

Stress sheet
Strep A card
014D300

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

The test also should pass following accelerating stability study in order assigning an EXP date.

Accelerated Stability of the ulti med Strep A Test Device 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 0, 7, 14, 21, 28, 35, 42, 56, 73, 84,90 and 120 days. Test Devices were assayed using negative, low positive, medium positive and high positive samples. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. The results are presented in Table

The Accelerated Stability Study

Day	Specimen	Lot		
		RDSTA1101-1	RDSTA1101-2	RDSTA1101-3
0	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
7	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
14	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
21	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
28	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
35	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
42	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
56	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
73	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+

	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
84	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
90	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+
120	Negative	3-	3-	3-
	1x10 ⁵ organismen/swab	3+	3+	3+
	2.5x10 ⁵ organismen/swab	3+	3+	3+
	1x10 ⁶ organismen/swab	3+	3+	3+

Note:

3- indicates negative test results with 3 replicates

3+ indicates positive test results with 3 replicates

Conclusion:

The ulti med Strep A Test Device is stable at 45°C for 120 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 36 months from the date of manufacture.

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ulti med Products (Deutschland) GmbH



Matthias W. Engel

Managing Director