

A Novel Specimen Collection Solution for Molecular Diagnostic Applications

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Abstract

Background: There is a major need for reliable, robust, and standardized sample collection reagents that specifically protect specimen nucleic acids. Currently, the majority of clinical diagnostic laboratories utilize traditional culture methods for pathogen detection requiring live specimen collection and preservation, cold-chain maintenance, and propagation for culture confirmation. However, many contemporary clinical diagnostic laboratories are transitioning away from traditional culture towards more rapid and sensitive nucleic acid based detection strategies, e.g., real-time PCR, gene chips, and microarray analysis. Preservation of high quality nucleic acids is critical for all of these assays. **Objective:** A novel sample collection reagent, referred to as PrimeStore Solution (PSS) was developed and optimized for: 1) procuring high quality nucleic acids from clinical or environmental specimens, 2) inactivation of potentially infectious biological pathogens for safe handling and transport of specimens, and 3) stabilization and preservation of released 'naked' RNA/DNA preventing hydrolysis/nuclease degradation for prolonged periods at ambient temperatures. **Methods:** Real-time RT-PCR was used to assay influenza A (H5N1) virus nucleic acid preserved in PSS. A time-course study at room temperature was carried out to evaluate the integrity of clinical specimens, cloacal samples, and cloned template avian influenza A virus (H5) RNA stored and extracted from PSS, Viral Transport Media, RNA Storage Solution, or nuclease-free water. PSS extraction efficiency was compared to three commercially available nucleic acid extraction kits. Furthermore, the ability of RNA contained in PSS to resist nuclease degradation was evaluated. **Results:** PSS inactivated microbial agents while preserving released RNA/DNA from clinical material, i.e., nasal washes, throat swabs, or environmental samples. Clinical specimens or environmental samples placed in this solution were stabilized at room temperature for up to 30 days while degradation of nucleic acids occurred in other transport media. PSS is compatible with commercially available RNA isolation kits and produced an increased nucleic acid yield. **Discussion:** PSS is a unique blend of reagents that lyses biological membranes instantaneously, promoting stabilization, and preservation of RNA/DNA from clinical/environmental samples for up to 30 days at room temperature. This solution is suited specifically for point of care, field studies, triage centers, or outbreak locations, and may be of considerable value during a pandemic influenza outbreak.