Biorex Labs

K-CHECK

Catalog No. 1555

For Urine, Serum, Plasma or whole Blood Ketones determination.

For *in vitro* diagnostic use only.

Caution: *Not for internal use*. Do not ingest.

Read complete instructions before performing the test.

Intended use: The K-Check tablets are intended to be used by trained laboratory professionals to determine the qualitative /semi-quantitative presence of two Ketone bodies i.e. acetone and acetoacetic acid in Urine, Serum, Plasma or Whole blood.

Quick Reference Instructions:

1. Place a tablet on a paper towel.
2. Add a drop of the test specimen or controls on to the tablet. Wait 60 seconds for urine; 2.5 minutes for serum/plasma and 10 minutes for blood.
3. Wipe off the excess serum or plasma and compare to the color chart below for results.

Principal and background: Pathologically, Ketosis may be caused by conditions such as diabetes mellitus, cortisol deficiency, growth hormone deficiency and toxic ingestion of ethanol or salicylates. Certain inborn errors of metabolism may also cause ketoacidosis. Mild to moderate elevation in serum levels of ketones is a physiological response to fasting (especially during infancy and pregnancy), prolonged exercise, or a ketogenic (high-fat, low-carbohydrate) diet.

Reagents: Active ingredients of K-Check tablets are sodium nitroprusside, aminoethanoic acid, dibasic sodium phosphate, sodium borate and lactose. The nitroprusside ion forms a purple colored complex with methyl ketones in the presence of aminoethanoic acid in an alkaline medium.

Specimen Requirement: Preferably, obtain a fresh specimen and perform the test promptly. If the test could not be performed immediately, the specimen may be refrigerated in a closed container for up to 48 hours.

Procedure :

1. Remove a tablet for each test and additional two tablets to perform the quality control. Securely recap the bottle.
2. Place the tablets on a white paper towel. With a marker/pen label below the tablets accordingly such as “Test”, “Positive” and “Negative” controls.
3. Using a disposable transfer pipette, place a drop of the test specimen (urine, serum, plasma or whole blood) directly onto the tablet. For quality control, place a drop of positive and negative controls onto the respectively labeled control tablets. Always use a separate pipette for each specimen and each of the controls.
4. To read results compare the developed color to the color chart. Wait 60 seconds for a urine test. For **serum or plasma** wait 2.5 minutes before reading the results. Wipe off the excess serum or plasma. **For blood**: wait 10 minutes, clean off the clot with a gauze or paper towel, and compare to the color chart below. Any development of lavender to purple color is a positive test.

NEGATIVE	SMALL	MODERATE	LARGE
Approximate conc. (acetoacetic acid)	20 mg/dl	40 mg/dl	80 mg/dl

5. Read the controls as follows after wiping off the excess control material:
   a. A pale white color development of the tablet after the appropriate wait time is a negative test for acetone and acetoacetic acid.
   b. Any development of a lavender/purple color after an appropriate wait time is a positive test for acetone and acetoacetic acid.
   c. Compare the color intensity to the color chart for semi quantification of the results.

If the positive and negative controls do not yield the expected results as above, do not report the test results and call for technical assistance at 1-866-342-9976 or report to your supervisor.

CLIA Categorization: The K-CHECK reagent tablets are waived for Urine testing only; however, they are categorized as moderately complex, for serum, plasma or whole blood testing. The procedure above conforms to QC guidelines for the waived tests.

Sensitivity and Limitations: K-Check tablets will detect as little as 5mg/dl of acetoacetic acid and 20-25 mg/dl of acetone in urine. For serum, plasma or whole blood the K-CHECK Tablets are approximately 50% less sensitive. Therefore the lower limit of sensitivity is approximately 10 mg of acetoacetic acid/dl of serum plasma or whole blood. The reagent tablets do not react with betahydroxybutyric acid. Ketones are not detected in urine serum, plasma or blood under normal carbohydrate metabolism. Levodopa may cause a false positive test. Bromosulphalein and phenylketones may cause a reaction with the reagent similar to acetone and acetoacetic acid. Urines preserved with 8-hydroxyquinoline may give reaction ranging from orange red to mauve which is a false positive reaction. Use the same color chart for reading urine, serum, plasma or whole blood. The lesser sensitivity of the test for serum, plasma or whole blood is compensated by the increased “time to read” for these specimens.

Quality Control (QC) for serum, plasma or whole blood: Laboratories should follow the applicable government regulations and local guidelines for quality control. The control intervals should be adapted to each laboratory’s requirements. The recommended **serum controls** can be purchased from BIOREX LABS **(Cat. No. B1777).** For further information on positive and negative controls, contact Biorex Labs at 866-342-9976 or info@biorexlabs.com . At least a positive and negative control must be run each time a new bottle of K –Check is opened. A positive control for urine can also be prepared by diluting 50 microlitres (one drop) of acetone to 40 ml of distilled water. The preparation should be comparable to “small” on the color chart.

Quality Control for Urine (CLIA waived): Perform QC with each test run. Follow the instructions under the “Procedure” section of the product insert.

