A Hypothetical Experimental Study:
Plaque – Away®

I.   Objectives of the "Plaque – Away" Exercise:

1. To develop a critical understanding of the concepts and skills required in writing a laboratory report.
2. To analyze data and present it, using graphs, in a clear manner.
3. To interpret and draw meaningful conclusions from the data.

The 5 Sections of a Scientific Report

Most experimental studies that appear in scientific journals include the following 5 sections:

(1) Abstract Section
> A brief summary of the entire report, including the principle question being studied, the experimental results, and conclusions.

(2) Introduction Section
> Describes the principal question(s) [objective; hypothesis] of the scientific study and includes a discussion of background information.

(3) Materials and Methods Section
> Describes the experimental procedure to answer the question [test the hypothesis].

(4) Results (Data) Section
> Presents the data together with a statistical analysis of the results (may include Chi-squared tests; linear regression; analysis of variance, etc). Often using graphs to describe the relationships.

(5) Discussion (Summary) Section
> Describes whether or not these results and statistical analyses are consistent with the hypothesis being tested.

(6) Conclusions Section
> A brief conclusion of the entire study.

II.   Introduction:

The following is a hypothetical experiment concerning an imaginary drug, "Plaque – Away", which supposedly reverses the symptoms of atherosclerosis by lowering blood cholesterol levels. As the clinical researcher, you are to investigate the principal therapeutic actions by measuring the blood cholesterol levels over a 10-week period. Since every therapeutic drug may also produce side-effects ("adverse reactions"), you will also be monitoring for possible injury caused by the drug.

Injury to tissues is often monitored by measuring the level of certain enzymes in the blood. Different tissue cells in the body contain different types and amounts of enzymes. When these tissue cells are injured, the enzyme may leak out of the cells, increasing the level of the enzyme in the bloodstream - the greater the injury, the higher the plasma enzyme level. Therefore, elevated levels of certain enzymes in the bloodstream would indicate which tissues

have been injured, and to what extent. (Unrelated to tissue injury, abnormally low levels of an enzyme would indicate a deficiency due to a genetic disease.)

Read through the entire experiment, keeping in mind the kind of information and conclusions that are being sought. The Results Section provides the opportunity to make an organized statement of the data obtained, and to relate two or more sets of data; ex: in the form of a graph. Complete the Results (Data) Sections in this exercise and use separate sheets of graph paper, or a computer program, for plotting the data as indicated.

The Discussion (Summary) Section allows the experimenter to draw inferences from the stated results. You should provide a summary statement for each set of data obtained that synopsizes or recapitulates the outcome of the experiment. Then, as part of your conclusions, give 'the meaning' or the interpretation of these experimental outcomes. Specifically, what is the clinical significance of the Plaque-Away experiment? Draw conclusions as to the effectiveness of Plaque-Away, and its possible side effects.

Though hypothetical, the formal and logic of this lab are very similar to those carried out in actual clinical research.

The chart below lists some of the more common enzymes that are measured in the bloodstream and the clinical disorder associated with elevated levels:

ENZYME	NORMAL VALUE	INCREASED LEVEL
Acid Phosphatase (ACP)	0.2 – 0.8 IU/L	Cancer of Prostate
Alakline Phosphatase (ALP)	30 – 120 U/L	Bone Injury
Cholinesterase (ChE)	4.7 – 11.8 U/ml	Kidney Disease
Creatine Phosphokinase (CPK)	2 – 82 U/L	Muscle Injury
Gamma Glutamyl Transpeptidase (GGT)	< 45 U/L	Liver Disease Kidney Disease
Glutamic-Oxaloacetic Transaminase (GOT) [Aspartate Aminotransferase (AST)]	5 – 22 IU/L	Muscle Injury
Glutamic-Pyruvate Transaminase (GPT) [Alanine Aminotransferase (ALT)]	5 -22 U/ml	Liver Injury
Hydroxybutyric Dehydrogenase (HBD)	66 – 156 U/L	Muscle Injury
Isocitric Dehydrogenase	50 – 180 units	Liver Disease
Lactic Acid Dehydrogenase (LDH)	50 – 150 U/L	Muscle Injury
Alpha-Fetoprotein (AFP) (in amniotic fluid)	< 25 ug/L	Spina Bifida

III. Plasma Cholesterol Levels

(1) A plasma sample from a patient treated with Plaque-Away was obtained once each week for ten weeks.

(2) Plasma cholesterol levels were determined for each weekly sample [according to the methods outlined in Clinical Chemistry by Teitz]

(3) Absorbance values for the weekly plasma samples, blank solution, and standard (known) solution are recorded in the chart below:

Sample	Absorbance	Concentration (mg/100 ml)
Blank	0.0	0.0
Standard	0.5	200.0
Week 1	0.98	
Week 2	0.95	
Week 3	0.95	
Week 4	0.65	
Week 5	0.64	
Week 6	0.50	
Week 7	0.48	
Week 8	0.60	
Week 9	0.58	
Week 10	0.64	

(4) Complete the chart on the previous page by calculating the cholesterol concentration for each weekly plasma sample using the equation below:

$$\text{Concentration}_{(plasma)} = \frac{\text{Concentration}_{(standard)} \ X \ \text{Absorbance}_{(plasma)}}{\text{Absorbance}_{(standard)}}$$

(5) Prepare a graph showing the relationship between the:
  Plasma Cholesterol level (plotted on the y-axis)
  and the
  Number of Weeks using Plaque-Away (plotted on the x-axis).

(6) Normal values for cholesterol are 130-200 mg/100 ml.

IV. Serum GPT Levels

(1) Light absorbance values for a blank solution and a standard (known) solution of Glutamic-Pyruvate Transaminase [Alanine Aminotransferase (ALT)] is recorded in the chart below:

Sample	Absorbance	GPT (Units/ml)
Blank	0.00	0.0
50 Units/ml GPT solution	0.19	50.0

(2) Construct a standard curve by plotting the light absorbance of these solutions on the y-axis versus their known concentrations on the x-axis.

(3) A serum sample from a patient treated with Plaque-Away was obtained once each week for ten weeks.

(4) GPT levels were determined for each weekly sample [according to the methods outlined in Clinical Chemistry by Teitz].

(5) Absorbance values for these weekly plasma samples are recorded in the chart below:

Week	Absorbance	SGPT (Units/ml)
Week 1	0.03	
Week 2	0.04	
Week 3	0.05	
Week 4	0.14	
Week 5	0.23	
Week 6	0.27	
Week 7	0.25	
Week 8	0.35	
Week 9	0.30	
Week 10	0.34	

(6) Complete the chart above by using the GPT standard curve (prepared in Step 2) to determine the concentrations of the weekly plasma samples.

(7) Prepare a graph showing the relationship between the serum GPT level (plotted on the y-axis) and the number of weeks using Plaque-Away (plotted on the x-axis).

(8) Normal values for serum GPT are 5 – 22 Units/ml.

V.   Comparison of Plasma Cholesterol with SGPT Levels

(1) Prepare a graph showing both the relationship between the plasma cholesterol level (plotted on the left y-axis) and the serum GPT level (plotted on the right y-axis) and the number of weeks using Plaque-Away (plotted on the x-axis). Use a different color for each line graphed.