



SAFETY DATA SHEET

1. IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER



Product Name: FastPack IP Testo Immunoassay
Product Number: 25000041, 25000058
Intended Use: In-Vitro Quantitative Testing
CAS No. Mixture
Einecs No. Mixture
Supplier's Name **Qualigen, Inc**
Address: 2042 Corte del Nogal, Carlsbad, CA 92011
Phone Number: (760) 918-9165
Emergency Phone Numbers: (877) 709-2169

2. HAZARD IDENTIFICATION – HAZARDOUS COMPONENTS

The following information is furnished for the kits' 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 significant diluted concentration in an aqueous solution yet the assessment below was made based on the hazards of its component parts at full concentration. This chemical is considered hazardous by the 2012 OSH Hazard Communication Standard (21 CFR 1910.1200)

HMIS: Health-1, Flammability-0 Reactivity-0

Code letter and hazard designation of product:

	
Xi Irritant	Danger

Hazard-determining components of labeling:
Hazard phrases:

Tris HCL, N,N-Dimethylformamide , Estradiol

Precautionary phrases:

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H351: Suspected of causing cancer.
H360: May damage fertility or the unborn child.
H362: May cause harm to breast-fed children.
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust or mist.
P263: Avoid contact during pregnancy/ while nursing.
P264: Wash (hands and exposed skin) thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P280: Wear protective gloves/protective clothing.
P281: Use personal protective equipment as required.
P501: Dispose of contents/container to: approved disposal facility.

3.	COMPOSITION/INFORMATION ON INGREDIENTS – HAZARDOUS COMPONENTS
----	--

This pouch 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 indicator of safety.

Chemical Ingredient	CAS No.	Quantity in Kit
Tris HCL	1185-53-1	1% - 2%
N,N-Dimethylformamide	68-12-2	≤ 0.11%
Estradiol	50-28-2	≤ 0.0001%

4.	EMERGENCY FIRST AID MEASURES
----	-------------------------------------

General Information: Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident is recommended

Eye Contact: Immediately flush eyes with plenty of tepid water for 15 minutes while separating eye lids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact: In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Inhalation: If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Ingestion: In case of ingestion, contact a poison control center or physician for instructions.

Notes to Physician: According to 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.

5.	FIRE FIGHTING MEASURES
----	-------------------------------

Flammable Properties: Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media: Use extinguishing media appropriate for the surrounding fire.

Unsuitable Extinguishing Media: Unknown

Special Fire Fighting Procedures: Conventional fire fighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

6.	ACCIDENTAL RELEASE MEASURES
-----------	------------------------------------

Personal Precautions:	Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.
Environmental Precautions:	This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosives metal azides. Follow proper disposal procedures.
Methods and Materials for Containment and Clean-Up:	Absorb spills with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7.	HANDLING AND STORAGE
-----------	-----------------------------

Handling:	Follow universal/standard precautions when handling this material. See Section 8. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.
Storage:	Store the kit components as specified in the product instructions/package insert provided with the test kit or the instrument operation manual.

8.	EXPOSURE CONTROL/PERSONAL PROTECTION MEASURES
-----------	--

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 cloths, skin, mouth, mucous membranes and eyes, 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 dedicated location.
Eye Protection:	Wear appropriate protective chemical safety glasses.
Protective Gloves:	Wear chemical resistant protective gloves
Protective Clothing:	Wear a labcoat, clinic jacket, gown, apron and/or smock.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriate designated area or container for storage, processing, decontamination or disposal.

9.	PHYSICAL AND CHEMICAL PROPERTIES
-----------	---

Appearance:	Packet containing 4 chemically filled chambers.
Fire Hazard:	None
Flash Point:	None
Auto Igniting:	None

10.	STABILITY AND REACTIVITY
------------	---------------------------------

Chemical Stability:	Stable under normal conditions
Incompatible Materials:	Strong Acids
Hazardous Decomposition Products:	Variable Oxides under fire conditions only.
Possibility of Hazardous Reactions:	Can react if in contact with – Strong acids (releases toxic gas)

11.	TOXICOLOGICAL INFORMATION
------------	----------------------------------

Acute Health Effects:	Harmful in contact with skin and if swallowed. May cause headache, nausea and vomiting.
Biohazard Potential:	Consists of <1% animal protein.
Carcinogenicity:	N,N-Dimethylformamide is present at levels greater than 0.1% and is identified as probable, possible or confirmed human carcinogen.
Reproductive Effects:	No information available

12.	ECOLOGICAL INFORMATION
------------	-------------------------------

Toxicity	No information available
Bioaccumulative Potential	No information available
Persistence and Degradability	No information available
Other Adverse Effects	None known

13.	DISPOSAL CONSIDERATIONS
------------	--------------------------------

Waste Treatment Methods	Disposal should be in accordance with local, state or national legislation. Do NOT dispose of via domestic waste. Ensure that all packaging is disposed of safely.
--------------------------------	--

14.	TRANSPORT INFORMATION
------------	------------------------------

Basic Shipping Description:	Not classified as dangerous for transport via land, sea, or air.
------------------------------------	--

15.

REGULATORY INFORMATION

**US Federal
Regulations:**

This preparation is a component of an FDA-regulated in vitro diagnostic device.

US State Regulations:



WARNING: This product can expose you to chemicals including N,N-Dimethylformamide and Estradiol, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

16.

OTHER INFORMATION

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.

Contact for general information:

Qualigen, Inc.
2042 Corte del Nogal, Suite B
Carlsbad, CA 92011
USA
Phone : (760) 918-9165 (8 am to 5 pm PST)
(877) 709-2169
Qualigeninc.com

Disclaimer:

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 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. In no event shall Qualigen, Inc. be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Qualigen, Inc. has been advised of the possibility of such damages.