

For Veterinary use only
Customer and Technical Service 1-800-822-2947

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1. Intended Use

The VetScan[®] Equine Profile Plus reagent rotor used with the VetScan Classic and VetScan VS2 Electrolytes, Immunoassay and blood gas Chemistry Analyzer utilizes dry and liquid reagents to provide *in vitro* quantitative determinations of albumin (ALB), aspartate aminotransferase (AST), blood urea nitrogen (BUN), total calcium (CA⁺⁺), creatine kinase (CK), creatinine (CRE), gamma glutamyl transferase (GGT), glucose (GLU), total bilirubin (TBIL), total protein (TP), potassium (K⁺), sodium (Na⁺), and total carbon dioxide (tCO₂) in heparinized whole blood, heparinized plasma, or serum. Certain analytes have been optimized for equine only.

2. Summary and Explanation of Tests

The VetScan Equine Profile reagent rotor and the VetScan Classic and VetScan VS2 Electrolytes, Immunoassay and blood gas Chemistry Analyzer comprise an *in vitro* diagnostic system that aids the veterinarian in diagnosing the following disorders:

Albumin (ALB)	Liver and kidney disease.
Aspartate Aminotransferase (AST)	Liver disease including hepatitis and viral jaundice; shock; and muscle damage. Used in conjunction with CK to assess muscle damage.
Blood Urea Nitrogen (BUN)	Liver and kidney diseases.
Calcium (CA⁺⁺)	Parathyroid, bone and chronic renal disease; tetany.
Creatine Kinase (CK)	Muscle damage, convulsions, heart disease; hypothyroidism; severe exercise, physical inactivity, decreased muscle mass.
Creatinine (CRE)	Renal disease.
Gamma glutamyl transferase (GGT)	Liver disease, primary and secondary liver tumors.
Glucose (GLU)	Diabetes, hyperglycemia, hypoglycemia, and liver disease.
Total Bilirubin (TBIL)	Hepatic disorders.
Total Protein (TP)	Dehydration; liver and kidney disease, metabolic and nutritional disorders.
Potassium (K⁺)	Renal glomerular or tubular disease, adrenocortical insufficiency, diabetic ketacidosis, excessive intravenous potassium therapy, sepsis, panhypopituitarism, <i>in vitro</i> hemolysis, hyperaldosteronism, malnutrition, hyperinsulinism, metabolic alkalosis and gastrointestinal loss.
Sodium (Na⁺)	Dehydration, diabetes insipidus, loss of hypotonic gastrointestinal fluids, salt poisoning, selective depression of sense of thirst, skin losses, burns, sweating, hyperaldosteronism, CNS disorders, dilutional, depletion and delusional hyponatremia and syndrome of inappropriate ADH secretion.

Total Carbon Dioxide (tCO₂)

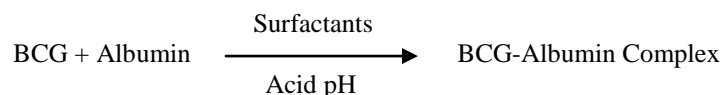
Primary metabolic alkalosis and acidosis and primary respiratory alkalosis and acidosis.

As with any diagnostic test procedure, all other test procedures including the clinical status of the patient should be considered prior to final diagnosis.

3. Principles of Procedure

Albumin (ALB)

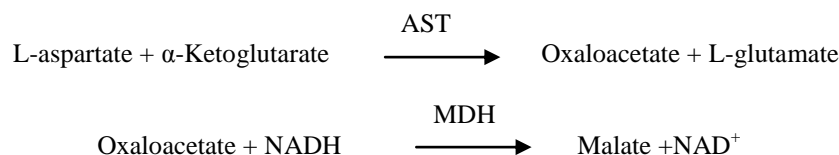
Dye binding techniques are the most frequently used methods for measuring albumin. Bromocresol green (BCG) is the most commonly used of the dye binding methods.¹



Bound albumin is proportional to the concentration of albumin in the sample. This is an endpoint reaction that is measured bichromatically at 630 nm and 405 nm.

Aspartate Aminotransferase (AST)

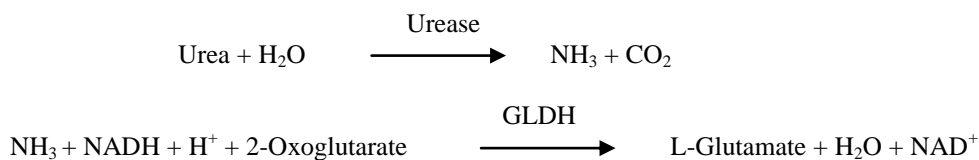
The Abaxis AST method is a modification of the IFCC reference method.^{2,3} This method catalyzes the reaction of L-aspartate and α -ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidized to NAD⁺ by the enzyme malate dehydrogenase (MDH).



