1. IDENTIFICATION		
1.1	Product identifiers	INSTI® HIV-1 Test Controls INSTI® HIV-1/HIV-2 Test Controls INSTI® Syphilis (Anti-T. pallidum) Test Controls
1.2	Relevant identified uses of the substance or mixture and uses advised against	The **INSTI® HIV-1 Test Controls, INSTI® HIV-1/HIV-2 Test Controls** and **INSTI® Syphilis (Anti-*T. pallidum*) Test Controls** are designed to validate the correct performance of the INSTI® test procedure in the hands of the operator. The HIV-1 and HIV-2 Positive Controls will produce a reactive test result and have been manufactured to produce a faint blue test dot on the test spot. The Syphilis (Anti-*T. pallidum*) Positive Control will produce a reactive test result and has been designed to produce a faint blue test dot on the test spot. The negative control will produce a non-reactive test result. The INSTI® HIV-1 Test Controls, INSTI® HIV-1/HIV-2 Test Controls and INSTI® Syphilis (Anti-*T. pallidum*) Test Controls are intended to be used with the INSTI® HIV-1/HIV-2 Antibody Test and/or the INSTI® Multiplex HIV-1/HIV-2/Syphilis Antibody Test.
1.3	Manufacturer:	Biolytical Laboratories Inc. 406 - 13251 Delf Place, Richmond, BC, Canada, V6V 2A2 Toll Free: 1-866-674-6784 Phone: 1-604-204-6784 Fax: 1-604-244-8399 Web: www.bioLytical.com Email: info@bioLytical.com
1.4	Emergency Telephone Number:	Phone: 1-866-674-6784

2. HAZARD IDENTIFICATION			
2.1	Classification of the substance or mixture		
	Kit Component[2]	**Description**	**Hazardous Components of Mixture Present Above Threshold Levels[1]**
	Negative Control	1 vial containing 1.0 mL of processed human serum substitute[3].	None
	HIV-1 Positive Control	1 vial containing 1.0 mL of heat-inactivated human plasma containing antibodies to HIV-1[3].	None
	HIV-2 Positive Control	1 vial containing 1.0 mL of heat-inactivated human plasma containing antibodies to HIV-2[3].	None
	Syphilis Positive Control	1 vial containing 1.0 mL of heat-inactivated human plasma containing antibodies to Treponema pallidum, the causative agent of syphilis.	None
	[1]According to the OSHA Hazard Communication Standard (29 CFR 1910.1200), if a mixture contains less than 1% of a hazardous chemical or 0.1% of a carcinogen, the mixture shall not be considered hazardous. Under GHS, the cut-off level for reproductive toxicity, carcinogenicity and category 1 mutagenicity is ≥ 0.1%. The cut-off level for all other hazard class is ≥ 1%. [2]Kit components are in compliance with the REACH Enforcement Regulations 2008 (UK), REGULATION (EC) No 1907/2006, and with REACH (EU) No 2015/830 amendment to EU 1907/2006.		
2.2	GHS label elements, precautionary statements:	None	
2.3	Hazards not otherwise covered	[3]According to the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030), all human blood components and certain body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.	

3. COMPOSITION		
3.1	Mixtures	
	Negative Sample	A biological matrix made from human blood fractions. Negative for HIV-1 and HIV-2 antibody, HIV-Ag and/or HIV NAT, anti-HCV, Syphilis and HBsAg by an FDA approved method.
	Plasma, HIV-1 Positive	Heat-inactivated HIV-1 antibody positive human plasma.
	Plasma, HIV-2 Positive	Heat-inactivated HIV-2 antibody positive human plasma.
	Plasma, Syphilis	Heat-inactivated T. pallidum antibody positive human plasma.

4. FIRST AID MEASURES		
4.1	Description of first aid measures	
	In case of skin contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with germicidal soap and water. If materials came in contact with non-intact skin, obtain medical attention.
	In case of eye contact:	Flush eyes with copious amount of water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. Obtain medical attention.
	If inhaled:	Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. If inhalation of aerosolized materials occurs, obtain medical attention.
	If swallowed:	Rinse out mouth thoroughly with water, provided the person is conscious, and obtain medical attention.
4.2	Most important symptoms and effects, both acute and delayed:	None known.
4.3	Indication of any immediate medical attention and special treatment needed:	See 4.1.

5. FIRE FIGHTING MEASURES		
5.1	Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
5.2	Specific Hazards Arising from Product:	Not considered to be a fire or explosion hazard.
5.3	Special equipment and precautions for fire-fighters:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

6. ACCIDENTAL RELEASE AND MEASURES		
6.1	Personal precautions, protective equipment, and emergency procedures:	If product/material is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment including gloves, protective clothing or laboratory coat and eye protection to avoid eye and skin contact.
6.2	Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
6.3	Methods and material for containment and cleanup:	Wear gloves and absorb spill with paper towel. Disinfect the area with 10% bleach or with an appropriate disinfectant with suitable contact time as indicated by the disinfectant manufacturer. Material used to absorb the spill may require hazardous material waste disposal. Infectious wastes must be handled and discarded in accordance with all local, regional and national regulations.
6.4	Reference to other sections	For disposal see section 13.

