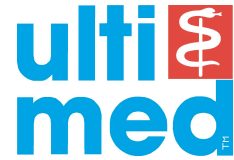


**Stress sheet**  
Drug-Adulteration Test Strip  
006T206-25



**Accelerated Stability**

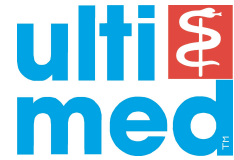
Accelerated Stability of the Drug-Adulteration Test Strips was evaluated using samples from three different lots. These were placed in an incubator with the temperature calibrated at 45°C and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56 and 77 days. Test strips were assayed using Creatinine, Glutaraldehyde, Nitrite, PCC/Oxidant, pH and Specific gravity standard solution. Run five replicates per sample for day 0 and one strip per sample for other time points. Read result at 1-2 minutes according to the color chart.

**Table: Result of the Accelerated Stability**

**pH reagent pad:**

Day	Lot	pH Standard Solution			
		pH 2.0	pH 4.0	pH 9.0	pH 11.0
0	A	5/pH 2.0	5/pH 4.0	5/pH 9.0	5/pH 11.0
	B	5/pH 2.0	5/pH 4.0	5/pH 9.0	5/pH 11.0
	C	5/pH 2.0	5/pH 4.0	5/pH 9.0	5/pH 11.0
7	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
14	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
21	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
28	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
35	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
42	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
56	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0
77	A	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	B	pH 2.0	pH 4.0	pH 9.0	pH 11.0
	C	pH 2.0	pH 4.0	pH 9.0	pH 11.0

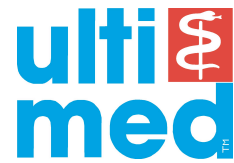
**Stress sheet**  
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**Specific gravity reagent pad:**

Day	Lot	Specific Gravity Standard Solution			
		1.000	1.003	1.025	1.035
0	A	5/1.000	5/1.003	5/1.025	5/1.035
	B	5/1.000	5/1.003	5/1.025	5/1.035
	C	5/1.000	5/1.003	5/1.025	5/1.035
7	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
14	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
21	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
28	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
35	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
42	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
56	A	1.000	1.003	1.025	1.035
	B	1.000	1.003	1.025	1.035
	C	1.000	1.003	1.025	1.035
77	A	1.000	1.005	1.030	1.035
	B	1.000	1.005	1.030	1.035
	C	1.000	1.005	1.030	1.035

**Stress sheet**  
Drug-Adulteration Test Strip  
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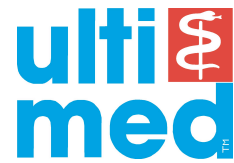
**Oxidant/PCC reagent pad:**

Day	Lot	Standard Solution			
		Neg.	NaClO 100 ppm	H <sub>2</sub> O <sub>2</sub> 20 ppm	PCC 20 mg/dL
0	A	5/-	5/+	5/+	5/+
	B	5/-	5/+	5/+	5/+
	C	5/-	5/+	5/+	5/+
7	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
14	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
21	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
28	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
35	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
42	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
56	A	-	+	+	+
	B	-	+	+	+
	C	-	+	+	+
77	A	-	+/-	+	+
	B	-	+/-	+	+
	C	-	+/-	+	+

**Creatinine reagent pad:**

Day	Lot	Creatinine Standard Solution			
		0 mg/dL	10 mg/dL	20 mg/dL	100 mg/dL
0	A	5/0	5/10 mg/dL	5/20 mg/dL	5/100 mg/dL
	B	5/0	5/10 mg/dL	5/20 mg/dL	5/100 mg/dL
	C	5/0	5/10 mg/dL	5/20 mg/dL	5/100 mg/dL
7	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
14	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL

**Stress sheet**  
Drug-Adulteration Test Strip  
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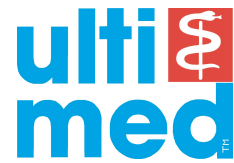


	C	0	10 mg/dL	20 mg/dL	100 mg/dL
21	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
28	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
35	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
42	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
56	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL
77	A	0	10 mg/dL	20 mg/dL	100 mg/dL
	B	0	10 mg/dL	20 mg/dL	100 mg/dL
	C	0	10 mg/dL	20 mg/dL	100 mg/dL

**Glutaraldehyde reagent pad:**

Day	Lot	Glutaraldehyde Standard Solution		
		Neg.	0.1 %	2.0 %
0	A	5/-	5/+	5/+
	B	5/-	5/+	5/+
	C	5/-	5/+	5/+
7	A	-	+	+
	B	-	+	+
	C	-	+	+
14	A	-	+	+
	B	-	+	+
	C	-	+	+
21	A	-	+	+
	B	-	+	+
	C	-	+	+
28	A	-	+	+
	B	-	+	+
	C	-	+	+
35	A	-	+	+
	B	-	+	+
	C	-	+	+
42	A	-	+	+
	B	-	+	+

**Stress sheet**  
Drug-Adulteration Test Strip  
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	C	-	+	+
56	A	-	+	+
	B	-	+	+
	C	-	+	+
77	A	-	+	+
	B	-	+	+
	C	-	+	+

**Nitrite reagent pad:**

Day	Lot	Nitrite Standard Solution		
		Neg.	20 mg/dL	50 mg/dL
0	A	5/-	5/20 mg/dL	5/50 mg/dL
	B	5/-	5/20 mg/dL	5/50 mg/dL
	C	5/-	5/20 mg/dL	5/50 mg/dL
7	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
14	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
21	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
28	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
35	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
42	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
56	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL
77	A	-	20 mg/dL	50 mg/dL
	B	-	20 mg/dL	50 mg/dL
	C	-	20 mg/dL	50 mg/dL

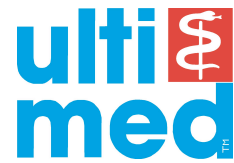
**Note:**

5/ or 5 mean five replicates

- mean negative result

+ mean positive result

**Stress sheet**  
Drug-Adulteration Test Strip  
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**Conclusion:** The Drug-Adulteration Test Strips is stable at 45°C for 77 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 production when stored properly in unopened canister with desiccant.

Ahrensburg, 28.09.2017

ulti med Products (Deutschland) GmbH

A handwritten signature in blue ink that reads "M. W. Engel".

Matthias W. Engel  
Managing Director