The rate of absorbance change caused by the conversion of NADH to NAD⁺ is determined bichromatically at 340 nm and 405 nm. This rate is directly proportional to the amount of AST present in the sample.

Blood Urea Nitrogen (BUN)

A coupled-enzymatic reaction is used by the Abaxis system. In this reaction, urease hydrolyzes urea into ammonia and carbon dioxide.⁴ Upon combining ammonia with 2-oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD⁺.

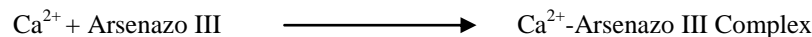


The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD⁺ and is directly proportional to the amount of urea present in the sample.

Total Calcium (CA⁺⁺)

The reference method for calcium is atomic absorption spectroscopy; however, this method is not suited for routine use.⁵ Spectrophotometric methods using either *o*-cresolphthalein complexone (CPC) or arsenazo III metallochromic indicators are most commonly used.⁶⁻⁸ Arsenazo III has a high affinity for calcium and is not as temperature dependent as CPC.

Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.



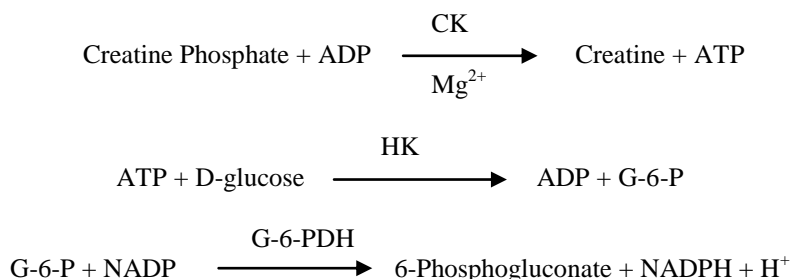
The endpoint reaction is monitored at 405 nm, 467 nm and 600 nm. The amount of calcium in the sample is proportional to the absorbance.

Creatine Kinase (CK)

Creatine kinase catalyzes the reversible phosphorylation of creatine by adenosine triphosphate (ATP). The phosphorylation reaction is favored by alkaline conditions (optimum at 9.0) and the dephosphorylation reaction is favored by acidic conditions (optimum at pH 6.5 at 37° C). Early CK measurement methods were based on the “forward reaction” with creatine phosphate and adenosine diphosphate (ADP) as the products.⁹⁻¹¹ The sensitivity of these tests was shown to be low due to problems with interferences. The procedure of choice utilizes the “reverse reaction” coupled with a reaction to produce NADPH, which is directly related to CK levels.¹²⁻¹⁴

The CK measurement procedure used by Abaxis is a modified version of the International Federation of Clinical Chemistry method (IFCC).¹⁵ Key modifications are sample volume fraction, buffer and temperature. N-acetyl cysteine (NAC) has been added to reactivate the CK.¹⁶ Magnesium is used as a cofactor for both CK and hexokinase. EDTA has been added as a stabilizer for NAC and for the removal of various cations, such as calcium and iron that inhibit CK. P¹, P⁵-di (adenosine-5') penta phosphate and adenosine monophosphate (AMP) have also been added to inhibit adenylate kinase, another skeletal muscle and erythrocyte enzyme that reacts with the substrates used to measure CK.

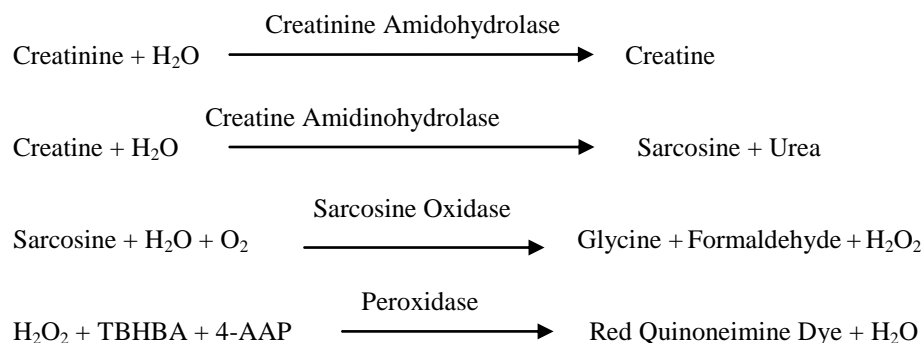
Creatine kinase catalyzes the formation of creatine and ATP from creatine phosphate and ADP at pH 6.7. With hexokinase (HK) as a catalyst, ATP reacts with D-glucose to form ADP and D-glucose-6-phosphate (G-6-P), which is reacted with nicotinamide adenine dinucleotide phosphate (NADP) in the presence of glucose-6-phosphate dehydrogenase (G-6-PDH) to produce G-6-P and NADPH.



