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Asanté™ Oral Ab

For the Collection, Preservation and Transport of an Oral Specimen Containing Antibody or Other Proteins

Cat. No. 1830

NAME AND INTENDED USE

The Asanté Oral Ab Specimen Collection Kit is intended for the collection, preservation and transport of an oral specimen containing antibody or other proteins. Although the Kit is designed to collect an oral specimen and preserve antibodies (especially IgG) and other proteins in particular, it may be useful for other biomarkers as well. Applications for specific diagnostic use should be used only with an appropriately validated assay in compliance with local regulations.

BACKGROUND

Concentrations of IgG and other antibodies of serum origin are present in the oral fluid collected by the Asanté Oral Ab Specimen Collection Kit at levels greater than ordinary saliva because it preferentially collects oral mucosal transudate (OMT) and gingival crevicular fluid, along with some saliva. Gingival fluid and OMT contain serum components passively transported through the oral mucosa into the mouth and thus have higher serum protein levels than whole saliva (1).

Oral fluid specimens are safe, low-cost, non-invasive clinical samples that do not require highly skilled technicians for collection. Historically, oral fluid specimens have been used to detect antibodies against a wide variety of disease states including Hepatitis A, B and C, Shigella, Haemophilus influenzae type B, Feline Leukemia Virus, pertussis toxin, HIV, Epstein Barr virus, and rubella (2-12). Oral fluid specimens have also been used to detect cardiovascular disease markers, determine immunization status, screen for drugs of abuse and monitor therapeutic drugs (13-17).

The Asanté Oral Ab Specimen Collection Kit uses a clean, untreated, inert swab and has been designed for optimal compatibility with traditional enzyme and other immunoassays. However specific test protocols for each assay must be optimized and validated when used with the Asanté Oral Ab Specimen Collection Kit for each application by the laboratory performing the test.

MATERIALS PROVIDED

Each individually packaged Asanté Oral Ab Specimen Collection Kit includes one each of the following:

- Oral Collection Swab
- Capped Specimen Tube with Sample Buffer containing stabilizing agents and a preservative.

Kits are provided in packages of 10 (Cat. No. 1830-010), 50 (Cat. No. 1830-050) and 250 (Cat. No. 1830-250).

WARNINGS AND PRECAUTIONS

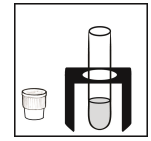
1. The performance characteristics of the Asanté Oral Ab Specimen Collection Kit have not been established for all applications. It is recommended that studies specific to the intended application be conducted by the user and properly validated.
2. Assays for specific diagnostic use should be used only with approved assays or appropriately validated methods in compliance with local regulations.
3. Storage conditons of collected specimens depend upon their application. Specimen stability studies have demonstrated the recovery of specific reactive antibody after three weeks of storage at up to 37˚C. However the storage of a specific antibody, protein or other biomarker must be validated prior to use.
4. Oral fluid specimens present, in most cases, lower risk of exposure to blood-borne pathogens. However, all human tissue and body fluid specimens, and materials they come in contact with, should be handled as if potentially infectious, in accordance with "Universal Precautions"[18]. In the U.S., Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910) apply to personnel collecting and handling human clinical specimens. Follow any other local regulations for biohazardous agents.
5. Federal, state and local regulations for human biological test specimens apply to the mailing, transportation or shipment of oral specimens which may contain infectious agents.
6. Do not touch the Oral Collection Swab pad with fingers before or after specimen collection.
7. Do not reuse the Oral Collection Swab, Specimen Tube or Sample Buffer.
8. Do not use the Asanté Oral Ab Specimen Collection Kit if the package has been opened or the Swab head has touched any foreign surface.

STORAGE AND EXPIRATION

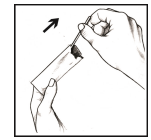
1. Store the Kit at temperatures in the range of 2˚ to 30˚C .
2. Do not use the Kit beyond the expiration date shown on the package.
3. Storage of collected specimens is recommended at or below 30˚C. Frozen storage should be evaluated on a biomarker by biomarker basis. Many antibodies and protein biomarkers lose activity or structural integrity when subjected to freeze-thaw transitions.

SPECIMEN COLLECTION PROCEDURE

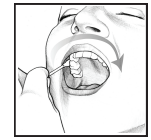
1. Open the Kit packaging and remove the contents. Remove the cap from the Specimen Tube and place the Tube in a suitable holder or rack.



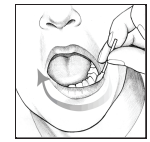
2. Remove the Swab from the packaging holding only the Swab handle. Do not touch the pad.



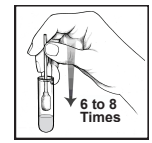
3. Insert the Oral Collection Swab into the mouth. Applying moderate pressure, slowly and gently brush the entire upper gum surface up and down with the Swab pad from one side of the mouth to the other. Brush back across the upper gums to return where you started.



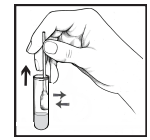
4. Turn the Swab over to use the other side of the pad, and repeat the procedure on the lower gums.



5. Carefully place the Oral Collection Swab in the open Specimen Tube. The Swab head will need to be slightly bent lengthwise to fit. Slowly plunge the Oral Collection Swab up and down 6-8 times in the Sample Buffer in the Specimen Tube.



6. Wring out fluid from the Oral Collection Swab by twisting the Swab pad against the side of the tube as it is being removed. Discard the Swab.



7. Cap the Specimen Tube and record the collection information on the label. Invert the tube 3-5 times or, preferentially, vortex to mix. The oral specimen is now ready for preservation, transport or testing.