

INSTRUCTIONS FOR USE

PERIO-ANALYSE®

Sampling kit for microbiological periodontal test

Intended use :

The sampling kit Perio-Analyse is intended for the collection and transport of samples containing periodontal and peri-implant pathogens.

Principle :

Dentist collects the specimen in one or several periodontal pockets of the patient with absorbent paper points. The paper points are inserted into a tube for storage. Transport of the specimen to the laboratory is performed with a safety Tyvek mailing envelope. At reception, the laboratory performs the Perio-Analyse Test (DNA extraction from paper points and real time PCR for micro-organisms quantification). A report of analysis is published and sent to the dentist.

Instructions for use :

1. Remove the supra-gingival dental plaque and isolate the sampling area with compresses or cotton rolls.
2. Open the sterile paper points' blister and insert one paper point in the periodontal pocket by using tweezers. Leave in contact for 15 seconds and take out the paper point. (Fig.A)
3. Insert the paper point into the tube. (Fig.B)
4. Repeat steps 2 and 3 with other paper points until the periodontal pocket(s) is dry.
5. Replace the cap on the tube and secure tightly.
6. Fill in the order form. (Fig.C)
7. Send the tube containing the sample and the order form to the laboratory in the provided business reply envelope. No stamp is required. (Fig.D)

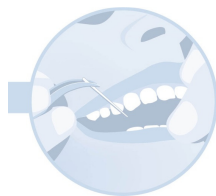


Fig.A



Fig.B



Fig.C

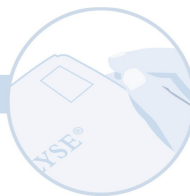


Fig.D

Kit Contents :

The sampling kit Perio-Analyse is a CE marked in vitro diagnostic medical device and consists of :

- 1 microtube
- 10 sterilized absorbent paper points
- 1 prescription form
- 1 postal packaging
- instructions for use

Materials required but not supplied :

- Compresses or cotton rolls
- Tweezers

Precautions :







Instructions for use must be followed carefully.

This product is for single use only. Do not use if there is evidence of damage or contamination to the product, the package is open, or there are other signs of deterioration. Do not use after the expiry date. Do not autoclave.

Sterile gloves and protective clothing should be worn when collecting and handling microbiology specimens. Samples should be processed within 10 days when stored at room temperature.

List of the periodontal pathogens quantified with real-time Polymerase Chain Reaction technology :

Basic Analysis	Premium Analysis	Platinum Analysis
<ul style="list-style-type: none">▪ <i>Aggregatibacter actinomycetemcomitans</i>▪ <i>Porphyromonas gingivalis</i>▪ <i>Tannerella forsythia</i>▪ <i>Treponema denticola</i>▪ <i>Prevotella intermedia</i>	<ul style="list-style-type: none">▪ <i>Aggregatibacter actinomycetemcomitans</i>▪ <i>Porphyromonas gingivalis</i>▪ <i>Tannerella forsythia</i>▪ <i>Treponema denticola</i>▪ <i>Prevotella intermedia</i>▪ <i>Parvimonas micra</i>▪ <i>Fusobacterium nucleatum</i>▪ <i>Campylobacter rectus</i>▪ <i>Eikenella corrodens</i>	<ul style="list-style-type: none">▪ <i>Aggregatibacter actinomycetemcomitans</i>▪ <i>Porphyromonas gingivalis</i>▪ <i>Tannerella forsythia</i>▪ <i>Treponema denticola</i>▪ <i>Prevotella intermedia</i>▪ <i>Parvimonas micra</i>▪ <i>Fusobacterium nucleatum</i>▪ <i>Campylobacter rectus</i>▪ <i>Eikenella corrodens</i>▪ <i>Candida albicans</i>

	Consult instructions for use
	Do not reuse
	Do not use if damaged
	Diagnostic in vitro
	Batch code
	Use by

Manufactured and distributed by :

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