The formation of NADPH is measured as a change in absorbance at 340 nm relative to 405 nm. This absorbance change is directly proportional to creatine kinase activity in the sample.

Creatinine (CRE)

The Jaffe method, first introduced in 1886, is still a commonly used method of determining creatinine levels in blood. The current reference method combines the use of Fuller's earth (floridin) with the Jaffe technique to increase the specificity of the reaction.^{17,18} Enzymatic methods have been developed that are more specific for creatinine than the various modifications of the Jaffe technique.^{19, 20,21} Methods using the enzyme creatinine amidohydrolase eliminate the problem of ammonium ion interference found in techniques using creatinine iminohydrolase.²²

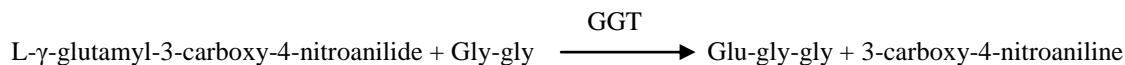


Two cuvettes are used to determine the concentration of creatinine in the sample. Endogenous creatine is measured in the blank cuvette, which is subtracted from the combined endogenous creatine and the creatine formed from the enzyme reactions in the test cuvette. Once the endogenous creatine is eliminated from the calculations, the concentration of creatinine is proportional to the intensity of the red color produced. The endpoint reaction is measured as the difference in absorbance between 550 nm and 600 nm.

Gamma Glutamyl Transferase (GGT)

The first quantitative methods developed to measure gamma glutamyl transferase (GGT) involved a second reaction to form an azo dye that combined with a chromophore.^{23,24} The change to L- γ -glutamyl-*p*-nitroanilide as the substrate in the reaction eliminated the dye-formation step.²⁵ Due to the poor solubility and stability of L- γ -glutamyl-*p*-nitroanilide, this procedure was modified to use the substrate L- γ -glutamyl-3-carboxy-4- nitroanilide.²⁶ The International Federation of Clinical Chemistry (IFCC) recommended GGT method is based on the latter substrate, with glycylglycine as the other substrate.²⁷

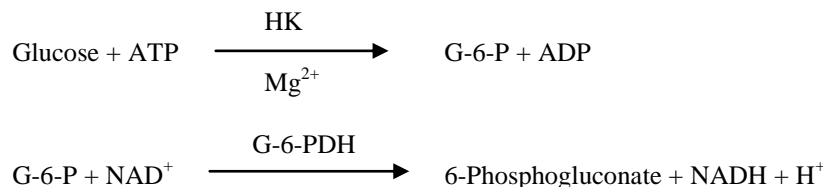
Abaxis has modified the IFCC method to react at 37° C. The addition of sample containing gamma glutamyl transferase to the substrates L- γ -glutamyl-3-carboxy-4- nitroanilide and glycylglycine (gly-gly) causes the formation of L- γ -glutamyl-glycylglycine (glu-gly-gly) and 3-carboxy-4-nitroaniline.



The absorbance of this rate reaction is measured at 405 nm. The production of 3-carboxy-4-nitroaniline is directly proportional to the GGT activity in the sample.

Glucose (GLU)

Measurements of glucose concentration were first performed using copper-reduction methods (such as Folin-Wu and Somogyi-Nelson).^{28, 29, 30} The lack of specificity in copper-reduction techniques led to the development of quantitative procedures using the enzymes hexokinase and glucose oxidase. The Abaxis glucose is a modified version of the hexokinase method, which has been proposed as the basis of the glucose reference method.³¹ The reaction of glucose with adenosine triphosphate (ATP), catalyzed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide (NAD⁺) to NADH.



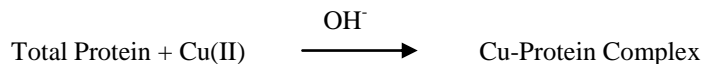
Total Bilirubin (TBIL)

Total bilirubin levels have typically been measured by tests employing diazotized sulfanilic acid^{32, 33} or the enzyme bilirubin oxidase.³⁴⁻³⁶ The total bilirubin test method used in this rotor makes use of a direct trichromatic photometric measurement of diluted sample to determine the total bilirubin concentration. The primary wavelength used to directly measure total bilirubin is 467 nm. Additional measurements at 340 and 405 nm are used to correct the bilirubin absorbance for absorbances from other possible endogenous substances in the sample. The resulting absorbance value at 467 nm is directly proportional to the total bilirubin concentration based on calibration of bilirubin in horse serum.

Total Protein (TP)

The total protein method is a modification of the biuret reaction, noted for its precision, accuracy, and specificity.³⁷ It was originally developed by Riegler and modified by Weichselbaum, Doumas, et al. The biuret reaction is a candidate total protein reference method.³⁸⁻⁴⁰

In the biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. Sodium potassium tartrate and potassium iodide are added to prevent the precipitation of copper hydroxide and the auto-reduction of copper, respectively.³⁷ The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a colored Cu-Protein complex.

