

Instructions for Use



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SaliCap Set

Sampling set for collection of saliva samples
to be used in the IBL Saliva Immunoassays.

REF **RE69981 / RE69985**

 **100 / 500**

  **18°C**  **25°C**

EU: **IVD** **C** **€**



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Always there for you



REVISION HISTORY OF INSTRUCTIONS FOR USE**Changes from the previous version 2015-01 to actual version 2022-05**

Cover page	Layout change
Chapter 1	Additional information
Chapter 2	Additional chapter
Chapter 3	Additional chapter to Scientific validity
Chapter 4	Additional information
Chapter 5	Update
Chapter 6	Additional information
Chapter 7	Additional chapter
Symbol page	Layout change

1. INTENDED USE

Sampling set for collection of saliva samples to be used in the IBL Saliva Immunoassays.

2. INTENDED PURPOSE

Sampling set for collection of saliva samples to be used in the IBL Saliva Immunoassays.

The SaliCap Set are a number of sampling tubes (100 or 500) for collection of saliva sample per tube that can be used with the IBL Saliva Immunoassays portfolio. The set contains tubes and labels to identify and handle the saliva samples in a GLP conform environment (clinical use). Product is not intended for infants. Children < 3 years need to be assisted by an adult.

3. SUMMARY AND EXPLANATION

The SaliCap Set is sampling tubes for collection of saliva samples to be used in the IBL Saliva Immunoassays.

The term saliva refers to the clear, slightly acidic, hypotonic and mucoserous exocrine secretion^[1; 2] composed of secretions from the major salivary glands as well as from the multitudes of minor salivary glands. A healthy person's daily saliva productions ranges between 1.0 - 1.5L per day.^[3]

It is important to be aware that saliva is different than blood and therefore has different needs.

Passive drooling is the most suitable sampling method for the determination of steroid hormones.^[4]

It is crucial to follow specific guidelines to ensure reliable results of hormone concentration in saliva because the concentration is lower than in serum or plasma. Polyethylene collection tubes should be avoided, since they may adsorb a considerable fraction of steroids, and the use of polypropylene tubes, which minimize steroid adsorption problems, is preferable.^[5;6]

Therefore, interactions with the collection device should be avoided. IBL international provides SaliCaps, which are ultra-pure polypropylene sampling devices with an absorption of less than 5%-especially for Progesterone this crucial due to its low concentration.

"Saliva collection devices solve some of the technical issues related to sampling and processing of saliva. However, the widely used Salivette cotton or polypropylene rolls interfere with down-stream analysis of some of the salivary compounds."^[7]

It is recommended not to eat, drink or chew gum 30 min before collecting a saliva sample since it might interfere with the results. Saliva samples with any blood contamination due to bleeding gums or wounds in the oral cavity should be discarded.^[8] The presence of blood in the oral mucosa has the potential to introduce unsystematic variance in the levels of hormones measured in saliva. It is obvious to observe any tint since the SaliCaps are made of transparent polypropylene.

It is recommended to collect more than one sample due to the diurnal rhythm of steroid hormones or melatonin. This means that the concentration of many analytes in saliva is highly dynamic over 24h. Therefore, multiple samples over a defined timespan should be collected to gain an elaborate picture of the concentrations and the rhythm of the analyte.^[9] Multiple samples as well as a pooling of samples can be done with SaliCaps. It is possible to open and securely close the SaliCaps multiple times. The attached lid avoids cross contamination due to mixing lids from different containers or devices.

Before analyzing the samples should be applied to a freeze and thaw cycle in order to reduce the viscosity by breaking up the proteins, which makes the solution easier to pipette and aliquot if necessary.^[10] The polypropylene of the SaliCaps allows multiple freeze and thaw cycles without the risk of breaking and protecting the integrity of the sample and the user from cuts and eventual direct handling with fluids of human origin.

4. WARNINGS AND PRECAUTIONS

1. For in-vitro diagnostic use only. For professional use only.*
2. Only to be used in connection with the IBL Saliva tests according to the instructions for use of the test.
3. Do not use other containers without validation. In general, plastic materials tend to adsorb steroids from saliva. The material used for SaliCaps does not adsorb steroids in significant amounts.
4. Do not reuse.
5. All serious incidents that have occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
6. Used SaliCaps have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.

*Professional use in regard to sample preparation and measurement. Non-professional use for home-sampling by lay persons after professional advice.

5. MATERIALS SUPPLIED

RE69981	RE69985	Component
100*	500*	SaliCap Tubes Ultrapure polypropylene tubes.
100*	500*	Label stickers Self-adhesive.

* approximately

6. SALIVA COLLECTION WITH SALICAPS

	The SaliCaps can be used by lay persons for saliva collection at home. It is very important that the professional user (lab personnel, medical personnel) communicates the handling (sample collection, storage and transport) clear and understandable to the lay person. Professional user has to take into account the physical and mental state of the lay person.
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SAMPLING NOTES

Please see the Instruction for Use of each corresponding assay for details regarding the product specific sampling methods and precautions

1. The concentration of many analytes in saliva is highly dynamic. Therefore a meaningful timing of the sampling procedure is required.
2. Collect Saliva **fasting or earliest 30 minutes after eating or drinking.**
3. Rinsing of the oral cavity with water is recommended just prior to saliva collection (especially after eating).
4. Do not use chewing gum. In case of poor saliva flow you may stimulate the flow by chewing on Parafilm®.
5. Do **not use even the slightest red saliva samples** (traces of blood can lead to false results).

SAMPLING PROCEDURE

1. Label SaliCaps with label stickers.
2. Release the saliva into the SaliCap.
3. It is sufficient to fill half of the tube with saliva.
4. Securely close the collection tube.
5. If the saliva sample is not returned to the laboratory or medical facility immediately it has to be stored in the refrigerator (maximum storage time depends on analyte to be tested and can be taken from product specific instruction for use).
6. It is possible to transport the saliva samples at ambient temperature without loss of analyte (maximum transport/storage time depends on analyte to be tested and can be taken from product specific instruction for use).

7. PRODUCT LITERATURE REFERENCES

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Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.-Cat.: / N.º Cat.: / Αριθμός-Κατ.:
	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro: / Usar até: / Χρησιμοποιείται από:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλοποιημένο
	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
	Unique Device Identification / Eindeutige Geräteerkennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / Διαβάστε τις οδηγίες πριν την χρήση
	Keep away from heat or direct sun light / Vor Hitze und direkter Sonneneinstrahlung schützen / Garder à l'abri de la chaleur et de toute exposition lumineuse / Manténgase alejado del calor o la luz solar directa / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Armazenar em: / Αποθήκευση στους:
	Store at: 2 - 8°C / Lagern bei: 2 - 8°C / Stocker à: 2 - 8°C / Almacene a: 2 - 8°C / Armazenar a: 2 - 8°C / Conservare a: 2-8°C / Armazenar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / Προσοχή!
	Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symboles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Για τα σύμβολα των συστατικών του ΚΙΤ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

Generic table, not all symbols are present in the product

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.

For further country-specific classifications, please refer to the corresponding safety data sheet.



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