EN

AMA DENT

Enzymatic express-test for the microbe-associated periodontal disease

For ***in vitro*** diagnostic use Store at +16 to +28 °C

Upon Receipt

EC REP

Authorized Representative in Europe "CMC Medical Devices & Drugs S.L." C/ Horacio Lengo № 18, C.P 29006, Malaga – Spain

REF 0503

IVD CE +16°C +28°C

Manufacturer "Association of Medicine and Analytics Company Limited", 17 line of Vasilievsky Island, 4-6, 199034, Saint-Petersburg, Russian Federation

INSTRUCTIONS FOR USE

EDITION 03, June, 2024

1. INTENDED USE AND PRINCIPLE OF OPERATION

The intended use is rapid "Red complex" oral bacteria qualitative detection by establishing the presence of proteolytic activity in a subgingival plaque taken from either adult or child patients. The device is applied by dentists, odontologists, laboratory assistants, chair-side assistants. "Red complex" bacteria (*Tannerella forsythia, Porphyromonas gingivalis, Treponema denticola*) produce trypsin-like proteases that hydrolyze the synthetic peptide, Benzoyl-DL-arginine-B-naphthylamide. The detection of the proteolytic activity is based on the following biochemical reactions:

Trypsin-like proteases

(1) Benzoyl-DL-arginine-B-napthylamide (BANA) ⟶ Nα-benzoyl-Larginine (BA) + β-naphthylamine (β-NA)

(2) β-naphthylamine (β-NA) + FBK salt ⟶ Blue color spot

The principle of operation of AMA DENT is based on the color change of the indicator element after its level-to-level alignment with the reactive element on which the biological sample has been placed. In the event of proteolytic activity in the biological sample, a light or dark blue spot appears on the indicator element of the test. The test is intended for the doctor's office. Only the fresh obtained biological samples should be used for the test.

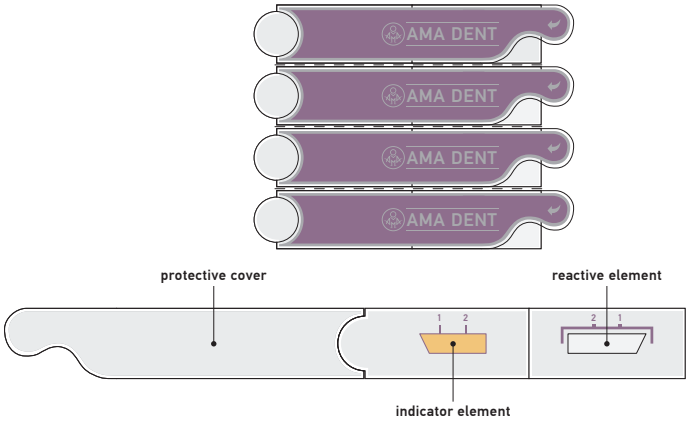
Biological test samples could be:

- Dental plaque
- Dental biofilm
- Subgingival calculus
- Gingival crevicular fluid

One or two samples of the one patient can be tested at the same time. The volume of a biological sample should be no less than 1.5 µl. If "Red complex" bacteria are present in the sample, a light or dark blue spot appears on the indicator element of the test within ten minutes.

2. DESIGN OF THE TEST

The test is a rectangular-shaped polymer basement with the test segments each having a reactive and an indicator element, hermetically sealed by a protective cover. Each segment allows to perform the diagnostic procedure: when one segment has been opened, other segments remain hermetically sealed and can be further used or stored.



The reactive element is white color and the indicator element is light-orange.
One or two samples from one patient can be tested at the same time.

3. DELIVERY SET

Delivery set should satisfy the requirements in the Table 1.

Table 1.

Product name	Quantity in the set, pcs.
AMA DENT (Enzymatic express-test for the microbe-associated periodontal disease)	1 block of 4/ 5 blocks of 4
Heaters	4/ 20
Instruction for use	1

4. WARNINGS AND PRECAUTIONS

For ***in vitro*** diagnostic use.
For use by trained personnel only. The device doesn't contain medicinal agents and organic materials. Materials that are dangerous to the environment and humans are not used in the manufacture of products.

Caution:

Handle biomaterial samples as potentially biohazardous material. All biomaterial samples should be regarded as potentially contaminated and treated accordingly. Please refer to the local or national regulations. Always use protective gloves when handling patient samples. Read all instructions prior to performing the test. Do not use the test or the heater beyond the expiry date. Discard the used tests and single-use heaters to biohazardous waste according to the local and national regulations.

