



Protocol

For samples that will be analyzed to meet GLP standards, the protocol must identify the collection time, the tests and the lab performing the analysis. It is best to also describe any sub-groups or differences between collection periods in the Clinical Pathology section of the protocol.

A few examples are provided to give an understanding of the detail to provide.

Clinical Pathology Evaluations

Clinical investigations (hematology, clinical chemistry, and urinalysis) will be conducted on 10 animals/group/sex at Week 6 and at termination. The order of bleeding and analysis will be alternating (1 animal from each dose group, then repeating) in order to reduce handling and time biases. All blood samples will be obtained from CO₂/O₂ anesthetized animals by puncture of the retroorbital sinus. Animals will be fasted overnight (approximately 16 to 18 hours) prior to the bleeding procedures. The exact time period the animals are fasted will be documented. Individual urine samples will be collected in metabolism cages over a 24-hour period during the week prior to the terminal sacrifice. Samples will be collected and stored as required for proper analysis. Samples will be sent by overnight delivery to:

ANTECH Diagnostics® GLP
600 Airport Blvd. Suite 500
Morrisville, NC 27560

The following parameters will be determined:

Hematology

Erythrocyte Count

Hematocrit

Hemoglobin

Mean Corpuscular Volume (MCV)

Mean Corpuscular Hemoglobin (MCH)

Mean Corpuscular Hemoglobin Concentration (MCHC)

Platelet Count

Total Leukocyte Count

Differential Leukocyte Count

Reticulocyte Count

ANTECH® GLP

600 Airport Blvd. Suite 500 | Morrisville, NC 27560
919.277.0822 | Fax: 919.277.0825

Clinical Chemistry

Alanine Aminotransferase (ALT)	Creatinine
Alkaline Phosphatase (ALK)	Glucose
Aspartate Aminotransferase (AST)	Total Protein
Creatine Kinase (CK)	Albumin
Gamma-glutamyl transferase (GGT)	Globulin (calculated)
Sorbitol Dehydrogenase (SDH)	Phosphorus
Bilirubin, Total	Sodium
Bilirubin, Direct; if Total Bilirubin >1.0 mg/dL	Potassium
Bilirubin, Indirect (calculated)	Chloride
Calcium	Urea Nitrogen

Urinalysis

specific gravity	blood1
pH1	urobilinogen1
protein1	total volume
glucose1	color and appearance
ketones1	microscopic elements
bilirubin1	

1 Semiquantitative

If only a specific test is to be completed at ANTECH Diagnostics®, please specify the testing to be completed at ANTECH Diagnostics®. Using the example above:

Clinical Chemistry

Alanine Aminotransferase (ALT)
Alkaline Phosphatase (ALK)
Aspartate Aminotransferase (AST)
Creatine Kinase (CK)
Gamma-glutamyl transferase (GGT)
Sorbitol Dehydrogenase (SDH)
Bilirubin, Total
Bilirubin, Direct; if Total Bilirubin >1.0 mg/dL
Bilirubin, Indirect (calculated)
Calcium

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Creatinine
Glucose
Total Protein
Albumin
Globulin (calculated)
Phosphorus
Sodium
Potassium
Chloride
Urea Nitrogen
Thyroid Stimulating Hormone (TSH)2
Thyroxine (T4) 2
Triiodotyronine (T3) 2

Analyses to be performed at:
ANTECH Diagnostics® GLP
600 Airport Blvd., Suite 500
Morrisville, NC 27560

Or

Urea Nitrogen
A separate 2.0 mL of blood will be collected and the serum sent to:
ANTECH Diagnostics® GLP
600 Airport Blvd., Suite 500
Morrisville, NC 27560

for determination of the following parameters:

Thyroid Stimulating Hormone (TSH)
Thyroxine (T4)
Triiodotyronine (T3)

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