SAFETY DATA SHEET

1.	**PRODUCT AND COMPANY IDENTIFICATION**		
(a)	Product Name:	Avioq VioOne™ HIV Profile™ Supplemental Assay	
(b)	Product Number:	700024	
(c)	Product Description:	The VioOne™ HIV Profile™ Supplemental Assay is an enzyme-linked immunosorbent assay (ELISA) for confirmation and differentiation of individual antibodies directed to various gene products of Human Immunodeficiency Virus Type 1 (HIV-1 Group M & Group O) and Type 2 (HIV-2) in human serum or plasma. Results of HIV Profile™ can also be used to distinguish recent from longstanding HIV-1 infection and thus be used for HIV-1 incidence estimation.	
(d)	Supplier Information:	Avioq 104 T.W. Alexander Drive Research Triangle Park, North Carolina 27709 Telephone: 919-314-5535 Fax: 919-314-5536	
(e)	Emergency Phone Number:	Telephone: 919-314-5535	
2.	**HAZARDS IDENTIFICATION**		
(a)	Classification of the substance or mixture:		
	Kit Component	**Description**	**[1]Hazardous Components of Mixture Present Above Threshold Levels**
	Microelisa Strips (2 Stripholders)	Twelve per holder, contained in a re-sealable foil pouch with silica gel desiccant. Each strip contains 8 wells coated with no viral antigen, HIV-1 antigens, and HIV-2 antigens contained in a foil pouch with silica gel desiccant.	None
	Sample Diluent (1 x 25 ml Bottle)	Liquid specimen diluent with biotinylated HIV-1 p24 antigen; contains animal proteins, salt, surfactants, Patent Blue V as coloring reagent, Triton x-100 (1/5% w/v) and (0.03% (w/v) bromonitrodioxane as preservative.	**Triton X-100,** CAS 9002-93-1: 1.5% Eye Irritation (Category 2B), H320 Skin Irritation(Category 3), H316
	Negative Control Serum (1 x 1.0 ml Vial)	[2]Contains human serum with protein stabilizers and 0.05% (w/v) bromonitrodioxane as preservative; nonreactive to HBsAg and HIV-1 antigen, antibodies to HIV, HTLV-I/II, and HCV.	None

2.	HAZARDS IDENTIFICATION (Contd.)		
(a)	Classification of the substance or mixture: (Contd.)		
	HIV-1/2 Positive Control Serum (1 x 1.0 ml Vial)	[2]Inactivated human serum containing protein stabilizers. Contains 0.05% (w/v) bromonitrodioxane as preservative and Amaranth as coloring agent; reactive for antibodies to HIV-1 / HIV-2.	None
	Conjugate (2 Vials)	Lyophilized, horseradish peroxidase conjugated NeutrAvidin, HIV-1 antigens, and HIV-2 antigens with protein stabilizers and Amaranth.	None
	Conjugate Diluent (1 x 55 ml bottle)	Phosphate buffered saline containing protein stabilizers and 0.03% (w/v) bromonitrodioxane as preservative.	None
	Peroxide Solution (1 x 22 ml bottle)	Citric acid/sodium citrate buffer containing 0.1% 2-Chloroacetamide and 0.04% urea peroxide.	**2-Chloroacetamde**, CAS 79-07-2: 0.1% Reproductive Toxicity (Category 2), H361
	TMB Solution (1 x 22 ml bottle)	Citric acid containing 0.03% (w/v) tetramethylbenzidine.2HCl	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 cutoff level for reproductive toxicity, carcinogenicity and category 1 mutagenicity is ≥0.1%. The cutoff level for all other hazard classes is ≥ 1%		
(b)	GHS label elements, precautionary statements:		
	Kit Component	GHS Label Elements, Precautionary Statements:	

2.	HAZARDS IDENTIFICATION (Contd.)	
(b)	GHS label elements, precautionary statements: (Contd.)	
	Sample Diluent (1 x 15 ml Bottle)	 Signal Word: Warning <u>Hazard Statements</u> H320: Causes eye irritation H316: Causes mild skin irritation <u>Precautionary Statements</u> P262: Do not get in eyes, on skin, on clothing. P280: Wear protective gloves and eye protection <u>Response Precautionary Statements</u> P305 + P351+358: IF IN EYES, Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists, get medical advice/attention. P302 + P353: IF ON SKIN, Rinse skin with water. P332 + P313: If skin irritation occurs, get medical advice/attention. P301 + 330 +331: IF SWALLOWED, Rinse mouth. Do not induce vomiting.

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2.	HAZARDS IDENTIFICATION (Contd.)	
(b)	GHS label elements, precautionary statements: (Contd.)	
	Peroxide Solution (1 x 22 ml bottle)	 Signal Word: Warning <u>Hazard Statements</u> H361: Suspected of damaging fertility or the unborn child. <u>Precautionary Statements</u> P262: Do not get in eyes, on skin, on clothing. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves and eye protection. <u>Response Precautionary Statements</u> P301 + P310 + P330 IF SWALLOWED: Immediately call a Poison Control Center or doctor/physician. Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P363 Wash contaminated clothing before reuse.
(c)	Hazards not otherwise covered:	[2]According to the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1450), all human blood components and certain body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. Handle all VioOne™ HIV Profile™ Supplemental Assay biological materials as though capable of transmitting infectious agents. Positive control sera have been inactivated but should be handled as though they contain potentially infectious agents. Other components prepared from human serum or plasma have been tested using FDA-licensed tests and found to be nonreactive for the presence of HIV antibody, HTLV-I/II antibody, Hepatitis B surface antigen (HBsAg) and HCV antibody. However, as no test method can offer complete assurance that infectious agents are absent all materials of human origin should be handled as though they contain infectious agents.

