

Active CEM Color Stability Test - Jun – 2024

1. Rational:

The aim of this evaluation was to test the color stability of B.J.M. Active CEM resin modified glass ionomer cement and demonstrate the color stability of the material after Xenon irradiation and after water sorption.

For this purpose, the validation batch of B.J.M. Active CEM was mixed utilizing a suitable production equipment and tested according to the applicable ISO standards methodology and requirements.

2. Materials:

- Active CEM RMGIC (B.J.M. Laboratories Ltd.)
 - Lot. 5100ACRMGIC, Exp. 01-2026

3. Equipment:

- IKA LR-2.ST mixer for mixing 2 kg of Active CEM.
- 3M Elipar™ DeepCure-L – Dental Light Cure LED device.
- Incubator constantly maintained at 37°C – for specimen storage prior to testing.
- Micrometer with accuracy of 0.01mm.
- Climate chamber – ATLAS Suntest CPS+ equipped with water bath SunFlood.

4. Test Methods:

4.1. Color Stability:

- 4.1.1. In accordance with ISO 9917-2:2017, ISO 7491:2000, ISO/TR 28642:2011, and internal requirements, four specimens (1, 2, 3a and 3b) were prepared and cured by a LED dental lamp.
- 4.1.2. Specimen 1 was stored in dark and dry incubator, in water at 37°±2°C for 7 days. This was the reference specimen.
- 4.1.3. Specimen 2 was stored in dark and dry incubator, in water at 37°±2°C for 24±2 hours. Afterwards half of the specimen was blanked with aluminum foil it was



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placed in a water bath SunFlood for ATLAS Suntest CPS+¹, while water is maintained at 37±5°C and at a depth of 10±5 mm above the specimen. The specimen was exposed to the radiation of a Xenon lamp for 24±2 hours. After exposure the metal foil was removed and the specimen transferred back to the incubator in water at 37°±2°C for 5 days.

- 4.1.4. The color comparison was made by visual inspection for no more than slight change in color with scale of: Excellent, Good, Poor, Unacceptable.

5. Color Stability Evaluation:

According to ISO 7491:2000 - Dental materials – Determination of color stability – Color stability will be tested by three people with normal color vision to compare by visual inspection the exposed and unexposed specimen for any color differences.

When the material is tested in accordance with ISO 9917-2:2017 and ISO 7491:2000, no more than a slight change in color shall be observed. In the event of disagreement between the observers, the majority view shall be reported

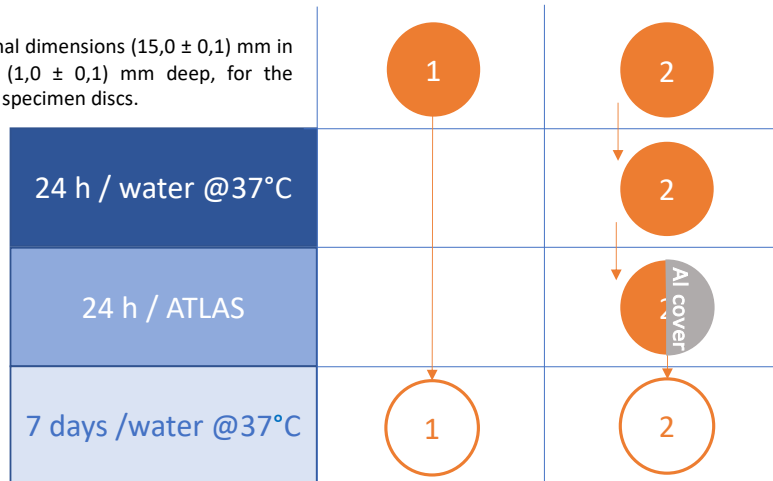
¹ Radiation source: ATLAS Suntest CPS+ equipped with Xenon medium pressure lamp with a color temperature of 5,000 K to 10,000 K and with an illuminance at the specimen of 150,000 LUX and UV filter



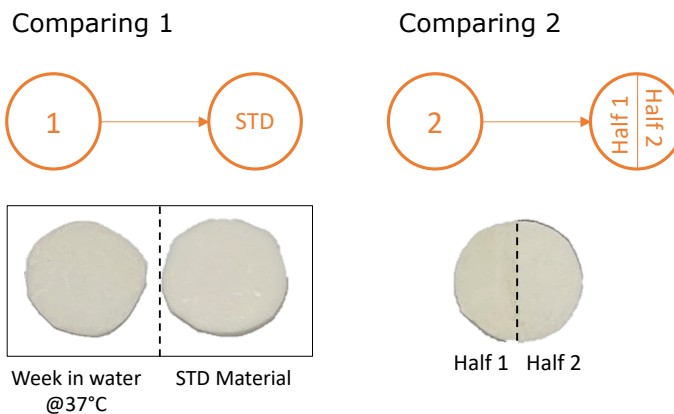
6. Results:

TESTS

Mold, of internal dimensions (15,0 ± 0,1) mm in diameter and (1,0 ± 0,1) mm deep, for the preparation of specimen discs.



RESULTS



Active CEM did not undergo any significant change in color during the performed test after exposure to irradiation and water conditions.

7. Conclusions:

Color stability was performed by a group of three people who visually inspected specimens of Active CEM that were tested.

Active CEM did not undergo any significant visual change in color during the performed test after exposure to irradiation and water conditions compared to the reference specimen.

Active CEM is color stable in accordance with ISO 9917-2:2019 and ISO 7491:2000.



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