

**Stress sheet**  
Anti-Syphilis Card Test  
004C054

The following acceleration study confirmed that the ulti med Syphilis test is stable under extreme storage conditions without lost of performance.

**Accelerated Stability**

Accelerated Stability of the ulti med Syphilis Rapid Test (Whole Blood/Serum/Plasma) was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at 45°C and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56 and 73 days. Test Devices were assayed using negative, low titer positive, medium positive and high positive specimens. Testing at each specific time interval consisted of 5 replicates for each specimen. The tests were performed according to the package insert. The results are presented in Table 1.

**Table 1: Accelerated Stability Summary**

Day	Specimen	Lot		
		A	B	C
7	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
14	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
21	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
28	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
35	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
42	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+
56	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+

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73	Negative	5-	5-	5-
	Low titer positive	5+	5+	5+
	Medium titer positive	5+	5+	5+
	High titer positive	5+	5+	5+

Note:

5- indicates negative test results with 5 replicates

5+ indicates positive test results with 5 replicates

Conclusion: The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is stable at 45°C for 73 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the date of manufacture.

Ahrensburg, 09.09.2010

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