*-specific detection probe target-hybridizing sequence comprising SEQ ID NO:9 or 11, or an RNA equivalent or DNA/RNA chimeric thereof.