5. MATERIALS REQUIRED, BUT NOT PROVIDED

- Powder-free gloves
- Dental explorer/applicator/dental paper point/toothpick/stick
- Timer

6. LIMITATIONS

Not recommended testing at an ambient temperature below +16 °C and above +28 °C.
Use fresh biological samples for the analysis.
The test should be performed on an empty stomach or at least 2 hours after meal or last brushing the teeth.

False results may occur if:
- the dental instrument used for the sampling was contaminated before testing;
- the test exposure time was not observed;
- an insufficient sample volume of the biological material was used;
- the concentration of bacteria of the "Red complex" (*Porphyromonas gingivalis, Treponema denticola and Tannerella forsythia*) in the test sample is below the test sensitivity limit.
- testing methodology was not followed.

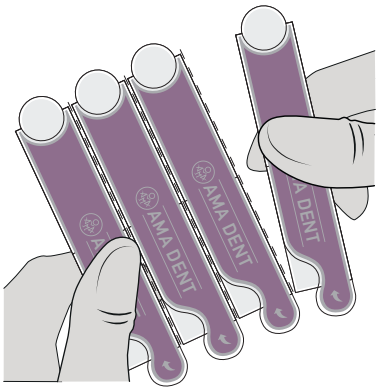
The sensitivity towards *Tannerella forsythia, Porphyromonas gingivalis, Treponema denticola* of the mouth cavity might be reduced in the course of oral sanitation procedures or an anti-microbial treatment.
As with any diagnostic procedure the test results must be interpreted in the light of the patient's clinical presentation and any other information available to the physician.
If there is a discrepancy with other diagnostic parameters it is recommended to make additional tests using other methods.

7. PREPARATION BEFORE THE TEST

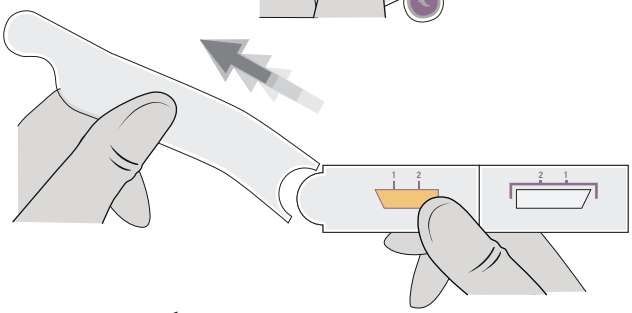
- Put on the gloves
- Open the package of the test

8. TEST PROCEDURE

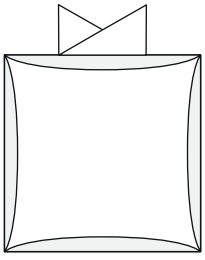
Separate the required number of the segments in the line of perforation and put it on a flat surface.



Open the protective cover of the test and carefully remove it. Discard the protective cover of the test.

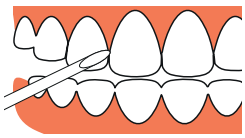


Take out the same amount of the heaters.
Take the heater out of its' bag.
After opening the bag with a heater, it should be used within 2 days.



Place the heater on a flat surface.

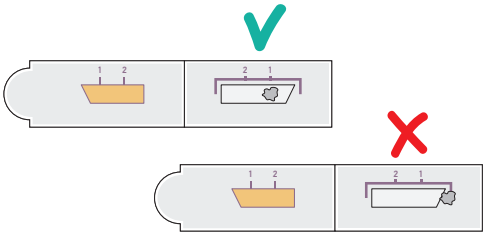
Biomaterial taken from the subgingival calculus, dental biofilm, gingival crevicular fluid and dental plaque is used as a biological sample. If subgingival calculus is used as a biological sample, then dental paper point or dental applicator are used for sampling. Choose dental papilla that appear to be inflamed.



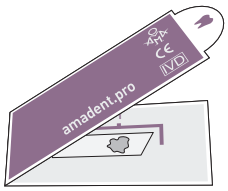
If you use dental plaque as a biological material, then use dental explorer/toothpick/stick. Based on the patient's clinical picture, select appropriate biological samples and medical devices.
Place first sample onto the reactive element, position 1.
Biomaterial can be taken from different areas of inflammation from one patient.
Take a new disposable dental paper point or stick (if you are using a disposable tool) in another quadrant. Again, place sample onto the reactive element, position 2.
Before taking second specimen, wipe the dental explorer/applicator on a clean piece of cotton or other suitable wipe to prevent carry-over of plaque.

Sample size: 1-2 mm

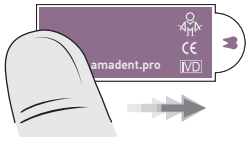
Make sure the biological sample is wet enough to spread well over the reactive element surface. If not, provide moisture to the sample using periodontal fluid or saliva near the inflammatory area.
Place biological sample on the white reactive element, marked “1” and “2”, but not beyond this element.