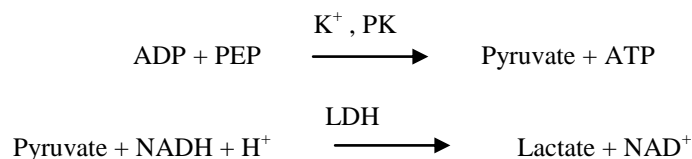


The amount of total protein present in the sample is directly proportional to the absorbance of the Cu-protein complex. The total protein test is an endpoint reaction and the absorbance is measured as the difference in absorbance between 550 nm and 850 nm.

Potassium (K⁺)

Spectrophotometric methods have been developed that allow the measurement of potassium concentration on standard clinical chemistry instrumentation. An enzymatic method based on the activation of pyruvate kinase with potassium show excellent linearity and negligible susceptibility to endogenous substances.^{51, 52, 53} Interference from sodium and ammonium ion are minimized with the addition of Kryptofix and glutamine synthetase, respectively.²⁰

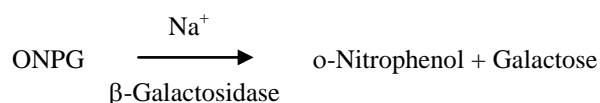
In the coupled-enzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD⁺.



The rate of change in absorbance difference between 340 nm and 405 nm is due to the conversion of NADH to NAD⁺ and is directly proportional to the amount of potassium in the sample.

Sodium (Na⁺)

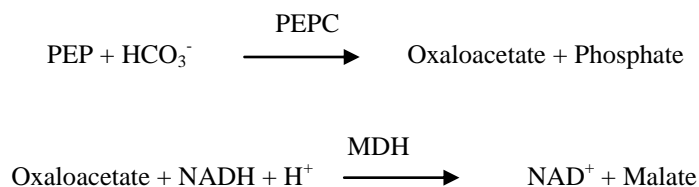
Colorimetric and enzymatic methods have been developed that allow the measurement of sodium concentration on standard clinical chemistry instrumentation.^{54, 55, 56} In the Abaxis enzymatic reaction, β-galactosidase is activated by the sodium in the sample. The activated enzyme catalyzes the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenol and galactose.



Total Carbon Dioxide (tCO₂)

Total carbon dioxide in serum or plasma exists as dissolved carbon dioxide, carbamino derivatives of proteins, bicarbonate and carbonate ions and carbonic acid. Total carbon dioxide can be measured by pH indicator, CO₂ electrode and spectrophotometric enzymatic methods, which all produce accurate and precise results.^{57, 58} The enzymatic method is well suited for use on a routine blood chemistry analyzer without adding complexity.

In the enzymatic method, the specimen is first made alkaline to convert all forms of carbon dioxide (CO₂) toward bicarbonate (HCO₃⁻). Phosphoenolpyruvate (PEP) and HCO₃⁻ then react to form oxaloacetate and phosphate in the presence of phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyzes the reaction of oxaloacetate and reduced nicotinamide adenine dinucleotide (NADH) to NAD⁺ and malate. The rate of change in absorbance due to the conversion of NADH to NAD⁺ is directly proportional to the amount of tCO₂ in the sample.



4. Principle of Operation

See the VetScan Chemistry Analyzer Operator's Manual and/ or the VetScan VS2 Operator's manual, for the Principles and Limitations of the Procedure.

5. Description of Reagents

Each VetScan Equine Profile reagent rotor contains dry test specific reagent beads. A dry sample blank reagent (comprised of buffer, surfactants, excipients and preservatives) is included in each reagent rotor for use in calculating concentrations of albumin, aspartate aminotransferase, blood urea nitrogen, calcium, creatine kinase, creatinine, gamma glutamyl transferase, glucose, total bilirubin, and total protein. Dedicated sample blanks are included in the rotor to calculate the concentration of creatinine, total bilirubin and total protein levels. Each reagent rotor also contains a diluent consisting of surfactants and preservatives.

Warnings and Precautions

- For Veterinary *In vitro* Diagnostic Use
- The diluent container in the reagent rotor is automatically opened when the analyzer drawer closes. A rotor with an opened diluent container cannot be re-used. Ensure that the sample or control has been placed into the rotor before closing the drawer.
- Reagent beads may contain acids or caustic substances. The operator does not come into contact with the reagent beads when following the recommended procedures. In the event that the beads are handled (e.g. cleaning up after dropping and cracking a reagent rotor), avoid ingestion, skin contact, or inhalation of the reagent beads.
- Some reagent beads contain sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Reagents will not come into contact with lead and copper plumbing when following recommended procedures. However, if the reagents do come into contact with such plumbing, flush with a large volume of water to prevent azide buildup.

