

HEALTH-CHEM DIAGNOSTICS, LLC

3341 S.W. 15th Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997 Website: www.healthchemdiagnostics.com

SANI-SAL® - SALIVA COLLECTION DEVICE

FOR THE UNIFORM COLLECTION OF SALIVA AS AN ANALYTICAL MEDIUM



INTRODUCTION


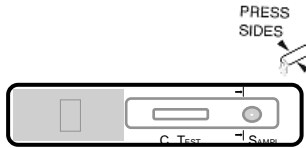
Saliva is a watery, viscous fluid composed of secretions of the parotid, submandibular sublingual and other minor salivary glands; serious transudate; cells {epithelial and leukocytes}; microorganisms; and food particles. Saliva contains a complex mixture of organic and inorganic materials that fall into the following categories:

Electrolytes – Enzymes – Low molecular weight compounds – Hormones – Proteins (Antibodies) – Vitamins

All “low-molecular-weight” materials present in serum can be demonstrated in saliva. For example, urea and uric acid concentrations correlate well with blood levels: glucose is detected in low concentrations and is low in diabetics.

The Sani-Sal® Saliva Collection Device provides a saliva sample which contains “low-molecular weight” compounds, hormones enzymes and proteins in levels that are representative of that in serum or plasma. The Sani-Sal® Saliva Collection Device provides a sample that is as fluid as water. This specimen is appropriate for use without further treatment such as centrifugation, filtration, etc. The foam composition of the collector absorbs mucopolysaccharides present in saliva, as well as food particles, cells and cellular fragments and microorganisms. The viscous, fibrous/gelatinous nature of saliva is changed without any further treatment. The foam composition of the Sani-Sal® Saliva Collection Device does not absorb the analytes presently under consideration for analysis, such as drugs of abuse hormones, enzymes, therapeutic drugs, vitamins or proteins (e.g., antibodies).

PROCEDURE

1/ Place sponge between tongue and cheek for 3 to 4 minutes.	
2/ Twist sponge into the soft elastimer	
	
	3/ Squeeze 1 drop of sample onto the test device, as per test instructions
4/ Twist the soft elastimer into the clear tube assembly for centrifugation, storage or disposal	

1. Open foil pouch holding the Sani-Sal® Saliva Collection Device by the cap, and place between the cheek and gum until the foam sponge has expanded and thoroughly wetted (usually about two to four minutes).
2. After removing the Sani-Sal® Saliva Collection Device from the mouth (again handling only by the plastic cap), the Sani-Sal® Saliva Collection Device should be assembled into its flexible plastic tube holder by twisting gently to insert the wet sponge.
3. Squeeze the flexible plastic tube to extract the saliva sample. Drops may be added directly to a test slide or may be collected in the bottom of the test tube. This will normally

yield a sufficient quantity of concentrated saliva for the test. If necessary, centrifugation can improve the yield.

4. Re-assemble the saliva collection device and appropriately discard with the attached cap. The individual One Step strip tests may be inserted into the test tube for direct analysis. Alternatively, the saliva sample may be transferred to a test site by squeezing the appropriate number of drops from the flexible plastic sponge holder. The saliva sample size and the sample handling procedures may be different for different test devices. Be sure to carefully read and follow the package insert instructions concerning the sample size and sample handling procedures for the particular test device which you are using.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
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U.S. and Foreign Patents Pending