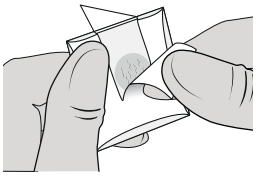
The sample should be taken within the test procedure. Pre-processing of samples is not required. After placing the biomaterial, bend the test so that the reactive element and the indicator element align and overlap.

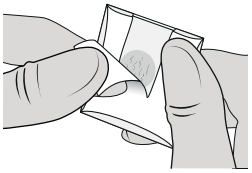


Gently smooth the cover with your finger all over the test.

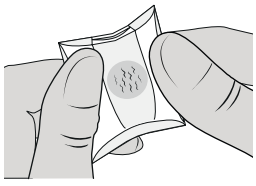


Carefully peel off the protective covers on both sides of the heater one by one.

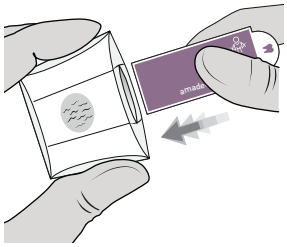


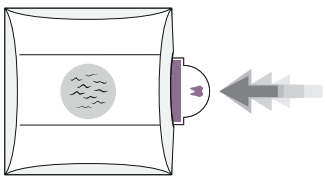


Bend the heater for activation.



Place the AMA DENT segment into the slot of the heater for an exposure time of 10 minutes.



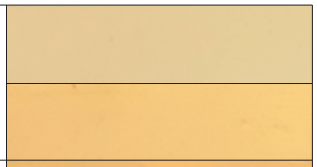
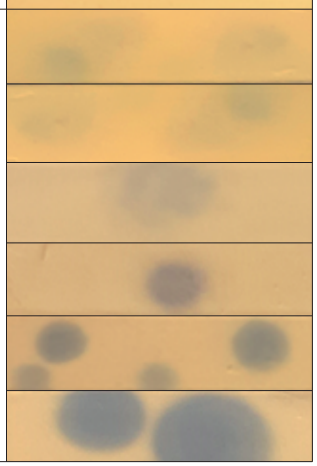


After the exposure period remove segment from the heater, open the segment and evaluate the results.

9. EVALUATION OF TEST RESULTS

The presence of a light blue or blue spot on the indicator element of the test indicates the proteolytic activity of the “Red complex” bacteria in the biological sample.
The blue color is permanent. The greater the proteolytic activity, the brighter spot will be. Negative reaction: no blue color is detected. If the indicator element does not change color, the enzymatic activity in the biological sample(s) is absent or below the sensitivity threshold (bacterial load of the “Red complex” bacteria below 10^4 GE/ml). Red or pink spots may appear. Evaluate only light blue or blue spots. Examples of test results are shown in Table 2.

Table 2. Matching the observed colors of the indicator element

Negative result	
Positive result	

10. STORAGE, STABILITY AND TRANSPORTATION TERMS

Store test:
- In the manufacturer’s packaging;
- In a dark, dry place with the temperature from +16 °C to +28 °C;
- In a place protected from mechanical actions (friction, pressure, strokes);
- Keep away from the moisture and direct sunlight.

The test must be used at a temperature from +16 °C to +28 °C.
When stored at this temperature the device is stable for 24 months.
Expiration date is indicated on the label of the package of the test.
Transport by any kind of transportation with the temperature from -20 °C to +40 °C, sealed.
The transport period must not exceed 1 month.

11. WARRANTY

The Manufacturer shall remedy all defects discovered in any test (the “Defective Product”) that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Product including, but not limited to, the functions specified in the Manufacturer’s specifications for the Product.
Any warranty will, however, be deemed as void if fault is found to have been caused by maltreatment, misuse, accidental damage, incorrect storage or use of the product for operations outside their specified limitation or outside their specifications, contrary to the instructions given in the instruction manual.
The period of this warranty is 24 months from the date of manufacture.

12. ORDERING INFORMATION

- Please place orders to Hexagon International (GB) Ltd ,UK

e-mail: info@HexagonLimited.com www.HexagonLimited.com

- Importer: AMA-Med ,Finland support@amamed.eu

Manufacturer : Association of Medecine andAnalytics Company Ltd . RF.
Details at top of page.

EXPLANATION OF THE SYMBOLS, USED IN LABELS

Manufacturer	Contents sufficient for N tests
Authorized Representative in the European Community	Do not reuse
Use by	Consult Instructions for use
Batch code	In vitro diagnostic medical device
Date of manufacture	Temperature limitation
CE certification	Catalogue number