

ARCHITECT Tacrolimus Whole Blood Precipitation Reagent

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Read Highlighted Changes: Revised November 2014.

INTENDED USE

The ARCHITECT Tacrolimus Whole Blood Precipitation Reagent is for the extraction of tacrolimus from samples (human whole blood patient specimens, controls and ARCHITECT Tacrolimus Calibrators) to be tested on the ARCHITECT iSystem.

Refer to the ARCHITECT Tacrolimus reagent package insert for pretreatment instructions.

CONTENTS

1 Bottle (20.4 mL) ARCHITECT Tacrolimus Whole Blood Precipitation Reagent containing zinc sulfate solution in methanol and ethylene glycol.

PRECAUTIONS

- IVD
- For In Vitro Diagnostic Use
- CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.¹⁻⁴

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The following warnings and precautions apply to:

DANGER	Contains methanol, ethylene glycol and	
	zinc sulfate.	
H225	Highly flammable liquid and vapor.	
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.	
H370	Causes damage to organs.	
H318	Causes serious eye damage.	
H411	Toxic to aquatic life with long lasting	
	effects.	
Prevention		
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition	
	sources. No smoking.	
P233	Keep container tightly closed.	
P260	Do not breathe mist / vapors / spray.	
P280	Wear protective gloves / protective	
	clothing / eye protection.	
P273	Avoid release to the environment.	

Response		
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P370+P378	In case of fire: Use CO2, dry chemical, dry	
	sand, alcohol resistant foam to extinguish.	
P304+P340	IF INHALED: Remove person to fresh air	
	and keep comfortable for breathing.	
P303+P361+P353	IF ON SKIN (or hair): Take off immediately	
	all contaminated clothing. Rinse skin with	
	water / shower.	
P301+P330+P310	IF SWALLOWED: Rinse Mouth.	
	Immediately call a POISON CENTER or	
	doctor / physician.	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for	
	several minutes. Remove contact lenses, if	
	present and easy to do. Continue rinsing.	
P310	Immediately call a POISON CENTER or	
	doctor / physician.	
Storage		
P403+P235	Store in a well-ventilated place. Keep cool.	
Disposal		
P501	Dispose of contents / container in	
	accordance with local regulations.	

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

STORAGE

- Reagents are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.

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BIBLIOGRAPHY

- US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- US Department of Health and Human Services. *Biosafety in* Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
- Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition. CLSI Document M29-A3. Wayne, PA: CLSI; 2005.

Key to Symbols

i	Consult instructions for use
	Manufacturer
X	Temperature limitation
2	Use by/Expiration date
CONTAINS: METHANOL	Contains Methanol
DANGER: ORGAN DAMAGE	Danger: Causes damage to organs.
ECREP	Authorized Representative in the European Community
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF USA	Product of USA
REF	List Number
WHOLE BLOOD PRECIPITATION REAGENT	Whole Blood Precipitation Reagent

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Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

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