

## Stability Testing: ATP Test Devices

### Objective

Analyze stability of the ATP Test Devices at 15 months to support 15 month shelf-life.

### Analysis of Data

Data from final quality control testing was gathered from 6 lots each UltraSnap™, SuperSnap™, and AquaSnap™ over 15 months, at 3 month intervals, using SystemSURE™ Plus. RLU measurements at time of manufacture (time 0) were normalized to 100% stability. Over time, all reagents endure a natural decay, which is reflected as the percent stability. This percentage was then used to calculate theoretical RLU scores at various RLU levels, to estimate impact on Pass/ Caution/Fail results as stability declines.

### UltraSnap Results

**Table 1: UltraSnap Percent Stability**

	Time 0	3 months	6 months	9 months	12 months	15 months
Percent Stability	100%	100%	99%	92%	77%	71%

**Table 2: UltraSnap Theoretical RLU Scores**

SystemSURE Plus RLU	Time 0	3 months	6 months	9 months	12 months	15 months
5 RLUS	5	5	5	5	4	4
10 RLUS	10	10	10	9	8	7
20 RLUS	20	20	20	18	15	14
30 RLUS	30	30	30	28	23	21
40 RLUS	40	40	40	37	31	28
50 RLUS	50	50	49	46	38	35

### SuperSnap Results

**Table 3: SuperSnap Percent Stability**

	Time 0	3 months	6 months	9 months	12 months	15 months
Percent Stability	100%	99%	96%	88%	81%	76%

**Table 4: SuperSnap Theoretical RLU Scores**

SystemSURE Plus RLU	Time 0	3 months	6 months	9 months	12 months	15 months
5 RLUS	5	5	5	4	4	4
10 RLUS	10	10	10	9	8	8
20 RLUS	20	20	19	18	16	15
30 RLUS	30	30	29	26	24	23
40 RLUS	40	40	38	35	32	30
50 RLUS	50	50	48	44	40	38

## AquaSnap Results

**Table 5: AquaSnap Percent Stability**

	Time 0	3 months	6 months	9 months	12 months	15 months
Percent Stability	100%	94%	91%	87%	80%	76%

**Table 6: AquaSnap Theoretical RLU Scores**

SystemSURE Plus RLU	Time 0	3 months	6 months	9 months	12 months	15 months
5 RLUS	5	5	5	4	4	4
10 RLUS	10	9	9	9	8	8
20 RLUS	20	19	18	17	16	15
30 RLUS	30	28	27	26	24	23
40 RLUS	40	38	36	35	32	30
50 RLUS	50	47	46	44	40	38

## Conclusion

- At 15 months the overall loss is 24 to 29%, depending on product.
- For a typical user, using Pass=10 and Fail=30 limits:
  - At a Fail level of 30 RLUs, a test in the SystemSure Plus theoretically retested using a 15 month old UltraSnap would yield an RLU of 21. This means true fails above 30 RLUs will never be measured as a Pass (<10 RLUS).