

Sirolimus Whole Blood Precipitation Reagent

Revised June 2019.

NAME

Alinity i Sirolimus Whole Blood Precipitation Reagent

INTENDED USE

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

For additional information, refer to the Alinity i Sirolimus package insert for pretreatment instructions.

CONTENTS

The **WHOLE BLOOD PRECIPITATION REAGENT** contains zinc sulfate solution in DMSO and ethylene glycol.


Reagent	Quantity
WHOLE BLOOD PRECIPITATION REAGENT	1 x 30 mL

PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- **Rx ONLY**

Safety Precautions

- **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 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	
P305+P351+P338	IF IN EYES: Rinse cautiously with water 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 Alinity ci-series Operations Manual, Section 8.

STORAGE

- The reagent is stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.

	Storage Temperature	Maximum Storage Time
Unopened	15 to 30°C	Until expiration date
Opened	15 to 30°C	Until 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—Fourth Edition*. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

ISO 15223 Symbols

	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
EC REP	Authorized Representative in the European Community
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot Number
REF	List Number

Other Symbols

INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF USA	Product of USA
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).
WHOLE BLOOD PRECIPITATION REAGENT	Whole Blood Precipitation Reagent

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