Instructions for Reagent Handling

Reagent rotors may be used directly from the refrigerator without warming. Open the sealed foil pouch and remove the rotor being careful not to touch the bar code ring located on the top of the reagent rotor. Use according to the instructions provided in the VetScan Operator's Manual. A rotor not used within 20 minutes of opening the pouch should be discarded. Rotors in opened pouches cannot be placed back in the refrigerator for use at a later time.

Storage

Store reagent rotors in their sealed pouches at 2-8°C (36-46°F). Do not expose opened or unopened rotors to direct sunlight or temperatures above 32°C (90°F). Do not allow the rotors sealed in their foil pouches to remain at room temperature longer than 48 hours prior to use. Open the pouch and remove the rotor just prior to use.

Indications of Reagent Rotor Instability or Deterioration

- All reagents contained in the reagent rotor, when stored as described above, are stable until the expiration date printed on the rotor pouch. Do **not** use a rotor after the expiration date. The expiration date is also encoded in the bar code printed on the bar code ring. An error message will appear on the VetScan Chemistry Analyzer display if the reagents have expired.
- A torn or otherwise damaged pouch may allow moisture to reach the unused rotor and adversely affect reagent performance. Do not use a rotor from a damaged pouch.

6. Instrument

See the VetScan Operator's Manual for complete information on using the analyzer.

7. Sample Collection and Preparation

The minimum required sample size is ~100 µL of heparinized whole blood, heparinized plasma, serum or control. The reagent rotor sample chamber can contain up to 120 µL of sample.

- Specimens collected in a heparinized micropipette should be dispensed into the reagent rotor **immediately** following sample collection.
- Use only lithium heparin (green stopper) evacuated specimen collection tubes for whole blood or plasma samples. Use no additive (red stopper) evacuated specimen collection tubes or serum separator tubes (red or red/black stopper) for serum samples.
- Whole blood samples obtained by venipuncture must be homogenous before transferring a sample to the reagent rotor. Gently invert the collection tubes several times just prior to sample transfer. Do **not** shake the collection tube. Shaking may cause hemolysis.
- The test must be started within 10 minutes of transferring the sample into the reagent rotor.
- Whole blood venipuncture samples should be run within 60 minutes of collection; if this is not possible, separate the sample and transfer it into a clean test tube.⁴¹ Run the separated plasma or serum sample within 5 hours of centrifugation. If this is not possible, refrigerate the sample in a stoppered test tube at 2-8°C (36-46°F) for no longer than 48 hours. A plasma or serum sample can be stored at -10°C (14°F) for up to 5 weeks in a freezer that does not have a self-defrost cycle.
- **Glucose** concentrations decrease approximately 5-12 mg/dL in 1 hour in uncentrifuged samples stored at room temperature.⁴²
- Refrigerating whole blood samples can cause significant changes in concentrations of **glucose** and **creatinine**.⁴³
- **Total bilirubin** results may be adversely affected by photodegradation.⁴⁴ Whole blood samples not run immediately should be stored in the dark for no longer than 60 minutes. If the sample can not be analyzed within that period, it should be separated into plasma or serum and stored in a capped sample tube in the dark at low temperatures.⁴⁵

- The concentration of total carbon dioxide is most accurately determined when the assay is done immediately after opening the tube and as promptly as possible after collection and processing of the blood in the unopened tube. Ambient air contains far less carbon dioxide than does plasma, and gaseous dissolved carbon dioxide will escape from the specimen into the air, with a consequent decrease in carbon dioxide value of up to 6 mmol/L in the course of 1 hour.⁵⁹
- Falsely elevated **CK** values may be reported due to aspiration of tissue fluid from subcutaneous muscles in proximity to the jugular vein. In these cases, careful venipuncture technique of an adequately restrained patient with attachment of the collection tube only after collection needle is well within the lumen of the vessel will reduce incidence of falsely elevated CK values due to difficult venipuncture.