7. HANDLING AND STORAGE		
7.1	Precautions for safe handling:	Wear appropriate personal protective equipment (PPE) including gloves, lab coat 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 test as though they were capable of transmitting infectious disease, as per Universal Precautions.
7.2	Precautions for safe storage:	Store between 2 to 8ºC or at -20ºC as indicated in product instructions.
7.3	Specific end use(s)	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION		
8.1	Permissible exposure limits:	No data available.
8.2.1	Appropriate engineering controls:	General ventilation is adequate.
8.2.2	Personal protective equipment:	Wear appropriate personal protective equipment (PPE) including gloves, lab coat and eye/face protection to avoid contact with skin and eyes.
8.2.3	Control of environmental exposure	See 13.

9. PHYSICAL AND CHEMICAL PROPERTIES		
9.1 Information on basic physical and chemical properties		
(a)	Appearance:	Variable, generally aqueous liquids.
(b)	Odour:	None reported.
(c)	Odour Threshold:	No data available.
(d)	pH:	No data available.
(e)	Melting point/freezing point:	No data available.
(f)	Initial boiling point/boiling range:	No data available.
(g)	Flash point:	No data available.
(h)	Evaporation rate:	No data available.
(i)	Flammability (solid/gas):	No data available.
(j)	Upper/lower flammability or explosive limits:	No data available.
(k)	Vapour pressure:	No data available.
(l)	Vapour density:	No data available.
(m)	Relative density:	No data available.
(n)	Solubility:	All controls are soluble in water.
(o)	Partition coefficient – n-octanol/water:	No data available.
(p)	Auto ignition temperature:	No data available.
(q)	Decomposition temperature:	No data available.

(r)	Viscosity:	No data available.
(s)	Explosive properties	No data available.
(t)	Oxidizing properties	No data available.
9.2	Other safety information	No data available

10. STABILITY AND REACTIVITY		
10.1	Reactivity:	No data available.
10.2	Chemical stability:	No data available.
10.3	Possibility of hazardous reactions:	No data available.
10.4	Conditions to avoid:	Avoid heat.
10.5	Incompatible materials:	No data available
10.6	Hazardous decomposition products:	No data available

11. TOXICOLOGICAL INFORMATION		
11.1	Information on toxicological effects	
(a)	Acute toxicity	No data available.
(b)	Skin corrosion/irritation	No data available.
(c)	Serious eye damage/eye irritation	No data available.
(d)	Respiratory or skin sensitisation	No data available.
(e)	Germ cell mutagenicity	No data available
(f)	Carcinogenicity	No data available.
(g)	Reproductive toxicity	No data available.
(h)	Specific target organ toxicity - single exposure	No data available.
(i)	Specific target organ toxicity - repeated exposure	No data available.
(j)	Aspiration hazard	No data available.
11.2	Additional Information	No data available.

12. ECOLOGICAL INFORMATION		
12.1	Eco-toxicity (aquatic and terrestrial, where available):	No data available.
12.2	Persistence and degradability:	No data available.
12.3	Bioaccumulation:	No data available.

12.4	Mobility in soil:	No data available.
12.5	Endocrine disrupting properties or Other adverse effect:	IARC: No component of this product present and/or at a level that is identified as probable, possible or confirmed to cause the Endocrine disrupting properties to the environment; This product released into the environment is not expected to have a significant impact.

13. DISPOSAL CONSIDERATIONS

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.

14. TRANSPORT INFORMATION

Transport in accordance with all federal, provincial and local transportation regulations.

15. REGULATORY INFORMATION

HPTA	This product does not contain any human pathogens or toxins as defined under the Human Pathogens and Toxins Regulations (SOR/2015-044).

16. OTHER INFORMATION

This document was developed from information obtained from reputable sources, but does not purport to be all-inclusive. The data contained herein, which is based on our present knowledge and is intended for information purposes only, shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Regulatory requirements are subject to change and vary from one location to another; thus, it is the buyer's responsibility to ensure that its activities comply with national, regional and local laws and regulations. bioLytical Laboratories Inc. makes no warranty, expressed or implied, regarding the accuracy or completeness of these data or the results to be obtained from the use thereof. Since the use of this information and the conditions of use of the product are not within the control of bioLytical Laboratories Inc., it is the user's obligation to determine the suitability of the information for the intended application and use appropriate safety procedures.