

SAFETY DATA SHEET (SDS)**SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**

Product Name: Kallestad™ Mouse Stomach Kidney Substrate Slides

Product Number: 26111, 26112, 26115 (8-Well Slide)

Intended Use: For the detection and semi-quantitation determination of autoantibodies to nuclear, mitochondrial, smooth muscle, and parietal cell antigens. These are replacement, optional or separately purchased components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories **Kallestad™ Mouse Stomach/Kidney** kits. Refer to the *Instructions For Use, Package Insert* for additional product information.

Manufactured by: Bio-Rad Laboratories, Inc.

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

Website: www.bio-rad.com

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

SDS e-mail contact: ro-sds@bio-rad.com

Technical Information Contacts: Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. *Refer to section 16 for non-US local Bio-Rad agent contact information.*

Authorized Representative in the European Community: **FRANCE: Bio-Rad**
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Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 / 001-703-527-3887** (international – can be called collect). Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. *Refer to section 16 for non-US local Bio-Rad agent contact information.*

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

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. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Component *	Content
Substrate Slides Mouse Stomach/Kidney (MSK), 8-Well Slide, <i>Catalog #26111, 26112, 26115</i>	- Mouse stomach/kidney substrate fixed onto glass slides. - Handle slides by the edges. Do not apply pressure to surface of foil bag.

* Replacement, optional and separately purchased component Catalog numbers are provided in this column where available.

Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (US HCS), European Community (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulations: This product is not subject to labeling classification or identification according to GHS, United States Hazard Communication Standard (US HCS), related European Community (EC) 2008/1272/EC (EC CLP) guidelines and applicable analogous GHS-based global regulations.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (LD₅₀, exposure limits, etc.). Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the Chemical Ingredient Data/Information box. The GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.

Chemical Ingredient: This product contains no chemical constituents that require regulatory control or disclosure at the concentration found in the product.

Biological Ingredient	Data / Information
Mouse Tissue [Slide Component]	<p>Mouse tissue substrate slides have been solvent fixed and are not considered infectious. Handle appropriately with the requisite Good Laboratory Practices and <i>Standard</i> and <i>Universal Precautions</i>. Dispose of this material in accordance with local, regional, national and international regulations.</p> <p>These slides consist of 96-100% inert glass with an ~0-4% inert polymer coating, which has been biologically and chemically processed. Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.</p>

NA: Not Applicable.

NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified

Related product information:

- Refer to section 16 for the full text of any Comprehensive GHS-based Classification statements coded above. Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	No significant health effect is known. Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped.
Eye Contact:	OBTAIN MEDICAL ATTENTION.
Skin Contact:	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:	No significant health effect is known.
If Swallowed:	OBTAIN MEDICAL ATTENTION. 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.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- ◆ 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. IF ON SKIN (or hair): Rinse skin with water. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup 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 cleanup. Avoid release to the environment.
- ◆ Clean the spill area with water and wipe dry. 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.
- ◆ Broken slides contaminated with blood or other human source or potentially infectious material must be handled as *Sharps* per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulations. Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware; however, dispose of this material in accordance with local, regional, national and international regulations.
- ◆ Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	<p>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.</p> <p>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE), including gloves, lab coat or equivalent and eye/face protection.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>Universal Precautions</i>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course.</p> <p>Consult with your Environmental Health & Safety Office for assistance.</p>
Storage:	Store the kit components as specified on the product label and/or in the product instructions provided with the test kit.
Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions.	
These are separately purchased components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories kits listed in Section 1.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

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, and to prevent 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 or patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye / Face 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.
Respiratory Protection:	Not 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Solid glass slides.		
Odor/odour:	Data is not available.	Odor/odour threshold:	Not established.
pH:	Not applicable.		
Boiling point:	Undetermined	Melting point:	Undetermined
Evaporation rate:	No applicable information was found.		
Flash point:	Not applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .		
Flammability (solid, gas):	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.		
Vapor/vapour pressure:	No applicable information was found.		
Vapor/vapour density:	No applicable information was found.		
Relative density:	Not applicable.		
Solubility:	Not miscible.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		

Viscosity:	No applicable information was found.
Danger of explosion:	Product is not known to present an explosion hazard.
Molecular mass:	Not applicable.
No Other Standard Characteristics applicable to the identification or hazards of the product are known.	

SECTION 10: STABILITY AND REACTIVITY INFORMATION

NOTE: Chemical reactions that could result in a hazardous situation (e.g., generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Stable under ordinary conditions of use and storage.
Conditions and Materials to Avoid:	None known when used as intended.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Hazardous Polymerization:	Has not been reported to occur.