Known Interfering Substances

- The only anticoagulant recommended for use with the VetScan Chemistry Analyzer is lithium heparin. Abaxis has performed studies demonstrating that EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one chemistry in the VetScan Equine Profile reagent rotor.
- Physical interferents (hemolysis, icterus, and lipemia) may cause changes in the reported concentrations of some analytes. The sample indices are printed on the bottom of each result card to inform the operator about the levels of interferents present in each sample. The VetScan Chemistry Analyzer suppresses any results that are affected by >10% interference from hemolysis, lipemia, or icterus. “HEM”, “LIP”, “ICT” is printed on the result card in place of the result.
- Bilirubin may interfere with the peroxidase used in the **creatinine** reaction.⁴⁶ Creatinine results are lowered when bilirubin levels are > 10 mg/dL.
- **Glucose** concentrations are affected by the length of time since the patient has eaten and by the type of sample collected from the patient. To accurately interpret glucose results, samples should be obtained from a patient that has been fasted for at least 12 hours.⁴⁷
- Interference may be seen in the total protein test when analyzing samples with a 3 + lipemic index.⁴⁵ Samples with a triglyceride concentration >400 mg/dL may show an increased total protein level. The VetScan Chemistry Analyzer suppresses any results that are affected by >10% interference from lipemia. “LIP” is printed on the result card in place of the result.
- Creatine kinase is inactivated both by bright daylight and by increasing specimen pH owing to loss of carbon dioxide; accordingly, specimens should be stored in the dark in tightly closed tubes.⁴⁸
- The potassium assay in the VetScan system is a coupled pyruvate kinase (PK) / lactate dehydrogenase (LDH) assay. Therefore, in cases of extreme muscle trauma or highly elevated levels of creatine kinase (CK), the VetScan may recover a falsely elevated potassium (K+) value. In such cases, unexpected high potassium recoveries need to be confirmed utilizing a different methodology

8. Procedure

Materials provided

- One VetScan Equine Profile Plus Reagent Rotor PN: 500 – 1043 (a box of 12 discs PN: 500-0043-12)

Materials required but not provided

- VetScan Chemistry Analyzer

Test parameters

The VetScan System operates at ambient temperatures between 15°C and 32°C (59-90°F). The analysis time for each VetScan Equine Profile Reagent Rotor is less than 14 minutes. The analyzer maintains the reagent rotor at a temperature of 37°C (98.6°F) over the measurement interval.

Test procedure

The complete sample collection and step-by-step operating procedures are detailed in the VetScan Operator’s Manual.

Calibration

The VetScan Chemistry Analyzer is calibrated by the manufacturer before shipment. The barcode printed on the barcode ring provides the analyzer with rotor-specific calibration data. Please see the VetScan Operator’s Manual.

Quality control

Controls may be run periodically on the VetScan Chemistry Analyzer to verify the accuracy of the analyzer. Abaxis recommends that a serum-based commercially available control be run. Run controls on the reagent rotor in the same manner as for patient samples. See the VetScan Operator’s Manual to run controls.

9. Results

The VetScan Chemistry Analyzer automatically calculates and prints the analyte concentrations in the sample. Details of the endpoint and rate reaction calculations are found in the VetScan Operator's Manual.

10. Limitations of Procedure

General procedural limitations are discussed in the VetScan Systems Operator's Manual.

- **If a result for a particular test exceeds the assay range, the sample should be analyzed by another approved test method or sent to a referral laboratory.**
- Samples with hematocrits in excess of 60% packed red cell volume may give inaccurate results. Samples with high hematocrits may be reported as hemolyzed. These samples may be spun down and the plasma then re-run in a new reagent rotor.

Warning: Extensive testing of the VetScan Chemistry Analyzer has shown that in very rare instances, sample dispensed into the reagent rotor may not flow smoothly into the sample chamber. Due to the uneven flow, an inadequate quantity of sample may be analyzed and several results may fall outside your established reference ranges. The sample may be re-run using a new reagent rotor.

11. Expected Values

These normal intervals are provided only as a guideline. The most definitive reference intervals are those established for your patient population. Test results should be interpreted in conjunction with the patient's clinical signs. To customize specific normal ranges in your VetScan Chemistry Analyzer for the "Other" bank, refer to your VetScan Operator's Manual under the Menu Key functions.

Table 1: Reference Intervals

	Equine	Canine	Feline
ALB	2.2 – 3.7 g/dL (22 – 37 g/L)	2.5 – 4.4 g/dL (25 – 44 g/L)	2.2 – 4.4 g/dL (22 – 44 g/L)
AST	175 – 340 U/L	14 – 45 U/L	12 – 43 U/L
BUN	7 – 25 mg/dL (2.5 – 8.9 mmol/L)	7 – 25 mg/dL (2.5 – 8.9 mmol/L)	10 – 30 mg/dL (3.6 – 10.7 mmol/L)
CA⁺⁺	11.5 – 14.2 mg/dL (2.9 – 3.6 mmol/L)	8.6 – 11.8 mg/dL (2.2 – 3.0 mmol/L)	8.0 – 11.8 mg/dL (2.0 – 3.0 mmol/L)
CK	120 – 470 U/L	20 – 200 U/L	50 – 450 U/L
CRE	0.6 – 2.2 mg/dL (0.53 – 194 µmol/L)	0.3 – 1.4 mg/dL (27 – 124 µmol/L)	0.3 – 2.1 mg/dL (27 – 186 µmol/L)
GGT	5 – 24 U/L	0 – 7 U/L	0 – 2 U/L
GLU	65 – 110 mg/dL (3.6 – 6.1 mmol/L)	60 – 110 mg/dL (3.3 – 6.1 mmol/L)	70 – 150 mg/dL (3.9 – 8.3 mmol/L)
TBIL	0.5 – 2.3 mg/dL (9 – 39 µmol/L)	0.1– 0.6 mg/dL (2 – 10 µmol/L)	0.1– 0.6 mg/dL (2 – 10 µmol/L)
TP	5.7 – 8.0 g/dL (57 – 80 g/L)	5.4 – 8.2 g/dL (54 – 82 g/L)	5.4 – 8.2 g/dL (54 – 82 g/L)
Potassium (K⁺)	3.7-5.8 mmol/L	3.7-5.8 mmol/L	2.5-5.2 mmol/L
Sodium (Na⁺)	138-160 mmol/L	142-164 mmol/L	126-146 mmol/L
Total Carbon Dioxide (tCO₂)	12-27 mmol/L	15-24 mmol/L	20-33 mmol/L

