

**MATERIAL SAFETY DATA SHEET****IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):**

**Product Name:** Kallestad™ Anti-Native DNA Positive Control

**Product Number:** Catalog 30400

**Intended Use:** These are kit optional components which are to be used exclusively with these Bio-Rad Laboratories kits: **Kallestad™ Crithidia luciliae Substrate**  
Refer to the *Instructions For Use, Package Insert* for additional product information.

**Supplier's Name:** Bio-Rad Laboratories, Inc.

**Address:** 6565 185th Avenue NE  
Redmond, WA 98052-5039

**Phone Number:** 1-800-2-BIORAD (1-800-224-6723); or (425) 881-8300 (daytime PST)

**Emergency Phone Number:** **This MSDS is listed with CHEMTREC (800) 424-9300.** Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT with this product.

**COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (2):**

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

Component	Content
<b>Kallestad™ Anti-Native DNA Positive Control, 0.5 mL</b> Catalog # 30400	- Pooled human serum with a specific autoantibody activity, 1% bovine serum albumin. - Preserved with 0.1% Sodium Azide [NaN <sub>3</sub> ], EINECS / ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC– dilution < 0.25%, but ≥ 0.1%).

**HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):**

The following information is furnished for those kit hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution, thus the assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists, and expanded upon from company and literature data.

Chemical Ingredient	Chemical Data / Information
<b>Sodium Azide</b> [0.1% w/v NaN <sub>3</sub> ]	CAS# 26628-22-8 (100%) + RTECS# VY8050000 (100%) LD50 (oral-rat): 27 mg/kg (100%) + PEL/TLV: 0.3 mg/m <sup>3</sup> (ceiling)(100%) + HMIS codes: H=2, F=0, R=1 ++ EU Classification: Harmful (Xn); R 22; S 24-35-37 (< 0.25% and ≥ 0.1%) ++ EINECS / ELINCS No: 247-852-1 (100%) + Flash Point: NE LC50 (inhalation-rat): 37 mg/m <sup>3</sup> (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + RCRA Code: P105 (undiluted, 100%) + Sodium azide, a biocidal preservative, is harmful if swallowed; it has been evident to kill at low concentrations, if enough is ingested (more than supplied in kit). May cause eye, skin or tissue irritation. Avoid contact. If swallowed, seek medical advice immediately. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up. This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulation. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions.

Chemical Ingredient	Chemical Data / Information
<b>Human Serum</b> [reactive and non-reactive]	The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2 by FDA approved methods. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Employ <i>Universal Precautions</i> when handling these reagents and all human blood, specimens or patient samples, which represent an unknown, heightened hazard. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> . Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional and national regulation. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Persons handling blood samples should have the option of receiving hepatitis B vaccination.
+ The kit concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses. ++ The kit concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution. NE: Not Established or Unknown (unable to locate data) Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity	

### **General Kit Composite Health Hazards:**

According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection, thus, they should be handled as though they contain an infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.

### **EMERGENCY FIRST AID MEASURES (4):**

Health Effects:	Symptoms of over exposure may include headache, dizziness, congestion, and breathing difficulty. Skin contact may result in dermatitis.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. <b>OBTAIN MEDICAL ATTENTION.</b>
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and <b>OBTAIN MEDICAL ATTENTION.</b> Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

### **FIREFIGHTING MEASURES (5):**

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

**ACCIDENTAL RELEASE MEASURES (6):**

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE), including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so, and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill clean-up materials and PPE are available and used.
- ◆ Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and clean up.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible, decontaminate Biohazard / Human Source Material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% Ethanol or Isopropanol, an iodophor (such as Wescodyne Plus), or a phenolic, etc.).
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, Chemical and Laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.

**HANDLING AND STORAGE INFORMATION (7):**

**Handling:** This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper good laboratory practices and safety guidelines for handling chemical, biological and laboratory hazards. Wear appropriate personal protective equipment (PPE), including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Universal Precautions*. Refer to Section 8 for more specifics. Consult with your Environmental Health & Safety Office for assistance.