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

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Acute Toxicity:	No significant toxic effect known.
Primary Irritant Effect:	No significant irritant effect known.
Serious Eye Damage / Irritation:	No significant irritant effect known.
STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Health Effects:	Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Biohazard Potential:

Uninfected cells of animal origin have been solvent fixed and are not considered infectious or carcinogenic. Patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *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*, *WHO Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin 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.
Germ Cell Mutagenicity:	Data is not available.
Reproductive hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.

Ecotoxicity:	No information found.
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse effects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international 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 Disposal: Broken slides contaminated with blood or other human source or potentially infectious material must be handled as *Sharps* per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations; however, dispose of this material in accordance with local, regional, national and international regulations.

Recommended Unclean Packaging Disposal: Dispose in accordance with all applicable local, regional, national and international regulations.

SECTION 14: TRANSPORT INFORMATION

Shipping of product, packaging and waste 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.

Recommended Unused Product Multi-Modal Transportation: According to US DOT, IATA and UN “Model Regulations”, the product must be transported as follows: No known transport restrictions.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating: Health: 0 Flammability: 0 Reactivity: 0

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 (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations – Other Domestic / Foreign Laws:

Hazard communication compliance – This SDS contains the required information for preparation in accordance with the following GHS-based global regulations:

- United States** – Occupational Safety Health Administration *Hazard Communication Standard* **29 CFR 1910.1200 (US HCS)**
- Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
- People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**

4. **New Zealand** – *Hazardous Substances and New Organisms Act 1996 (HSNO), Hazardous Substances (Classification) Regulations 2001 and Thresholds and Classifications January 2012* (as published in 2008)
5. **Mexico** – **Standard NMX-R-019-SCFI-2011**
6. **Korea** – **Public Notice 2008-26** for the hazard classification criteria for this product
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
8. **European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
10. **Brazil** – Regulation **NRB 14725:2009**
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
Australian Inventory of Chemical Substances (AICS): All pertinent ingredients are listed.
12. Analogous GHS-based global regulations

Inventory status

Country(s) or region	Inventory name	In Compliance (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS) or European List of Notified Chemical Substances (ELINCS)	Yes
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

United States SARA:

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Regulation (EC) No. 1907/2006 (REACH): Included in the Candidate List of Substances of Very High Concern (SVHC):
None

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

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s): *None*

This product 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 replacement, optional or separately purchased components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories kits listed in Section 1.

Sources of key data used to compile the Safety Data Sheet:

Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (US HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
Mexican Standard (NMX-R-019-SCFI-2011) [regulatory translation and summaries]
European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
Australian Code of Practice – Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
New Zealand – Hazardous Substances and New Organisms Act 1996 (HSNO)
The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean Public Notice 2008-26 [regulatory translation if available and summaries]
Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
 Registry of Toxic Effects of Chemical Substances (RTECS)
 Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO* databases, etc.
 International Agency for Research on Cancer (IARC)
 American Conference of Governmental Industrial Hygienists (ACGIH)
 National Toxicity Program (NTP)
 Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
 National Institute for Occupational Safety and Health (NIOSH)
 World Health Organization. *Laboratory Biosafety Manual*
 CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
Australian Inventory of Chemical Substances (ACIS) Listing
 California Proposition 65

Chemical safety assessment: Mixtures covered in this SDS were classified using the US HCS, EC CLP and/or UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists
 ANSI – American National Standards Institute
 CAS – Chemical Abstracts Service
 CDC – Centers for Disease Control, USA
 CNS – Central Nervous System
 DGSMA – Dangerous Goods Safety Management Act
 DOT – Department of Transportation
 EC₅₀ – half maximal effective concentration
 EU – European Union
 GHS – Globally Harmonized System
 HNOC – Hazard Not Otherwise Classified
 HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
 IARC – International Agency for Research on Cancer
 IATA – International Air Transport Association
 ICAO - International Civil Aviation Organization
 IDLH – Immediately Dangerous to Life or Health
 IMDG – International Maritime Dangerous Goods
 IPCS – International Programme on Chemical Safety
 ISHA – Industrial Safety and Health Act
 LC₅₀ – median lethal concentration, 50%
 LD₅₀ – median lethal dose, 50%
 NIOSH – National Institute for Occupational Safety and Health
 NTP – National Toxicity Program
 OEL – Occupational Exposure Limit
 PEL – Permissible Exposure Limit
 ppm – parts per million
 RTECS – Registry of Toxic Effects of Chemical Substances
 SDS – Safety Data Sheet
 STEL – Short Term Exposure Limit
 TCCA – Toxic Chemical Control Act
 TLV/TWA – Threshold Limit Value / Time-Weighted Average
 UN – United Nations
 US EPA – United States Environmental Protection Agency
 US HCS – Hazard Communication Standard, USA

US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS – Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations)

Additional information: The lists that were valid during the creation were used as basis.

This Revision: Updated, reformatted and added new GHS information.

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

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Telefax 91-124-2398115 • *24h/365d:* 91-124-2398112/113/114
- Israel**, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129 •
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