

Technical Sheet

PerioSafe®
dentognostics GmbH



PRODUCT INDICATION

Product type	Lateral flow rapid test
Indication	<ul style="list-style-type: none">• The product detects elevated levels of the collagenase, aMMP-8 (active matrix metalloproteinase-8), an enzyme that destroys tissue, in oral lavage fluid• If detected in time, the development of periodontitis can usually be halted and existing periodontitis successfully treated by a dentist or periodontist in cooperation with a dental hygienist or dental assistant

PRODUCT PROPERTIES

Origin	dentognostics GmbH, Tatzendpromenade 2, 07745 Jena, Germany
Storage temperature	2°C–25°C
Product specifications	<ul style="list-style-type: none">• The PerioSafe® tests should be administered by the dental assistant or hygienist as the first thing immediately when the patient sits in the dental chair. There should be no treatment or activity in the mouth before the test• Patients should avoid eating, drinking anything but water, smoking, using mouthwash, or brushing their teeth for at least 20 minutes before the test. If they have eaten, then they should rinse with water and then wait at least 60 seconds for the saliva to return to the mouth before proceeding with the sample collection• The PerioSafe® test is meant to be used to screen generally healthy looking patients or patients in a recall phase after periodontal treatment. It is not indicated to use on patients with acute periodontitis. For these patients, the PerioSafe® POOL test should be used instead• Retesting should occur no sooner than 2 weeks after basic preventive treatments and no sooner than 6 weeks after periodontal therapy
Component Parts	<ul style="list-style-type: none">• 1. Test cassette: for applying a sample and displaying the test result [REF 32501ETDE aMMP-8 Test]• 2. Rinsing solution: of purified water for obtaining samples [REF 32505ETDE Purified Water 5 ML CE0459]• 3. Cup: for holding rinsing solution and catching the sample [REF 32508ETDE Cup]• 4. Syringe: for applying the sample to the test cassette [REF 32507ETDE Syringe 3 ML SoftJect®]• 5. Filter: for mounting on the syringe and to filter the sample BEFORE applying to the test cassette [REF 32506ETDE Filter Acrodisk 25 MM]• 6. QR Code: on the outside of packaging [REF 960-00104]• 7. Short instructions: with the pictograms• 8. Instructions for use: detailed information on the test
Sterilization / Disinfection	<ul style="list-style-type: none">• The product is aseptically manufactured and sterile• The product is for single use only
Shelf life	18 months
Regulatory status	In vitro diagnostic device (IVD) with CE mark
Entry on the market	2010

AVAILABLE PRODUCT LINE

Product	Type/Size/Amount	Art.-No.
PerioSafe®/ImplantSafe® DR	25 Tests	970-00225
PerioSafe®/ImplantSafe® DR	50 Tests	970-00250
PerioSafe®/ImplantSafe® Pool DR	25 tests	970-00325
PerioSafe®/ImplantSafe® Pool DR	50 tests	970-00350
ORALyzer®	complete, incl. Drawer 4&5, Printer	970-00001
Drawer for PerioSafe® PRO DRS	1 drawer	970-00005
Drawer for PerioSafe®/ImplantSafe® DR	1 drawer	970-00007

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