12. Performance Characteristics (Linearity)

The chemistry for each analyte is linear over the dynamic range listed below when the VetScan System is operated according to the recommended procedure (see the VetScan Operator's Manual). The Dynamic Range table referenced below represents the spectrum that the VetScan System can detect. **The intervals below do not represent normal ranges.**

Table 2: VetScan Dynamic Ranges

Analyte	Dynamic Ranges Common Units	SI Units
ALB	1-6.5 g/dL	10-65 g/L
AST	5-2000 U/L	5-2000 U/L
BUN	2-180mg/dL	0.7-64.3 mmol urea/L
CA ⁺⁺	4 -16 mg/dL	1.0-4.0 mmol/L
CRE	0.2-20 mg/dL	18-1768µmol/L
CK	5-14,000 U/L	5-14,000 U/L
GGT	5-3000 U/L	5-3000 U/L
GLU	10-700 mg/dL	0.6-39mg/dL
TBIL	0.1-30 mg/dL	1.7-513 µmol/L
TP	2-14 g/dL	20-140 g/L
K ⁺	1.5-8.5 mmol/L	1.5-8.5 mmol/L
Na ⁺	110-170 mmol/L	110-170 mmol/L
TCO2	5-40 mmol/L	5-40mmol/L

Precision

Precision studies were conducted using the NCCLS EP5-A.⁴⁹ Guidelines with modifications based on NCCLS EP18-P⁵⁰ for unit-use devices. Results for within-run and total precision were determined by testing bi-level controls.

Table 3: Precision

Analyte	Sample Size	Within-Run	Total
Albumin-BCG (g/dL)	n=80		
<u>Control 1</u>			
Mean		3.9	3.9
SD		0.13	0.14
%CV		3.3	3.6
<u>Control 2</u>			
Mean		2.3	2.3
SD		0.09	0.10
%CV		3.9	4.3
Aspartate Aminotransferase (U/L)	n=80		
<u>Control 1</u>			
Mean		47	47
SD		0.98	0.92
%CV		2.1	2.0
<u>Control 2</u>			
Mean		145	145
SD		1.83	1.70
%CV		1.3	1.2

Table 3: Precision (Continued)

Analyte	Sample Size	Within-Run	Total
Blood Urea Nitrogen (mg/dL)	n=120		
<u>Control 1</u>			
Mean		19	19
SD		0.35	0.40
%CV		1.8	2.1
<u>Control 2</u>			
Mean		65	65
SD		1.06	1.18
%CV		1.6	1.8
Calcium (mg/dL)	n=80		
<u>Control 1</u>			
Mean		8.6	8.6
SD		0.21	0.25
%CV		2.4	2.9
<u>Control 2</u>			
Mean		11.8	11.8
SD		0.39	0.40
%CV		3.3	3.4
Creatinine (mg/dL)	n=80		
<u>Control 1</u>			
Mean		1.1	1.1
SD		0.14	0.14
%CV		12.7	12.7
<u>Control 2</u>			
Mean		5.2	5.2
SD		0.23	0.27
%CV		4.4	5.2
Creatine Kinase (U/L)	n=120		
<u>Control 1</u>			
Mean		105	105
SD		2.89	3.74
%CV		2.8	3.6
<u>Control 2</u>			
Mean		469	469
SD		12.23	28.32
%CV		2.6	6.0
Glucose (mg/dL)	n=80		
<u>Control 1</u>			
Mean		66	66
SD		0.76	1.03
%CV		1.2	1.6
<u>Control 2</u>			
Mean		278	278
SD		2.47	3.84
%CV		0.9	1.4
Total Bilirubin (mg/dL)	n=80		
<u>Control 1</u>			
Mean		0.8	0.8
SD		0.06	0.07
%CV		7.5	8.8

Table 3: Precision (Continued)

