

typically collects and releases in excess of 50,000 copies of DNA per mL. DNA has been correctly amplified from unpurified samples as confirmed by sequencing, although users may wish to use a purification protocol to maximize the concentration of DNA in the specimen. For users who do not have an established method for purification of DNA from the specimen, the Asanté DNA Purification Kit (Cat. No. 1802) is available from Sedia Biosciences. Alternatively, the method of Boom et al (2) is recommended.

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#### Note:

1. The preservation buffer contains 10 mM EDTA, which must be removed or saturated (e.g. by the addition of  $Mg^{+2}$  salts) before PCR.
2. The DNA preservation solution is NOT suitable for preservation of RNA.

#### REFERENCES

1. Centers for Disease Control and Prevention. Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. MMWR, June 24, 1988/37(24):377-388.
2. Boom R, Sol CJA, Salimans MMM, Jansen CL, Wertheim-vanDillen PME, vander Noordaa J. Rapid and simple method for purification of nucleic acids. J Clin Microbiol 1990; 28(3):495-503.

FDA Registration Listing D129152

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# Asanté™ DNA

## For the Collection, Preservation and Transport of a DNA Specimen

Cat. No. 1800

#### **NAME AND INTENDED USE**

The Asanté DNA Specimen Collection Kit is intended for the collection, preservation and transport of a DNA specimen. The Kit is designed especially to collect and preserve an oral specimen, but may be used for collecting specimens from other mucous membranes, epithelial cell surfaces and tissues. DNA specimens collected by this Kit are suitable for testing by most in vitro DNA amplification methods including polymerase chain reaction (PCR) and modifications, pretreatments and extensions thereof, helicase-dependent amplification (HDA), ligase chain reaction (LCR), loop-mediated isothermal amplification (LAMP) and others. Applications for specific diagnostic use should be used only with an appropriately validated assay in compliance with local regulations.

#### **MATERIALS PROVIDED**

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

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

The Asanté DNA Specimen Collection Kit is available in 3 package sizes:

Cat. No. 1800-010 10 Kits

Cat. No. 1800-050 50 Kits

Cat. No. 1800-250 250 Kits

An Asanté DNA Purification Kit (Cat. No. 1802) is available separately in matching sizes for use in extracting and purifying DNA from the Asanté DNA Specimen Collection Kit.

#### **WARNINGS AND PRECAUTIONS**

1. The performance characteristics of the Asanté DNA Specimen Collection Kit have not been established for all applications. It is recommended that studies specific for 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.

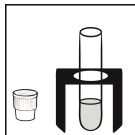
- Storage conditons of collected specimens depend upon application. Specimen stability studies have demonstrated the recovery of DNA with high integrity after several weeks of storage at ambient temperature. Less than 10% degradation of human DNA was observed in oral fluid specimens when stored in the Asanté DNA Sample Buffer for one month at temperatures of up to 37°C. Lower temperature storage is always preferable.
- 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" (1). 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.
- Federal, state and local regulations for human biological test specimens apply to the mailing, transportation or shipment of human specimens which may contain infectious agents.
- Do not touch the DNA Collection Swab pad with fingers before or after specimen collection.
- Do not reuse the DNA Collection Swab, Specimen Tube or Sample Buffer.
- Do not use the DNA Collection Kit if the package has been opened or the Swab head has touched any foreign surface.
- The Asanté DNA Specimen Collection Kit is not intended for the collection and preservation of RNA.

### STORAGE AND EXPIRATION

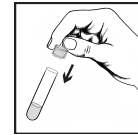
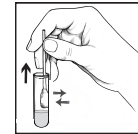
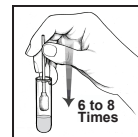
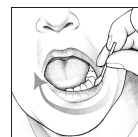
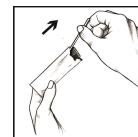
- Store the Kit at temperatures in the range of 2° to 30°C .
- Do not use the Kit beyond the expiration date shown on the package.
- In general, storage of collected specimens is recommended at or below 30°C. Long term storage is recommended at -20°C or below. Storage above this range may reduce the amount of DNA recovered from the specimen. Storage conditions for specific specimens should be validated relative to their intended use.

### PROCEDURE FOR ORAL SAMPLES

- 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.



- Remove the Swab from the packaging holding only the Swab handle. Do not touch the pad.
- Insert the DNA 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.
- Turn the Swab over to use the other side of the pad, and repeat the procedure on the lower gums.
- Carefully place the DNA Collection Swab in the open Specimen Tube. Slowly plunge the DNA Collection Swab up and down 6-8 times in the Sample Buffer in the Specimen Tube.
- Wring out fluid from the DNA Collection Swab by twisting the Swab pad against the inside of the tube as it is being removed. Discard the Swab.
- Cap the Specimen Tube and record the collection information on the label. Invert the tube 3-5 times to mix. The DNA specimen is now ready for preservation, transport or testing.



### RECOVERY OF DNA FROM SPECIMEN COLLECTION TUBE

The Asanté DNA Specimen Collection Kit is intended to collect, preserve and transport DNA for future use and testing. The inert nature of the Asanté DNA Specimen Collection Kit is compatible with a variety of DNA purification methods. Epithelial cells collected and absorbed by the Swab are readily released into the Sample Buffer. Cells lyse and DNA is preserved by the Sample Buffer in the Specimen Collection Device. The Swab has low binding properties for both protein and DNA and is designed to readily release DNA. The Swab pad material is a proprietary synthetic fiber similar to Dacron® (polyester).

Testing applications involve amplification of the DNA, so it is therefore important that sufficient quantities of DNA be recoverable to allow amplification. Studies conducted by Sedia have established that the Asanté DNA Specimen Collection Kit