



FDA Registration Number 3012101172



**Sample Transport Reagent
Catalog Number: SSFIN-0007**

INTENDED USE:

ZeptoMetrix Sample Transport Reagent™ (ZMC STR™)* is a general purpose reagent and non-propagating buffer designed to stabilize nucleic acids within intact cells for long term storage prior to molecular diagnostic testing.

PRODUCT SUMMARY AND EXPLANATION:

ZMC STR™ is a non-volatile, non-flammable collection buffer that stabilizes intact cells for extended storage at 2-28°C. ZMC STR™ maintains cellular integrity by inhibiting biochemical processes and stabilizing cellular membranes, proteins, and nucleic acids. Collected samples can also be frozen and thawed without losing reduction in cell count and the nucleic acid amplification and detection.

Reagent is provided in labeled screw –cap tubes designed for sample transport of clinical samples.

Each package contains 10 x 20 mL tubes.

*Patents Pending

PRINCIPLE:

ZMC STR™ stabilizes human cell integrity for extended storage at 2-28°C prior to diagnostic molecular testing. Healthcare providers may perform a standard clinical sample collection procedure, such as with a swab or brush collection device, and store specimen in ZMC STR™. Specimens in ZMC STR™ may be transported to a secondary location prior to testing.

PRECAUTIONS:

Collection procedure must be empirically determined.

All specimens and materials used to collect should be treated as potentially infectious. Use universal precautions when handling and disposing of this product when it contains clinical specimens. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

This transport buffer does not contain material of human and animal origin and/or animal origin however the user should observe Universal Precautions once a clinical specimen is added.

Do not ingest.

To avoid cross-contamination, use separate collection devices for each specimen.

Do not use beyond the expiration date shown on the label.

If product is received damaged or leaking, contact ZeptoMetrix for instructions.

NOT FOR USE IN HUMANS:

Do not immerse collection device into Transport Buffer prior to patient sampling. Buffer is not designed to be used internally. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under the USA Food and Drug Administration Section 351 of the Public Health Service Act or for any other product intended for administration to humans.

RECOMMENDED STORAGE:

Store at 2-28°C.

INSTRUCTIONS FOR USE:

Collect specimens with collection device according to established protocols; see below for examples of devices. Add specimen to collection buffer, mix gently for 30 seconds, remove and discard collection device and close cap tightly.

Manufacturer	Device Name	Device Type
Jinpu Yuan Brush Co., Ltd	Just For Me Brush	Cytology Brush
Cooper	Surgical Medscand Cytobrush	Cytology Brush - Traditional Wire and Bristle
	Surgical Medscand Pap-Perfect Plastic Spatula	Cervical Spatula - Plastic
Puritan	CerviSoft Foam Swab	Foam swab for cytology
	Polyester Swab (6")	Polyester/Dacron Swab
	Hydraflock Flocked Swab	Flocked Swab
Wallach	Wallach Pappette	Cervical Broom

Follow the manufacturer instructions for use as a clinical sample.

LIMITATIONS:

This product is *For In Vitro Diagnostic Use*.

The use of this product with diagnostic test or instrumentation should be previously validated by the user.

To be used by trained personnel only.

The following exogenous substances interfered with the Cepheid Xpert® HPV Assay:

- Clotrimazole Vaginal Cream at ≥1% w/v
- Miconazole 3 at ≥1% w/v
- Monistat 1 at ≥0.25% w/v
- VCF® Vaginal Contraceptive Foam at ≥10% w/v

EXPECTED RESULTS:

After collection, cells will remain full and intact for up to 7 months.



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PRODUCT WARRANTY:

ZeptoMetrix Corporation's limited product warranty and other terms and conditions related to the purchase and use of ZeptoMetrix products are set forth in ZeptoMetrix's Terms and Conditions of sale found on ZeptoMetrix's website at [Sales Terms and Conditions](#). If you have any questions, please contact ZeptoMetrix Customer Service at custserv@zeptometrix.com.

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LEGEND OF LABELING SYMBOLS:

	Manufacturer
	<i>In vitro</i> Diagnostic Use
	Catalog Number
	Batch Code
	Temperature Limitation
	Expiration Date
	Consult Instructions For Use
	Do Not Reuse

 Manufacturer:
ZeptoMetrix Corporation
878 Main Street
Buffalo, NY 14202, USA

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