Analyte	Sample Size	Within-Run	Total
<u>Control 2</u>			
	Mean	5.2	5.2
	SD	0.09	0.15
	%CV	1.7	2.9
Total Protein (g/dL)	n=80		
<u>Control 1</u>			
	Mean	6.8	6.8
	SD	0.05	0.08
	%CV	0.7	1.2
<u>Control 2</u>			
	Mean	4.7	4.7
	SD	0.09	0.09
	%CV	1.9	1.9
Potassium (mmol/L)	n=80		
<u>Control 1</u>			
	Mean	6.7	6.7
	SD	0.26	0.26
	%CV	3.9	3.9
<u>Control 2</u>			
	Mean	4.3	4.3
	SD	0.22	0.22
	%CV	5.1	5.1
Sodium (mmol/L)	n=80		
<u>Control 1</u>			
	Mean	148	148
	SD	5.1	5.1
	%CV	3.4	3.4
<u>Control 2</u>			
	Mean	118	118
	SD	3.2	3.2
	%CV	2.7	2.7
Total Carbon Dioxide (mmol/L)	n=80		
<u>Control 1</u>			
	Mean	19	19
	SD	1.39	1.39
	%CV	7.3	7.3
<u>Control 2</u>			
	Mean	9	9
	SD	0.60	0.60
	%CV	6.8	6.8

Correlation

Field studies were conducted at a veterinary teaching hospital. Serum samples were analyzed by the VetScan Chemistry Analyzer and a comparative method. Representative correlation statistics are shown in Table 4.

Table 4: Correlation of the VetScan Chemistry Analyzer with Comparative Method(s)

	Sample Type	Correlation Coefficient	Slope	Intercept	N	Sample Range
Albumin (g/dL)	Equine	0.89	0.99	-0.6	7 - 101	1.2 - 3.2
	Canine	0.96	0.99	0.1	22 - 180	1.3 - 4.6
	Feline	0.75	1.02	0	21 - 55	2.1 - 4.8
Aspartate Aminotransferase (U/L)	Equine	1.00	0.94	16	7 - 101	107 - 1787
	Canine	1.00	1.02	1	22 - 180	18 - 176
	Feline	1.00	1.03	1	21 - 55	18 - 125
Blood Urea Nitrogen (mg/dL)	Equine	1.00	0.95	-1	7 - 101	3 - 64
	Canine	1.00	0.98	-2	22 - 180	4 - 117
	Feline	1.00	1.07	-5	21 - 55	14 - 165
Calcium (mg/dL)	Equine	0.94	1.18	-0.8	7 - 101	7.2 - 15.1
	Canine	0.84	1.24	-1.9	22 - 180	7.3 - 13.0
	Feline	0.77	1.24	-2.1	21 - 55	6.3 - 12.4
Creatine Kinase (mg/dL)	Equine	1.00	0.97	-2	7 - 101	69 - 14000
	Canine	*	*	*	*	*
	Feline	*	*	*	*	*
Creatinine (mg/dL)	Equine	0.95	1.00	-0.4	7 - 101	0.3 - 6.2
	Canine	0.99	1.00	0.0	22 - 180	0.6 - 10.6
	Feline	1.00	1.01	-0.1	21 - 55	0.3 - 13.6
Gamma glutamyl transferase (U/L)	Equine	0.99	1.11	0	7-101	5 - 317
	Canine	1.00	0.96	2	22-180	5 - 65
	Feline	*	*	*	*	*
Glucose (mg/dL)	Equine	0.97	0.94	16	7 - 101	36 - 353
	Canine	0.96	1.01	-6	22 - 180	28 - 348
	Feline	1.00	0.97	3	21 - 55	52 - 607
Total Bilirubin (mg/dL)	Equine	1.00	0.90	0.1	7 - 10	0.6 - 26.1
	Canine	0.87	0.84	0.1	122 - 180	0.1 - 3.2
	Feline	1.00	0.92	-0.3	21 - 55	0.4 - 15.0
Total Protein (g/dL)	Equine	0.99	0.97	0.3	7 - 101	3.0 - 9.5
	Canine	0.98	1.03	0.1	22 - 180	2.6 - 10.7
	Feline	0.97	0.96	0.4	21 - 55	4.8 - 8.5
Potassium (mmol/L)	Equine	0.84	0.97	0.1	7-101	1.8 - 4.6
	Canine	0.96	0.92	0.4	22-180	3.2 - 6.9
	Feline	0.91	0.92	0.5	21-55	2.7 - 5.3
Sodium (mmol/L)	Equine	0.86	1.00	-0.01	7-101	110 - 166
	Canine	0.89	0.97	4.8	22-180	118 - 183
	Feline	0.86	1.08	-12.2	21-55	122 - 166
Total Carbon Dioxide (mmol/L)	Equine	0.97	0.93	2.1	7-101	9 - 39
	Canine	0.81	0.86	3.5	22-180	6 - 23
	Feline	0.93	0.90	2.4	21-55	7 - 31

* Not available

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