

Aptima General Purpose Reagents (GPR) 250 Kit

For Laboratory Use.

Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Catalog Number: 2081	250 reactions
GPR Refrigerated box (2° to 8°C):	
Aptima Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 x 4.4 mL lyophilized
Aptima Oligoless Amplification Reagent <i>Nucleotides dried in buffered solution containing < 5% bulking agent.</i>	1 x 10.2 mL lyophilized
GPR Non-refrigerated box (15° to 30°C):	
Aptima Amplification Reconstitution Solution <i>Aqueous solution containing preservatives.</i>	1 x 27.7 mL
Aptima Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 11.1 mL
Aptima Hybridization Buffer <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 35.4 mL
Aptima Selection Reagent <i>600 mM borate buffered solution containing surfactant.</i>	1 x 108 mL
Aptima Target Capture Reagent <i>Buffered salt solution containing solid phase (<0.5 mg/ml) poly-deoxythymidine oligomers.</i>	1 x 54 mL
Reconstitution Collars	3 each

Product Description

The Aptima General Purpose Reagents (GPRs) feature Transcription-Mediated Amplification (TMA®) and Hybridization Protection Assay (HPA) technologies. Aptima GPRs may be used to facilitate the development of tests by CLIA-certified high complexity laboratories or research laboratories for the qualitative detection of nucleic acid-based analytes.

Principles of the Technology

The Aptima family of assays is designed to follow a standard protocol that combines the technologies of target capture, TMA, and HPA.

Target Capture

Target nucleic acid molecules are isolated by the use of capture oligomers (which are added by the customer to the Target Capture Reagent) and magnetic microparticles in a method called target capture. The capture oligomers contain sequences complementary to specific regions of the target molecules as well as a string of deoxyadenosine residues. The sequence specific region of the capture oligomer binds to a specific region of the target molecule. The capture oligomer:target complex is then captured out of solution via hybridization between the deoxyadenosine region on the capture oligomer and the poly-deoxythymidine molecules that are covalently attached to the magnetic particles. The microparticles, including the captured target molecules bound to them, are pulled to the side of the reaction vessel using magnets and the supernatant is aspirated. The particles are washed to remove residual specimen matrix that may contain amplification reaction inhibitors. After the target capture steps are completed, the specimens are ready for amplification.

TMA and HPA

The Hologic TMA reaction replicates a specific region of a nucleic acid target using specific primer sets complementary to the target molecule. Detection of the RNA amplification product (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes, which are complementary to a region of the target amplicon, are labeled with an acridinium ester molecule. The labeled DNA probe combines with amplicon to form a stable RNA:DNA hybrid. HPA allows for the differentiation of hybridized probe from unhybridized probe such that signal from unhybridized probe is eliminated. During the detection step, light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer and are reported as Relative Light Units (RLU).

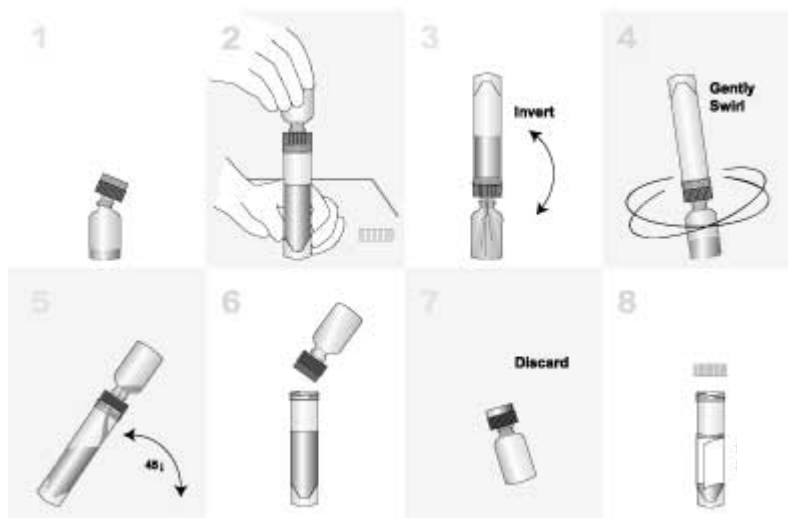
Storage and Handling Requirements

- A. Prior to addition of probe oligonucleotides, visually inspect the Aptima Hybridization Buffer. If the Aptima Hybridization Buffer contains precipitate that does not return to solution at room temperature, heat at 62°C for 1 to 2 minutes. After this heat step, the Aptima Hybridization Buffer may be used even if residual precipitate remains. After resuspension, mix the vial by gentle inversion.
- B. The Aptima Hybridization Buffer with oligonucleotides added is photosensitive. Store the solution protected from light.
- C. The Target Capture Reagent is stable when stored at room temperature (15° to 30°C). Do not store at temperatures below 15°C.
- D. DO NOT FREEZE THE REAGENTS.



Reagent Reconstitution/Preparation

1. To reconstitute the Aptima General Purpose Enzyme and Amplification Reagents:
 - a. Pair the appropriate reconstitution solution with the dried reagent.
 - b. Open the dried reagent and firmly insert the notched end of the reconstitution collar into the glass vial (figure 1).
 - c. Open the reconstitution solution (save the cap) and, while holding the solution bottle on the bench, firmly insert the other end of the reconstitution collar into the bottle (figure 2).
 - d. Invert the assembly, allow the solution to drain into the glass container (figure 3), and then swirl gently (figure 4). Invert the assembly and tilt at a 45° angle (figure 5). Allow all of the liquid to drain back into the plastic bottle.
 - e. Remove the reconstitution collar and the glass vial (figure 6).
 - f. Discard both the reconstitution collar and glass vial (figure 7).
 - g. Re-cap the plastic bottle. Record required information on the label of the remaining bottle (figure 8).
2. If using previously reconstituted Amplification and Enzyme Reagents, allow them to reach room temperature (15° to 30°C) prior to the start of the assay.

**Warnings And Precautions**

- A. Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas. Wear disposable, powderless gloves and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.
- B. A separate area for HPA is strongly recommended to minimize amplicon contamination in the assay. This dedicated area should be away from the reagent preparation, target capture, and amplification area.
- C. To help prevent lab areas from becoming contaminated with amplicon, the laboratory area should be arranged with a unidirectional workflow: from reagent preparation through HPA. Specimens, equipment, and reagents should not be returned to the area where a previous step was performed. Also, personnel should not move back into previous work areas without proper contamination safeguards.
- D. Tips with hydrophobic plugs must be used. A minimum of two repeat pipettors must be dedicated for use with this assay: one for use in the Target Capture and Amplification steps, and one for use in the HPA steps. Two micropipettors must be dedicated for use in this assay: one for use in specimen transfer and one for use in reagent preparation.
- E. When using repeat pipettors for reagent addition, do not touch the tube with the pipettor tip to prevent carryover from one tube to another.
- F. Separate water baths must be dedicated for the target capture, amplification, and HPA steps in the assay.

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