Precautions: Protect the reagent tablets from humidity and light. Do not use if the tablets develop a tan or any other color than white. Do not use if the expected results are not obtained by known positive and negative controls.

Storage: 15-30^{o}C; K-Check tablets are adversely affected by humidity / moisture. The bottle should be closed promptly and securely after removing the test tablets.

Availability: K-Check is available in a bottle of 100 tablets.

Bibliography:

1. Henry, John B**;** *Clinical Diagnosis and Management by Laboratory Methods*, 1979; pp 593-95; W B Saunders Company Philadelphia

2. Dawson, R. M. C., et al., *Data for Biochemical Research*, Oxford, Clarendon Press, 1959

3. Free HM, Smeby RR, Cook MH, FREE AH. A comparative study of qualitative tests for ketones in urine and serum. *Clin Chem*. 1958 Aug;4(4):323-30.

4. Lillian Mundt, Kristy Shanahan MS MT(ASCP) *Text book of urinalysis and Body Fluids* 2nd Ed, Lippincott Williams & Wilkins, 2011; Philadelphia

5. *Urinalysis and Body Fluids*, Susan King Strasinger DA MLS(ASCP); Marjorie Schaub Di Lorenzo MLS(ASCP)SH; F.A. Davis Company 6th Ed, 2014

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Biorex Labs

K-CHECK® CONTROLS FOR SERUM and PLASMA DETERMINATIONS

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Issue Date:09/02/2018 Date of Rvision: 09/02/2018

SECTION1:IDENTIFICATION

1.1. Product Identifier

Product Name: K-CHECK Controls for serum or plasma

Product Code: B1777-0, B1777-01, B1777-02

1.2. Intended Use of the Product

Quality Control Materials for use by Clinical Laboratory Professionals.

Name, Address, and Telephone of the Responsible Party

Company

BIOREX LABS LLC.

194 E WALLINGS RD. Ste 1

CLEVELAND, OH 44147

1.3. www.biorexlabs.com

1.4. Emergency Telephone Number **: 440-824-3000**

SECTION2:HAZARDSIDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US) : P261 - Avoid breathing vapors, mist, or spray.

P272 - Contaminated work clothing must not be allowed out of the workplace. P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixture

Name	Product Identifier	% (V/V)	GHS-US classification
2,4-Pentanedione	(CAS No) 123-54-6	0.1 – 0.4	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:vapour), H331 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

SECTION4:FIRSTAIDMEASURES

4.1. Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause an allergic reaction in sensitive individuals.

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Eye Contact: May cause eye irritation.

Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic Symptoms: None expected under anticipated conditions of normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection. **Hazardous Combustion Products**: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing vapor, mist, or spray. Avoid contact with skin, eyes, or clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material, then place in suitable container.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

2,4-Pentanedione (123-54-6)		
USA ACGIH	ACGIH TWA (ppm)	25 ppm
USA ACGIH	ACGIH chemical category	Skin-potential significant contribution to overall exposure by the cutaneous route

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eyewash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Amber Yellow
Odor:		Odorless
Odor Threshold	:	Not available
pH	:	6
Evaporation Rate	:	Not available

Melting Point	:	Not available
Freezing Point	:	Not available
Boiling Point	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	Not available
Vapor Pressure	:	Not available
Relative Vapor Density at 20°C	:	Not available
Specific Gravity	:	1
Solubility	:	Not available
Partition Coefficient: N-Octanol/Water	:	Not available
Viscosity	:	Not available
Explosion Data – Sensitivity to Mechanical Impact	:	Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge	:	Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Product is stable.

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous Decomposition Products: The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion / Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified **Teratogenicity:** Not available **Carcinogenicity:** Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea

Chronic Symptoms: None expected under anticipated conditions of normal use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

2,4-Pentanedione (123-54-6)	
LD50 Oral Rat	760 mg/kg
LD50 Dermal Rabbit	770 mg/kg
LC50 Inhalation Rat	5.01 mg/l/4h
LC50 Inhalation Rat	

SECTION 12: ECOLOGICAL INFORMATION

12.2 Toxicity	
2,4-Pentanedione (123-54-6)	
LC50 Fish 1	98.3-110mg/l(Exposuretime:96h-Species:Pimephalespromelas[flow-through])
EC50 Daphnia 1	34.4 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	50.3-71.8mg/l(Exposuretime:96h-Species:Lepomismacrochirus[flow-through])

12.1. Persistence and Degradability

K-CHECK® CONTROLS FOR SERUM and PLASMA	
Persistence and Degradability	Not established.

12.2. Bioaccumulative Potential

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
Bioaccumulative Potential	Not established.

2,4-Pentanedione (123-54-6)	
Log Pow	0.34

12.3. Mobility in Soil Not available

12.4. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

2,4-Pentanedione (123-54-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	S-S- indicates a substance that is identified in a proposed or final Significant New Uses Rule.

15.2 US State Regulations

2,4-Pentanedione (123-54-6)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 09/02/2018

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1

STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation

H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Party Responsible for the Preparation of This Document

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