

Cyclosporine
1L75
093282.00 Rev 000 / R06
H1L750

Read Highlighted Changes: Revised October 2014.

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.¹⁻⁴

The following warnings and precautions apply to: WHOLE BLOOD SOLUBILIZATION REAGENT	
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WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
Prevention	
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.
Response	
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.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings WHOLE BLOOD PRECIPITA	s and precautions apply to:
DANGER:	Contains methanol, ethylene glycol and zinc sulfate heptahydrate.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.
H370	Causes damage to organs.
H226	Flammable liquid and vapor.
H319	Causes serious eye irritation.
H412	Harmful 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	
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.
P308+P311	IF exposed or concerned: 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

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

accordance with local regulations.

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.

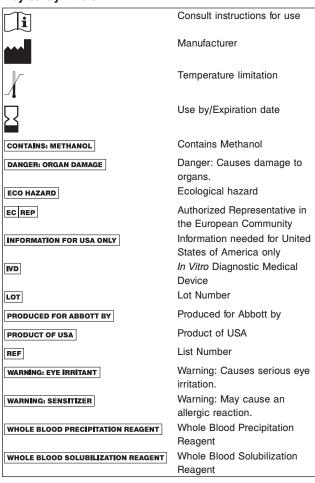


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- US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
- World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: 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



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