1. IDENTIFICATION		
1.1	Product Name:	INSTI® HIV-1 / HIV-2 Antibody Test Kit
1.2	Intended Use:	The **INSTI® HIV-1/HIV-2 Antibody Test** is a single use, rapid, *in vitro* qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2 (HIV-1/HIV-2) in human venipuncture whole blood, fingerstick blood, serum, or plasma specimens. The test is intended for use by trained personnel in point of care and laboratory situations to aid in the diagnosis of HIV infections.
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 Phone Number:	Phone: 1-604-204-6784

2. HAZARD IDENTIFICATION			
2.1	Classification of the substance or mixture		
	Kit Component[1]	**Description**	**Hazardous Components of Mixture Present Above Threshold Levels[2]**
	Membrane Unit	Foil sealed membrane unit containing nitrocellulose membrane and nylon fibre absorbent pad.	None
	Sample Diluent	Solution 1, containing 1.5 mL of Tris-glycine buffered solution containing cell lysis reagents.	None[3]
	Colour Developer	Solution 2, containing 1.5 mL or 85 mL (48 Tests Kit) of a blue-coloured Borate buffered proprietary indicator solution.	None[3]
	Clarifying Solution	Solution 3, containing 1.5 ml or 85 mL (48 Tests Kit) of a proprietary Tris-glycine buffered clarifying solution.	None[3]
	Droppers (48 test kits only)	White and blue droppers with closure. Bulb: Monprene; Pipette: Low-density polyethylene (LDPE); Closure: Polypropylene; Bag: Polyethylene	None
	Disposable Transfer Pipette	Low-density polyethylene (LDPE)	None
	Alcohol Swab	Contains 70% IPA	None
	Lancet	Sterile single-use safety lancets	None
	[1]Components of the package may vary based on the configuration [2]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%. [3]Sample Diluent, Colour Developer and Clarifying Solution contains 0.1% Sodium Azide (NaN3, EC No 247-852-1 and CAS# 26628-22-8) as a preservative.		

2.2	GHS label elements, precautionary statements:	
	Kit Component	GHS label elements, precautionary statements:
	Sample Diluent, Colour Developer, Clarifying Solution Contains: 0.1% sodium azide as preservative	**Component of Sodium Azide 0.1%** Sodium azide [NaN3], CAS# 26628-22-8 and EC No 247-852-1 (≥ 0.1% dilution < 1%) **GHS \ 2008/1272/EC Classification:**  Label(s): GHS07 Signal Word: WARNING Label Hazard Statement: H302: Harmful if swallowed H413: May cause long lasting harmful effects to aquatic life. Supplemental Hazard Statement: None Specified. Precautionary Statement – Prevention: P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. Precautionary Statement – Response: P330: Rinse mouth. P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Precautionary Statement – Storage: None Specified Precautionary Statement – Disposal: P501: Dispose of contents and container in accordance to local, regional, national and/or international regulations. This material and its container must be disposed of in a safe way.
2.3	Hazards not otherwise covered	None

3. COMPOSITION		
3.1	Mixtures	Refer to table of Kit Components in Section 2.1.

4. FIRST AID MEASURES		
4.1	Description of first aid measures	
	In case of skin contact:	Wash off with soap and plenty of water.
	In case of eye contact:	Flush eyes a minimum of 10 minutes with water as a precaution.
	If inhaled:	Generally, this aqueous product is not an inhalation hazard in the kit volumes and concentrations present.
	If swallowed:	Rinse out mouth thoroughly with water, provided the person is conscious, and obtain medical attention. Call a physician or the local poison control center. Do not induce vomiting without medical advice.

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	Suitable extinguishing media:	Use extinguishing media appropriate for the surrounding fire.
5.2	Specific hazards arising from the substance or mixture:	Not considered to be a fire or explosion hazard.
5.3	Advice for firefighters:	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.
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:	Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material. Dispose of the cleaning material by an acceptable method.
6.4	Reference to other sections	For disposal see section 13.

7. HANDLING AND STORAGE		
7.1	Precautions for safe handling:	Not a hazardous substance or mixture.
7.2	Conditions for safe storage, including any incompatibilities	Store between 2 and 30 ºC as indicated in product instructions. Storage class (TRGS 510): Non-combustible Liquids.
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:	See 7.1.
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. Exceptions are the solid cartridges, solution bottles, droppers, lancet, alcohol pad and transfer pipet.
(b)	Odour:	No data available.
(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:	No data available.
(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 excessive heat; maintain ambient temperatures.
10.5	Incompatible materials:	Heavy metals may form extremely explosive azides.
10.6	Hazardous decomposition products:	Nitrocellulose may emit toxic fumes under normal fire conditions.

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	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
(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	Results of PBT and vPvB assessment:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
12.6	Other adverse effect:	This product released into the environment is not expected to have a significant impact.

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods
This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. According to the Ordinance On Movements Of Waste of 22 June 2005 (oMoD); Chemical Risk Reduction Ordinance (ORRChem) of 18 May 2005 and The Federal Department of the Environment, Transport, Energy and Communications (DETEC) Regulation on Waste List, sharps (i.e. lancets) are considered as Special Waste and should be disposed off in accordance with the local regulations.

14. TRANSPORT INFORMATION			
Transport in accordance with all federal, provincial and local transportation regulations.			
14.1	UN number		
	ADR/RID: -	IMDG: -	IATA: -
14.2	UN proper shipping name		
	ADR/RID: Not dangerous goods	IMDG: Not dangerous goods	IATA: Not dangerous goods
14.3	Transport hazard class(es)		
	ADR/RID: -	IMDG: -	IATA: -
14.4	Packaging group		
	ADR/RID: -	IMDG: -	IATA: -
14.5	Environmental hazards		
	ADR/RID: no	IMDG Marine pollutant: no	IATA: no
14.6	Special precautions for user		No data available
14.7	Transport in bulk according to Annex II of the Marpol Convention and the IBC code		Not applicable

15. REGULATORY INFORMATION	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture

	CEPA	This product contains Sodium Azide ($Na(N_3)$) CAS#26628-22-8 listed on the Domestic Substances List (DSL). This product does not contain any substances new to Canada.
	California Prop 65 Components	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
	REACH (EU) No 2015/830 amendment to EU 1907/2006	The product has been classified and labeled in accordance with EC Directives. If sodium azide is used at dangerous amount, it will lead to acute toxicity, but the amount of sodium azide used is limited to 0.1%, product is not considered hazardous.
15.2	Chemical Safety Assessment	For this product a chemical safety assessment was not carried out.

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.