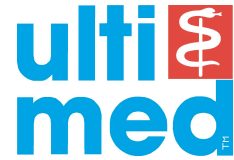


Stress sheet
H.pylori Antibody Test
012L400



The following acceleration study confirmed that the ulti med H.pylori Antibody Test 012L400 is stable under extreme storage conditions without loss of performance.

Accelerated Stability of the ulti med H.pylori Antibody Test was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45°C and 55°C. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 84 days for 45°C. About 55°C, some performance study would be tested at 0, 7, 14, 21, 28, 35, 42 days according to Arrhenius Plot. See Table in below. Test cassettes were assayed using negative, low positive, middle positive and high positive standard specimens. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert. Results are presented in Table below.

Table: Timeline for Accelerate Stability Study

Day \ Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45°C	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	X	X	X

Table: 45°C Accelerated Stability Summary

Day	Specimen	012L400								
		HPB14060004-T			HPB14060005-T			HPB14060006-T		
7	Negative	-*	-	-	-	-	-	-	-	-
	Low positive	+**	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-

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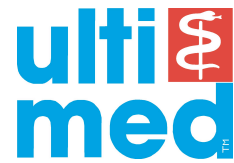
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
77	High positive	+	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
84	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-	-

Note: “-” mean negative result, “+” mean positive result

Table: 55°C Accelerated Stability Summary

Day	Specimen	012L400								
		HPB14060004-T			HPB14060005-T			HPB14060006-T		
0	Negative	-*	-	-	-	-	-	-	-	-
	Low positive	+**	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+

Stress sheet
H.pylori Antibody Test
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	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+

Note: “+” mean positive result, “-” mean negative result

Conclusion: The H.pylori Antibody Test was stable at 45°C for 84 days and at 55°C for 42 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 data of manufacture.

Ahrensburg, 01.03.2016

ulti med Products (Deutschland) GmbH

A handwritten signature in cursive script that reads 'Matthias W. Engel'.

Matthias W. Engel

Managing Director