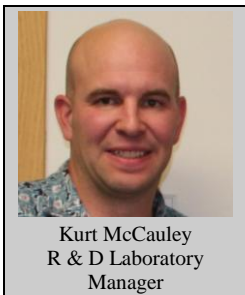


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Read Out Times of Smart-Read EZTest® Exposed at Elevated Temperatures



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Recently, we were asked about the reduced incubation time (RIT) claims of the Smart Read EZTest BI exposed at elevated steam temperatures. SGM had assumed that spores injured by moist heat, no matter the temperature, would germinate and grow out in a similar fashion. We decided to test this assumption and performed additional RIT testing at 132°C, 134°C, and 135°C, which are commonly used higher sterilization temperatures.

The FDA Reduced Incubation Time protocol¹, designed to focus on the “last surviving spore”, was used in an all testing. See attachment II of the linked guidance document for test methods: (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071261.htm#a2>).

Note: Further detailed discussions about Reduced Incubation Time can be found in the “spores news” and “technical papers” tabs at www.sgmbiotech.com,

The data presented here are from six unique spore crops and includes the original data collected at 121°C on three of the crops and data collected at the elevated temperatures on the remaining three crops. The current RIT claim based on the data collect at 121°C is 10 hours. A summary of read out times at each temperature is presented in Table 1.

Table 1 - Read out times* for EZTest BIs exposed at four sterilization temperatures

Lot	121°C	132°C	134°C	135°C
031005	8:40			
062906A	10:00			
031804	8:13			
052109		6:50	9:38	7:22
030309		7:45	8:16	8:22
033109		8:33	8:32	8:36

*Times are expressed in hours and minutes

¹ The Center for Devices and Radiological Health, FDA Guide for Validation of Biological Indicator

The times presented in Table 1 were rounded up to the next whole hour to make the data more user friendly and to present a conservative read out time. These values are displayed in Table 2 with the longest read out times in bold. Table 3 displays the progression of positives from the initial positive up to the time when the last positive unit was detected. Figure 1 is a graphical representation of the data presented in Table 3.

Table 2 - RIT times from Table 1 rounded up to the nearest whole hour.

BI lot	121°C	132°C	134°C	135°C
031005	9 hours			
062906A	10 hours			
031804	9 hours			
052109		7 hours	10 hours	8 hours
030309		8 hours	9 hours	9 hours
033109		9 hours	9 hours	9 hours

Table 3 – The actual incubation time that illustrates the progression of positive test results.

Temperature	BI lot	Start Time 1 st Positive	50% Positives	95% Positives	97% Positives	100% Positives
121°C	031005	5:50	6:53	8:33	8:40	8:41
	062906A	3:37	6:16	9:18	10:00	12:33
	031804	5:29	6:41	8:11	8:13	11:05
132°C	052109	3:29	4:16	6:46	6:50	7:00
	030309	3:21	4:49	7:22	7:45	<120hrs
	033109	3:28	4:35	7:39	8:22	8:55
134°C	052109	3:14	4:47	8:43	9:38	<168 hrs
	030309	3:03	4:33	7:56	8:16	8:44
	033109	3:31	5:20	8:15	8:32	9:46
135°C	052109	3:18	4:50	7:13	7:22	7:39
	030309	3:23	4:58	8:18	8:22	9:59
	033109	3:28	4:54	8:29	8:36	9:34

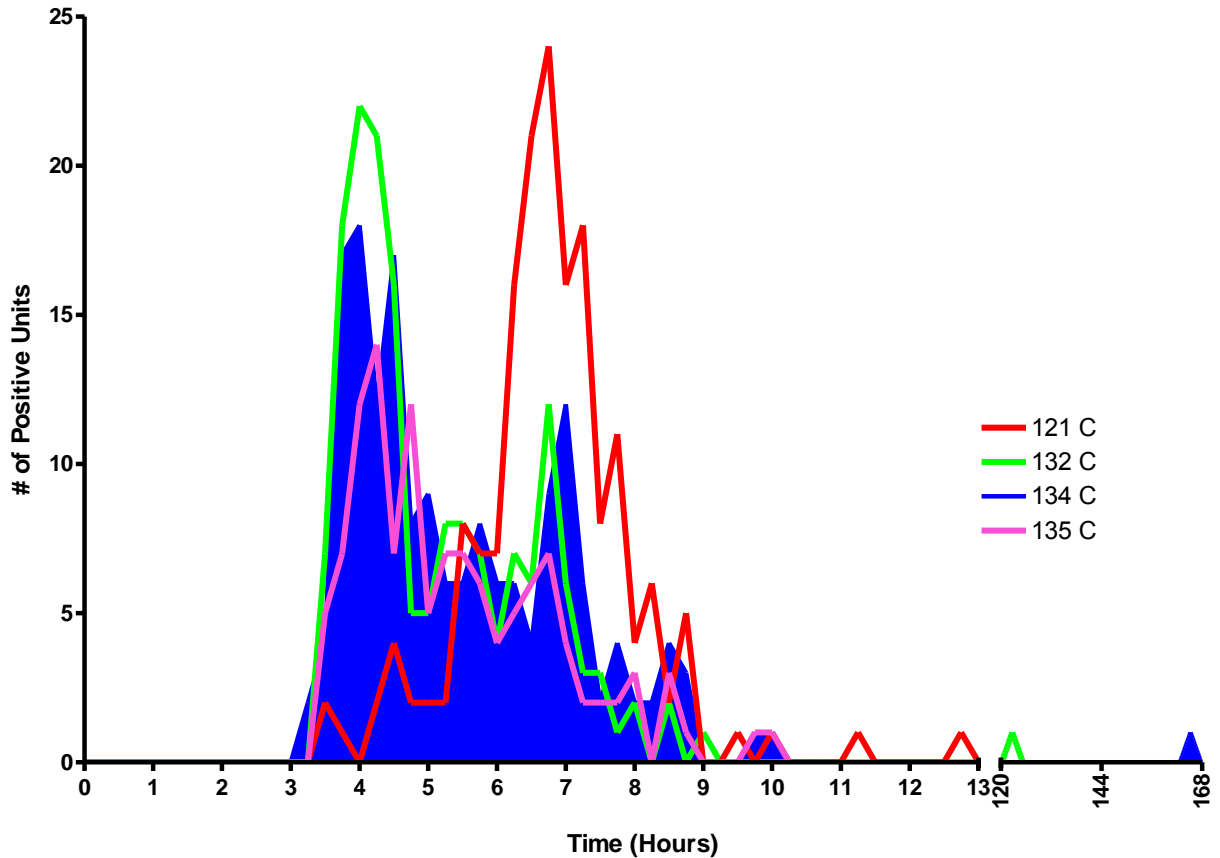


Figure 1 – A graphic representation of the clock time when individual exposed units were detected as positive.

The data indicate that read out time for BIs exposed at elevated temperatures is comparable to those exposed at 121°C. If anything, the raw data suggest that a slight decrease in read out time occurs to BIs exposed at the elevated temperature. It also appears that the growth response time has fewer spores with delayed germination. This is likely due to severe collateral damage—damage so great, the spore cannot repair itself—preventing delayed germination and outgrowth. It may be concluded that a more robust process will result in less injured spores and thus less tailing. The spores are either alive, or damaged beyond repair, resulting in a sharp endpoint.

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