**Storage:** Store according to product label instructions (generally at 2-8 °C).

Read and follow all the precautions and warnings in the kit product instructions (e.g. *PREPARATION AND STORAGE OF REAGENTS, WARNINGS FOR USERS, PRECAUTIONS FOR USERS*).

**EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):**

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes, and eyes, or hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

**Ventilation:** Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.

**Eye Protection:** Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

**Protective Gloves:** Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as nitrile, neoprene and vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.

**Protective Clothing:** Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.

**Other:** All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.

Note: Exposure limit values and health hazard data were given in Section 3. Environmental Controls are included in the following sections.

**PHYSICAL AND CHEMICAL PROPERTIES (9):**

Appearance: Yellow aqueous liquid.  
Fire Hazard: Although the components have not been tested for fire hazard and explosion data, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.  
Flash Point: Not established.  
Auto Igniting: Product is not known to be self-igniting.  
Danger of Explosion: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.  
Boiling Point: Not established. Melting point: Not established.  
Solubility: Miscible in water.  
pH: Neutral, pH between 6 and 9.  
Specific Gravity: Not established.  
No other standard characteristics applicable to the identification or hazards of the kit are known.

**STABILITY AND REACTIVITY INFORMATION (10):**

Stability: Stable under ordinary conditions of use and storage.  
Conditions and/or Materials to Avoid: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.  
Hazardous Decomposition Products: Oxides of carbon or nitrogen may form when heated to decomposition.  
Hazardous Polymerization: Has not been reported to occur.

**TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):**

Refer to Section 3 for the kit component concentrations. The composite toxicological information for this product is:

**Acute Health Effects:**

Toxicity: Harmful if swallowed.

Primary Irritant Effect: May slightly irritate eyes or skin, depending on amount and contact time.

Other Acute Health Effects: No significant other acute health effect known.

**Biohazard Potential:**

The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ Universal Precautions; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

**Chronic Toxicity:**

Sensitization: No sensitization effect known.

Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.

Reproductive hazard: No reproductive toxic effect known.

Additional Toxicological Information: The chemical, physical and toxicological properties have not been thoroughly investigated.

**ECOLOGICAL INFORMATION (12):**

No data is available for this highly dilute concentration (less than one percent).

**DISPOSAL CONSIDERATIONS (13):**

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures. Recommended Product and/or Packaging Disposal:

**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your national, regional and local ordinances accordingly.

All human source and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your national, regional and local ordinances accordingly.

**TRANSPORT INFORMATION (14):**

Recommended Product Shipping: Shipping must be conducted in accordance with all applicable local, regional and national regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Unused Product Multi-Modal Transport: No known transport restrictions.

**REGULATORY INFORMATION (15):**

**Composite HMIS Rating:** Health: 2 Flammability: 0 Reactivity: 1

**California Proposition 65:** The Product does not contain listed substances.

**Carcinogenicity Categories:** No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA.

**WHMIS Classification:** This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

**Markings according to European guidelines:** This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Designation of Composite Product: HARMFUL (Xn)



Hazard Determining Substance(s) of Labeling (rated under 1999/45/EC unless otherwise specified):

0.1% Sodium Azide (< 0.25% and ≥ 0.1%), EINECS / ELINCS No: 247-852-1 and CAS# 26628-22-8 [Xn: Harmful; R 22; S 24-35-37].

Risk Phrases:

R 22 Harmful if swallowed.  
Caution Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:

S 24 Avoid contact with skin.  
S 35 This material and its container must be disposed of in a safe way.  
S 37 Wear suitable gloves.

**OTHER INFORMATION (16):**

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards.

Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

These are kit optional components, which are to be used exclusively with the Bio-Rad Laboratories kits listed in Section 1.

This Revision: Reformatted existing information.

Contact for general information: Bio-Rad Laboratories, Redmond Operations  
Environmental Health & Safety  
6565 185<sup>th</sup> Ave. NE  
Redmond, WA 98052  
Phone: 425-881-8300 (8 am to 5 pm PST)

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