

Sirolimus 1L76 093374.00 REV 000 / R07 H1L760

Read Highlighted Changes: Revised June 2017.

# **INTENDED USE**

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

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

### **CONTENTS**

1 Bottle (30 mL) ARCHITECT Sirolimus Whole Blood Precipitation Reagent containing zinc sulfate solution in DMSO 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: WHOLE BLOOD PRECIPITATION REAGENT WARNING Contains ethylene glycol, dimethyl sulfoxide and zinc sulfate. H373 May cause damage to organs through prolonged or repeated exposure. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects Prevention P260 Do not breathe mist / vapors / spray. P264 Wash hands thoroughly after handling. P280 Wear protective gloves / protective clothing / eye protection. P273 Avoid release to the environment. Response IF IN EYES: Rinse cautiously with water P305+P351+P338 for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice / attention. P314 Get medical advice / attention if you feel unwell. 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.



### **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—Fourth Edition. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.

# **Key to Symbols**

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Ţ <u>i</u>	Consult instructions for use
	Manufacturer
<b>1</b>	Temperature limitation
$\Sigma$	Use by/Expiration date
EC REP	Authorized Representative in the European Community
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	In Vitro 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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