BACKGROUND
There has 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. Ellison et al. confirmed the presence of immunoglobulin in saliva in 1960. In two studies the late 70's reported the use of oral fluid collected with swabs for hepatitis B surface antigen and feline leukemia virus (FeLV) over 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 referenced, the impressive applications approved by 16 FDA, including those for HIV, as well as a wide variety of publications in the scientific literature. These published studies support the efficacy of oral fluid testing in a manner similar to blood testing (i.e., detection of antibody to H1 influenza and other bacterial diseases (such as syphilis diabetes, Haemophilus influenzae and Bordetella pertussis), HIV, hepatitis A, B, C (HAV, HBV, HCV), Epstein-Barr virus, HCV infection, and rubella). Theme et al. expanded upon these studies to conclude that simultaneous detection of seroconversion occurs in serum and oral fluid samples for diseases such as rubella, HIV, and after vaccination to measles, mumps, and rubella. Other studies demonstrated the applicability of oral fluid for the detection of viral antigen (HIV), drugs of abuse, and for the therapeutic monitoring of drugs.

Saliva is a complex mixture of protein, submandibular and sublingual and minor salivary gland secretions, leucocytes, fibrinogen, fibronectin, plasma, platelets, red cells, and gingival crevicular fluid. Gingival crevicular fluid, or oral mucosal transudate (OMT), is 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 untrained swab made of a soft absorbent material that targets those HIV-1 rich areas in the mouth when used as instructed. After a brief brushing of the gum line, the oral fluid on the swab is briefly mixed with the proprietary Aware Messenger® sample buffer containing preservatives, stabilizing agents, immunospecific-friendy detergents, and other components. Finally, the sample is discarded. The sample is ready for testing at a later time.

The Aware Messenger™ device, used in conjunction with traditional immunassays (e.g. ELSA), adds the advantages of an oral fluid specimen, as ease of collection and transport, to the benefits offered by conventional laboratory-based testing such as high throughput, correct processing, automation, quantitative results, and lower costs.

Although the Aware Messenger™ sample buffer has been formulated for compatibility with immunassays, specific test protocols for any given assay must be optimized and the performance of the Aware Messenger™ specimen should be validated for each individual application by the laboratory conducting the testing. In stability studies conducted by Calypte, specific antibody was shown to be preserved for at least 3 weeks at up to 37°C. However, it is recommended that the stability of the specific antibody or analyte in question be asessed by a validated method.

BIBLIOGRAPHY


The Aware Messenger™ collection device is intended for the collection, stabilization, and transport of an oral fluid specimen to be used for the detection of specific antibodies or antigens. Applications for specific diagnostic use may be used only with an appropriately validated assay in compliance with local regulations.

MATERIALS PROVIDED
Each individually packaged Aware Messenger™ collection device includes one of the following:
- Clean Collection Swab
- Specimen Collection Tube with Sample Buffer containing protein stabilizers, salts, detergents, and preservatives.

WARNINGS AND PRECAUTIONS (continued)
- Use facility prepared 10% bleach to decontaminate surfaces in the event of a spill of collected specimen.
- Avoid contamination of Collection Swab and sample buffer with foreign matter.
- Do not use the Collection Swab if the package has been opened.
- Do not touch the Collection Swab pad with fingers before or after specimen collection.
- Do not re-use the Collection Swab or sample buffer.
- Do not use device beyond the expiration date shown on the device package.

PROTOCOL
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 gum line up and down with the cloth end of the swab until reaching the other corner of the mouth (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 for the lower gums (for Figures 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 swab handle firmly and slowly plunge the swab up the down 6-8 times (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).
11. The sample is now ready for testing or transport.

Manufactured in the USA by:
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