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3.	**COMPOSITION**	
(a)	Mixtures:	Refer to table of Kit Components in Section 2(a).
4.	**FIRST AID MEASURES**	
(a)	Route of Exposure	
	In case of skin contact:	Refer to Section 2(b).
	In case of eye contact	Refer to Section 2(b).
	If inhaled:	Not an expected route of exposure.
	If swallowed:	Refer to Section 2(b).
(b)	Symptoms of exposure:	Refer to Section 2(b).
(c)	Indication of immediate medical attention	Refer to Section 2(b).
5.	**FIRE-FIGHTING MEASURES**	
(a)	Extinguishing media:	The components in this kit do not burn. Use extinguishing media that is appropriate for surrounding fire.
(b)	Specific hazards arising from the product:	Not considered to be a fire or explosion hazard
(c)	Special equipment and precautions for fire-fighters:	None.
6.	**ACCIDENTAL RELEASE MEASURES**	
(a)	Personal precautions, protective equipment, and emergency procedures:	Use suitable personal protective equipment such as gloves, protective clothing or laboratory coat and eye or face protection to avoid skin and eye contact.
(b)	Methods and materials for containment and cleaning up:	Immediately clean up any spillage of material potentially containing antigen or antibody with a 1:10 dilution of 5% sodium hypochlorite. Allow 30 minutes contact time. Dispose of the cleaning material by an acceptable method.
7.	**HANDLING AND STORAGE**	
(a)	Precautions for safe handling:	Avoid contact with skin and eyes. Avoid ingestion and inhalation.
(b)	Precautions for safe storage:	Store between 2-8°C as indicated in the package insert.
8.	**EXPOSURE CONTROLS/PERSONAL PROTECTION**	
(a)	Permissible exposure limits:	No data available.
(b)	Appropriate engineering controls:	General laboratory ventilation is adequate.
(c)	Personal protective equipment:	Appropriate personal protective equipment should be worn to avoid contact with skin and eyes.

9.	**PHYSICAL AND CHEMICAL PROPERTIES:**	
(a)	Appearance:	Multiple kit components.
(b)	Odor:	None reported.
(c)	Odor threshold:	No data available.
(d)	pH:	No data available.
(e)	Melting point/freezing point:	No data available.
(f)	Initial boiling point and 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)	Vapor pressure:	No data available.
(l)	Vapor 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.
10.	**STABILITY AND REACTIVITY**	
(a)	Reactivity:	No data available.
(b)	Chemical stability:	No data available.
(c)	Possibility of hazardous reactions:	No data available.
(d)	Conditions to avoid:	No data available.
(e)	Incompatible materials:	No data available.
(f)	Hazardous decomposition products:	No data available.

11.	**TOXICOLOGICAL INFORMATION**	
(a)	Information of likely routes of exposure:	No data available.
(b)	Symptoms related to the physical, chemical and toxicological characteristics:	No data available.
(c)	Delayed and immediate effects and also chronic effects form short- and long-term exposure:	No data available.
(d)	Numerical measures of toxicity:	No data available.
(e)	Carcinogenicity:	No component of this product present at levels greater than 0.1% are listed by OSHA, IARC, NTP, or CA Prop 65
12.	**ECOLOGICAL INFORMATION**	
(a)	Eco-toxicity (aquatic and terrestrial, where available):	No data available.
(b)	Persistence and degradability:	No data available.
(c)	Bioaccumulation:	No data available.
(d)	Mobility in soil:	No data available.
(e)	Other adverse effects:	This product released into the environment is not expected to have a significant impact.
13.	**DISPOSAL CONSIDERATIONS**	
	In accordance with 40 CFR Parts 261.3t this product is not considered to be an EPA Hazardous Waste. Waste generators should always consult with state and local regulations to ensure complete and accurate classification.	
14.	**TRANSPORT INFFORMATION**	
	Not regulated as a hazardous material.	
15.	**REGULATORY INFORMATION**	
	SARA 302 Components	No ingredients in this product are subject to the reporting requirements of SARA Title III, Section 302.
	SARA 313 Components	This product does not contain any ingredients with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
	SARA 311/312 Hazards	No SARA Hazards
	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.

16.	OTHER INFORMATION		
	Kit Component	NFPA Rating	HMIS Rating
	Sample Diluent (1 x 15 ml Bottle)	Health Hazard: 1 Fire Hazard: 0 Reactivity Hazard: 0	Health Hazard: 2 Fire Hazard: 0 Physical Hazard: 0
	Peroxide Solution (1 x 22 ml bottle)	Health Hazard: 2 Fire Hazard: 0 Reactivity Hazard: 0	Health Hazard: 2 Fire Hazard: 0 Physical Hazard: 0