



RAVEN LABS

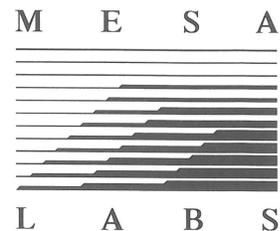
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ProSpore Media Integrity Study

November 2, 2009

Purpose:

When Raven's ProSpore ampoules are exposed to long cycle times in steam sterilizers the sugars in the media caramelize and cause the media to turn brown. This study was performed to test the ability of the ProSpore media to promote growth after caramelization of the media when exposure to extended cycle times.

Test Method:

The contents of twenty-three individual ampoules of ProSpore lot # 498 were transferred into individual glass test tubes and exposed in a steam autoclave for two hours at 132°C. The media filled tubes were allowed to cool to room temperature and then twenty of the tubes were inoculated with *Geobacillus stearothermophilus* spores. All twenty-three tubes were then placed in a 55-60°C incubator for 7 days. The three additional tubes that were not inoculated served as negative controls. The tubes were checked daily for growth / no-growth.

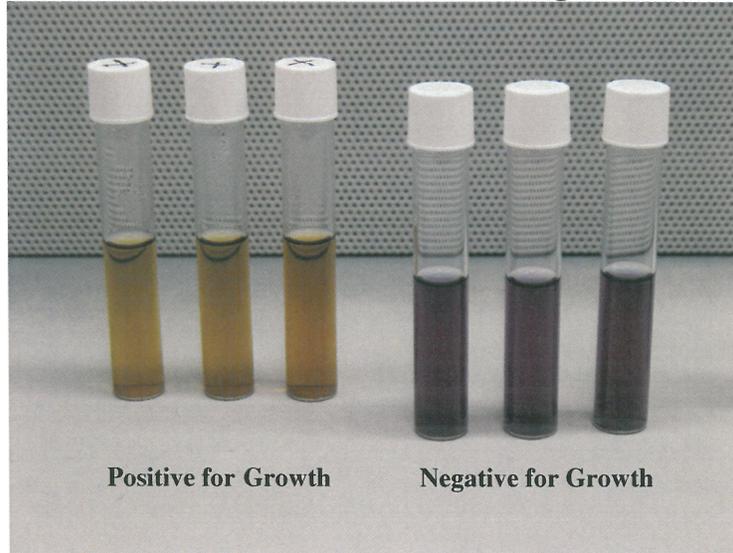
Results:

Exposure: 132°C for 2 hours					
BI #	Results	BI #	Results	BI #	Results
1	Growth	9	Growth	17	Growth
2	Growth	10	Growth	18	Growth
3	Growth	11	Growth	19	Growth
4	Growth	12	Growth	20	Growth
5	Growth	13	Growth	NC1	No Growth
6	Growth	14	Growth	NC2	No Growth
7	Growth	15	Growth	NC3	No Growth
8	Growth	16	Growth		

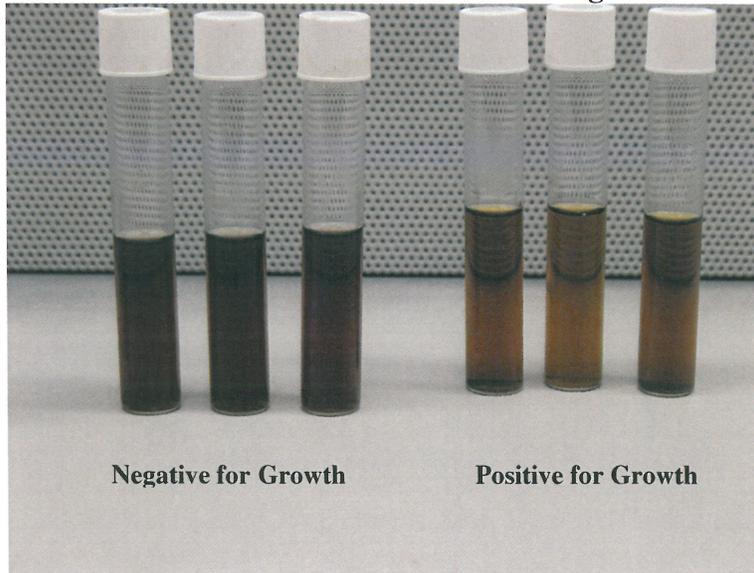
All twenty inoculated tubes were positive for growth within 48 hours. The results confirm that even though the sugars in the media were caramelized and dramatically changed the color of the media it did not affect the media's ability to promote growth. The caramelized media retained the ability to promote growth but the color change between a positive test and a negative test was not as dramatic as would be observed from a non-caramelized ampoule. For the caramelized media ampoules the best indicator of growth is turbidity.

The following photos illustrate the difference in the color change of positive tests for both standard and caramelized media.

Standard Media Color Change



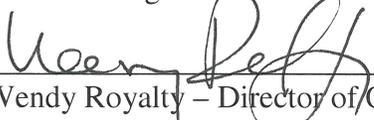
Caramelized Media Color Change



Approved By:


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11/02/2009
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Date