



# 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<sup>®</sup> Assay on the GeneXpert<sup>®</sup> 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:

<b>Maine Molecular Quality Controls, Inc (MMQCI)</b> 23 Mill Brook Road Saco, Maine 04072 (USA) E-mail: info@mmqci.com <a href="http://www.mmqci.com">www.mmqci.com</a> Emergency telephone number: 207-885-1072	<b>Manufacturer Phone Number</b> 207-885-1072	<b>Manufacturer Fax Number</b> 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

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**Flash Point (Method Used):** 32°C (90°F) (ethanol vapor), Closed Cup  
**Flammable Limits:** N/A  
**Extinguishing Media:** CO<sub>2</sub> or Dry Chemical / ABC Fire Extinguisher or water  
**Auto-ignition Temperature:** 363°C (ethanol vapor)  
**Special Fire Hazards:** N/A  
**Explosion Hazards:** N/A

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## Section 6 – ACCIDENTAL RELEASE MEASURES

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**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

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## Section 7 – HANDLING AND STORAGE

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

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## Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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**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:

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

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## Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

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<b>Component:</b>	Ethanol (23%)	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	N/A
<b>Boiling Point:</b>	86°C (186.8°F)	<b>Evaporation Rate (Butyl Acetate = 1):</b>	N/A
<b>Melting Point:</b>	N/A	<b>Solubility in Water:</b>	Yes
<b>Vapor Density (AIR = 1):</b>	N/A	<b>pH:</b>	N/A
<b>Vapor Pressure (mmHg):</b>	N/A	<b>Odor:</b>	Fruity
<b>Appearance:</b>	Liquid, colorless		

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## Section 10 – STABILITY AND REACTIVITY

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**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.