



**ARCHITECT**  
**Cyclosporine Whole Blood**  
**Precipitation Reagent Kit**

REF 1L75-55



**en**  
**Cyclosporine**  
**1L75**  
**093417.00 Rev 000 / R07**  
**H1L750**

Read Highlighted Changes: Revised February 2019.

**INTENDED USE**

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

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

**CONTENTS**

1 Bottle (12.3 mL) ARCHITECT Cyclosporine Whole Blood Solubilization Reagent containing surfactant in water. Preservative: ProClin 300.

1 Bottle (45.0 mL) ARCHITECT Cyclosporine 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.<sup>1-4</sup>

The following warnings and precautions apply to:	
<b>WHOLE BLOOD SOLUBILIZATION REAGENT</b>	
<b>WARNING</b>	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
<b>Prevention</b>	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
<b>Response</b>	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
<b>Disposal</b>	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.

The following warnings and precautions apply to:	
<b>WHOLE BLOOD PRECIPITATION REAGENT</b>	
<b>DANGER</b>	Contains methanol, ethylene glycol and zinc sulfate.
H225	Highly flammable liquid and vapor.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H370	Causes damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
<b>Prevention</b>	
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.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
<b>Response</b>	
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.
P308+P311	IF exposed or concerned: Call a POISON CENTER or doctor/physician.
<b>Storage</b>	
P403+P235	Store in a well-ventilated place. Keep cool.
<b>Disposal</b>	
P501	Dispose of contents / container in accordance with local regulations.

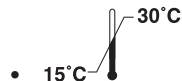
\* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

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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.



### BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. 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

	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
<b>CONTAINS: METHANOL</b>	Contains Methanol
<b>EC REP</b>	Authorized Representative in the European Community
<b>INFORMATION FOR USA ONLY</b>	Information needed for United States of America only
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>PRODUCED FOR ABBOTT BY</b>	Produced for Abbott by
<b>PRODUCT OF USA</b>	Product of USA
<b>REF</b>	List Number
<b>WHOLE BLOOD PRECIPITATION REAGENT</b>	Whole Blood Precipitation Reagent
<b>WHOLE BLOOD SOLUBILIZATION REAGENT</b>	Whole Blood Solubilization Reagent

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