

Accelerated Stability

Accelerated Stability of the ulti med DrugControl COT Cassette was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45° C and 55° C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56, 77, 84 days. Tests were assayed using COT concentration at 0, 100, 300ng/ml urine specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in tables 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

Stress sheet
DrugControl COT Test
008Q086

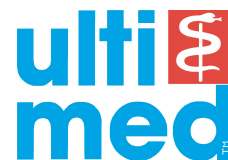
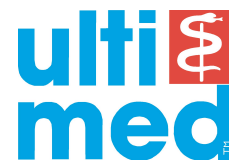


Table: Accelerated Stability Summary

Accelerated Stability Study Results at 45°C										
Day	Specimen	Batch No.								
		Lot 1			Lot 2			Lot 3		
0	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
7	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
14	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
21	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
28	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
35	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
42	0ng/ml COT	-	-	-	-	-	-	-	-	-

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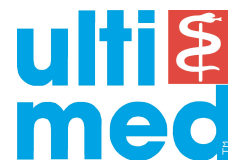


	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
56	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
77	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
84	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+

Accelerated Stability Study Results at 55°C

Day	Specimen	Batch No.								
		Lot 1			Lot 2			Lot 3		
0	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
7	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
14	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+

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21	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
28	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
35	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+
42	0ng/ml COT	-	-	-	-	-	-	-	-	-
	100ng/ml COT	-	-	-	-	-	-	-	-	-
	300ng/ml COT	+	+	+	+	+	+	+	+	+

Conclusion: The **ulti med DrugControl COT Test** is stable at 45°C for 84 days or 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 27 months from the data of manufacture.

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