

**Stress sheet**  
H. pylori Antigen rapid test  
009AF401

The following acceleration study confirmed that the ulti med H. pylori Ag test 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 H. pylori Antigen Test Device (Feces) 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, 77 and 84 days. Test devices were assayed using negative, middle positive and high positive specimens. 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 the table below.

**The Accelerating Stability Study;**

Day	Specimen	Lot SHP0812001	Lot SHP0812002	Lot SHP0812003
0	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
7	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
14	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
21	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
28	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
35	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
42	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
56	Negative	3-	3-	3-
	Medium positive	3+	3+	3+
	High positive	3+	3+	3+
77	Negative	3-	3-	3-
	Medium positive	3+	3+	3+

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	<b>High positive</b>	3+	3+	3+
<b>84</b>	<b>Negative</b>	3-	3-	3-
	<b>Medium positive</b>	3+	3+	3+
	<b>High positive</b>	3+	3+	3+

Note:

3- indicates negative test results with 3 replicates

3+ indicates positive test results with 3 replicates

**Conclusion:**

The ulti med H. pylori Antigen Test Device (Feces) is stable at 45°C for 84 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.

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