

# CHRONO-LOG CORPORATION

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## Technical Report 6271 - CHRONO-PAR Reagent Stability Testing

### 1. Objective

The purpose of this study was to establish the stability of the CHRONO-PAR reagents for platelet aggregometry during shipping at ambient temperature. Tests were performed at 3 time points during the shelf life of the reagent. Whole Blood-Lumi Aggregation (WBA) and Light Transmission Aggregation (LTA) testing methods were used.

The study was performed at Medical Research Technology Laboratory, University of Maryland, Baltimore, Maryland, USA.

### 2. Reagent Information

The CHRONO-PAR reagents are intended to be used for analysis of platelet function via aggregation secretion studies in whole blood and platelet rich plasma.

### 3. Materials

Reagent	Part No.	Lot No.	Expiration Date
ADP	384	3400	1/2011
Arachidonic Acid	390	4191	7/2011
Collagen	385	3399	9/10
Epinephrine	393	B-913-2	5/2012
Ristocetin	396	B-1186-1	4/2012
Chrono-Lume	395	6170	5/2011

**Instrumentation Used:** Chrono-log Whole Blood/Optical Lumi-Aggregometer

### 4. Reagent Stability

Testing was done on one lot each of six CHRONO-PAR reagents. Each reagent was shipped at ambient temperature, stored in one of three different manners and then tested at various time points.

#### Storage Specifications:

Group A - Stored properly.\*

Group B – Stored at ambient temperature\*\* for 30 days, then stored properly\* for a minimum of 7 days

Group C – Stored properly\* for 72 hours, then stored at ambient temperature\*\* for 72 hours, followed by proper\* storage

\* Proper storage = According to the storage recommendations in the CHRONO-PAR reagent package insert.

\*\* Ambient temperature is approximately 72°F (22°C)

#### Assays:

Whole Blood-Lumi Aggregometry (WBA) and Light Transmission Aggregometry (LTA) was utilized. At each testing day citrated whole blood and/or platelet rich plasma from a single donor was analyzed in accordance with the Chrono-log Whole Blood-Lumi Aggregation and/or Chrono-log PRP Aggregation procedure on a Chrono-log Whole Blood/Optical Lumi-Aggregometer. Maximum Amplitude was evaluated. Tests were run following the manufacturer recommended procedures. A single donor was used throughout the study.

#### Stability Claim:

ADP: Until the expiration date when stored below 0°C

Arachidonic Acid:

Albumin: Until the expiration date stored in the refrigerator at 2-8°C

A/A Oily Drop: Until the expiration date when stored below -20°C

Collagen: Until the expiration date when stored in the refrigerator at 2-8°C

Epinephrine: Until the expiration date when stored in the refrigerator at 2-8°C

Ristocetin: Until the expiration date when stored in the refrigerator at 2-8°C

Chrono-Lume: Until the expiration date when stored below -20°C

#### Aim:

Chrono-log has been shipping reagents at ambient temperature for more than 30 years without incident. The object of this study was to verify that storage at ambient temperature would have no adverse effect on the reagents. We were looking to get equivalent results with three different storage conditions. Our aim was to get a CV of less than 15% which is considered normal for platelet aggregation.<sup>1</sup>

A random donor was selected for this study. There were no restrictions for diet or lifestyle which are known to effect platelet aggregation. Therefore we were unconcerned as to whether the results are within the normal range provided that all three results gave the same results.

<sup>1</sup>Mackie et al. Platelet Impedance Aggregation in Whole Blood and its Inhibition by Antiplatelet Drugs. J Clin Pathol 1984; 37: 874-878.

Results:

**Whole Blood-Lumi (WBA) Aggregometry**

REAGENT	Group A	Group B	Group C	MEAN	SD	CV
Arachidonic Acid @ 0.5 mM	12.67	11.33	10.00	11.3	1.33	12%
ADP @ 10 uM	12.67	12.00	10.67	11.8	1.02	9%
Collagen @ 1 ug/mL	30.67	29.67	31.33	30.6	0.84	3%
Collagen @ 5 ug/mL	43.67	35.00	38.67	39.1	4.35	11%
Ristocetin @ 1mg/mL	19.67	17.67	16.00	17.8	1.84	10%
Chrono-lume Kit	56%	53%	54%	54%	0.01	2%

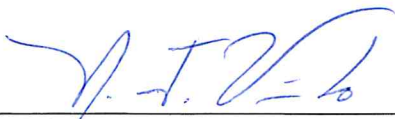
**Light Transmission (LTA) Aggregometry**

REAGENT	Group A	Group B	Group C	MEAN	SD	CV
Arachidonic Acid @ 0.5 mM	99.33	90.33	97.67	95.8	4.79	5%
ADP @ 10 uM	80.33	74.00	70.33	74.9	5.06	7%
Collagen @ 2 ug/mL	96.33	96.67	103.67	98.9	4.14	4%
Ristocetin @ 1.25mg/mL	94.33	82.00	98.33	91.6	8.51	9%
Epinephrine @ 10 uM	50.33	50.67	44.33	48.4	3.56	7%

Results and Conclusions:

The data shows that

1. The CHRONO-PAR reagents are stable when stored properly\* (Group A).
2. The CHRONO-PAR reagents are stable when stored at ambient temperature\*\* for 30 days before storing properly\* (Group B).
3. The CHRONO-PAR reagents are stable when subject to simulated shipping stress before storing properly\* (Group C).
4. The CHRONO-PAR reagents are not affected by transportation at ambient temperatures\*\*.



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3/21/16  
Date