



SAFETY DATA SHEET

REVISION DATE: 3 August 2016

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Section 1 – PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Xpert FII & FV NOR/MUT Control
SYNONYMS: N/A
PRODUCT CODES: G116, G11601, G11602

<u>G116 Kit Components:</u> (2 bottles of each)	<u>P/N</u>	<u>Description</u>
Xpert FII & FV Normal Control	G116a	1.0mL Homozygous WT for FII & FV
Xpert FII & FV Mutant Control	G116b	1.0mL Homozygous Mutant for FII & FV
<u>G11601 Kit Components:</u> (2 bottles of each)	<u>P/N</u>	<u>Description</u>
Xpert FII & FV Normal Control	G116a01	0.5mL Homozygous WT for FII & FV
Xpert FII & FV Mutant Control	G116b01	0.5mL Homozygous Mutant for FII & FV
<u>G11602 Kit Components:</u> (2 bottles of each)	<u>P/N</u>	<u>Description</u>
Xpert FII & FV Normal Control	G116a02	1.7mL Homozygous WT for FII & FV
Xpert FII & FV Mutant Control	G116b02	1.7mL Homozygous Mutant for FII & FV

USE OF THE SUBSTANCE PREPARATION: Xpert FII & FV NOR/MUT Control is intended for *in vitro* use as a quality control to monitor analytical performance of the Xpert HemosIL[®] Assay on the GeneXpert[®] System. Xpert FII & FV NOR/MUT Control is formulated to monitor the detection of mutations Factor II G20210A and Factor V Leiden G1691A, the most common genetic risk factors for thrombotic events.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET AND MANUFACTURER NAME AND ADDRESS:

Maine Molecular Quality Controls, Inc (MMQCI) 23 Mill Brook Road Saco, Maine 04072 (USA) E-mail: info@mmqci.com www.mmqci.com Emergency telephone number: 207-885-1072	Manufacturer Phone Number 207-885-1072	Manufacturer Fax Number 207-885-1079
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Section 2 – HAZARD(S) IDENTIFICATION

HAZARDOUS INGREDIENTS:

23% Ethyl Alcohol

Classification: Void

This product is not considered to be flammable under ordinary laboratory conditions based on studies performed by MMQCI.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	23	None	None

Dangerous Components According to EC Criteria: None

Section 4 – FIRST AID MEASURES

General: No emergency care is anticipated.

In all cases of doubt or when symptoms occur, do the following:

Inhalation: Remove affected person to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Ingestion: Rinse mouth with water. Seek medical attention if signs of toxicity occur.

Skin: Remove contaminated clothing. Wash affected area with plenty of soap and water. Seek medical attention if irritation develops.

Eyes: Rinse immediately with plenty of water. Remove contact lenses if worn. Seek medical attention if redness or irritation develops.



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Section 5 – FIRE FIGHTING MEASURES

Flash Point (Method Used): 32°C (90°F) (ethanol vapor), Closed Cup
Flammable Limits: N/A
Extinguishing Media: CO₂ or Dry Chemical / ABC Fire Extinguisher or water
Auto-ignition Temperature: 363°C (ethanol vapor)
Special Fire Hazards: N/A
Explosion Hazards: N/A

Section 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate protective clothing.
Steps to be Taken in Case Material is Released or Spilled: Wipe up with appropriate absorbent material.
Waste Disposal Method: Normal disposal container

Section 7 – HANDLING AND STORAGE

Handling: Handle per package insert instructions.
Storage: Store at 2°- 8°C. Do not freeze.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Values: None
Exposure Controls: This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash station.

PERSONAL PROTECTIVE EQUIPMENT:

Respiratory Protection:	None required	Eye Protection:	Safety glasses
Skin Protection:	Lab coat, gloves	Work / Hygiene Practices:	Standard laboratory precautions
Ventilation:	Normal	Other Protective Equipment:	None required

Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

Component:	Ethanol (23%)	Specific Gravity (H₂O = 1):	N/A
Boiling Point:	86°C (186.8°F)	Evaporation Rate (Butyl Acetate = 1):	N/A
Melting Point:	N/A	Solubility in Water:	Yes
Vapor Density (AIR = 1):	N/A	pH:	N/A
Vapor Pressure (mmHg):	N/A	Odor:	Fruity
Appearance:	Liquid, colorless		

Section 10 – STABILITY AND REACTIVITY

Stability: Stable
Incompatibility (Materials to avoid): None known
Hazardous Decomposition or Byproducts: None known
Conditions to Avoid: Avoid high heat with flames and other sources of ignition.
Hazardous Polymerization: Will not occur



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Section 11 – TOXICOLOGICAL INFORMATION

Routes of Entry: N/A
Health Hazards (Acute and Chronic): None known
Carcinogenicity: No
IARC Monographs: N/A
Signs and Symptoms of Exposure: None known
Medical Conditions generally aggravated by Exposure: None known
NTP: N/A
OSHA Regulated: No

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity: Regarded as having low toxicity to aquatic organisms.
Mobility: Water soluble, will partition to aqueous phase. Lost within short period through evaporation and dissolution. Poorly absorbed into soils and sediments.
Bioaccumulation: Low bioaccumulation potential.
Degradability: Readily biodegradable.

Section 13 – DISPOSAL CONSIDERATIONS

Appropriate Disposal / Product: Dispose of unused product, spilled substance and waste in normal disposal container.

Section 14 – TRANSPORT INFORMATION

Land Transport: Not restricted. Not regulated as hazardous goods.
Sea Transport: Not restricted. Not regulated as hazardous goods.
Air Transport: Not restricted. Not regulated as hazardous goods.

Section 15 – REGULATORY INFORMATION

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	23	None	None

California Proposition 65: This product does not contain any substances listed on California's listing of known or potential carcinogens.
Chemical Safety Assessment: Observe general laboratory safety regulations when handling chemicals.

Section 16 – OTHER INFORMATION

SDS Prepared by: MMQCI
Preparation Date: 3 August 2016

Disclaimer: The information contained in this SDS is provided only for use as a guide. The SDS was carefully prepared based on references and tests believed to be reliable; however, MMQCI makes no guarantee of the accuracy and completeness of the data. Any use of the data must be in accordance with applicable federal, state and local regulations.