BACKGROUND

There has long been an attraction to oral fluid as a specimen for the detection of various analytes because of the inexpensive, safe, and non-invasive methods for sample collection as compared to blood testing. Elion et al. confirmed the presence of immunoglobulin in saliva in 1960. Two studies in the late ’70s reported the use of oral fluid collected with swabs for hepatitis B surface antigen and feline leukemia virus12. Throughout the next 30 years, increasing numbers of oral fluid testing studies were published.

Today, the testing of oral fluid for antibodies, antigens, and other analytes is a well-established and accepted form of clinical care, monitoring, and research throughout the world as evidenced by the numerous applications approved by US FDA, including those for HIV diagnosis, as well as a wide variety of publications in the scientific literature. These published studies support the efficacy of oral fluid testing in a number of diverse applications including detection of antibody to (1) infectious bacterial diseases (such as shigellosis5), (2) viral infections (e.g., hepatitis A14, hepatitis B, HIV10, Epstein-Barr virus14, and rubella16), Lyme disease17, and HIV15). These studies emphasized the advantages of oral fluid testing in comparison to blood testing including ease of collection and transport, lower costs, and lower likelihood of detecting false positive or false negative results.

Saliva consists of a complex mixture of parotid, submandibular, and sublingual and minor salivary gland secretions mixed with mucin, bacteria, leukocytes, sloughed epithelial cells, and gingival crevicular fluid. Gingival crevicular fluid and oral mucosal transudate (OMT), the fluid derived from the passive transport of serum components through the oral mucosa into the mouth. The concentrations of Immunoglobulin G (IgG) and other serum components in this fluid are significantly higher than in whole saliva. Consequently, collection of oral fluid from this area of the mouth was identified as the most promising source of fluid for diagnostic testing.

The Aware Messenger™ device utilizes a clean untreated swab made of a soft absorbent material that targets those OMT-rich areas in the mouth when used as instructed. After a brief brushing along the gum lines, the oral fluid on the swab is briefly mixed with the detergents and preservative, and the swab is placed back in the Specimen Collection Tube where the fluid is stored until ready for transport.

PROEDURE

1. Remove the cap from the tube (Figure 1).
2. Remove the clean Collection Swab from the pouch. Grasp the swab by the handle. Avoid touching the cloth end of the swab (Figure 2).
3. Insert the swab into the back corner of the upper gum line in the mouth. Apply moderate pressure to slowly and gently brush the entire upper gum line up and down with the cloth end of the swab until reaching the other corner of the mouth (about 10 seconds) (Figure 3).
4. Swab back across the upper gum line to where you started (about 10 seconds) (Figure 4).
5. Turn the swab to use the other side of the swab for the lower gums (Figure 5).
6. Repeat procedure, gently brushing the lower gum line (Figures 6 and 7).
7. Immediately and carefully place the swab in the Specimen Collection Tube (Figure 8).
8. Grasp the handle firmly and slowly plunge the swab up the double 6-8 times in the tube, rubbing both sides of the swab against the sides of the tube (Figures 9 and 10).
9. Wring out fluid as the swab is being removed from the tube and discard swab (Figures 10 and 11).
10. Cap the tube (Figure 12). The specimen is ready for testing at a later time.

WARNINGS AND PRECAUTIONS

1. Use freshly prepared 10% bleach to decontaminate surfaces in the event of a spill of collected specimen.
2. Do not use the Collection Swab if the package has been opened.
3. Do not touch the Collection Swab pad with fingers before or after specimen collection.
4. Do not reuse the Collection Swab or sample buffer.
5. Do not use device beyond the expiration date shown on the device package.