

Dear Customer,

The U.S. Food and Drug Administration (FDA) has issued specific guidelines for the use and distribution of reagents labeled and intended “For Research Use Only” applications. The products manufactured or distributed by ZeptoMetrix Corporation are currently subject to these guidelines because they are not licensed by the FDA for clinical use in the United States.

As a manufacturer and distributor of products intended and labeled “For Research or Manufacturing Use Only”, it is the responsibility of ZeptoMetrix Corporation to ensure that our customers/distributors understand this intended use and that each customer uses the products for bonafide research endeavors. The test kits and reagents supplied by ZMC are intended for research or manufacturing use only. They are not intended for use in the diagnosis or prognosis of disease, or for screening, and may not be used as confirmatory tests in diagnostic situations.

In the event that the product is intended to be used as a raw material in an *in vitro* diagnostic kit, it is the manufacturer’s responsibility to ensure that the product usage meets the guidelines intended by the FDA or the regulatory organization in the destination country.

To ensure a mutual understanding of this matter, we respectfully request that you review the above statements and complete the attached Certificate of Compliance. Please fax the completed Certificate to my attention at 716-882-0959. Upon receipt of the completed certification, all orders will be sent without delay.

Should you have any further questions, please feel free to contact me at 800-274-5487 or 716-882-0920. I apologize for any inconvenience this may cause. Please do not hesitate to contact me with any questions regarding this information.

Sincerely,

Anna L. Schendel  
Manager Customer Service  
ZeptoMetrix Corporation  
Attachment



**CERTIFICATE OF COMPLIANCE**

\_\_\_\_\_  
Facility/Laboratory

\_\_\_\_\_  
Customer ID #

\_\_\_\_\_  
Street

\_\_\_\_\_  
Telephone #

\_\_\_\_\_  
City/ State/ Zip

\_\_\_\_\_  
Fax#

The undersigned has read and understands the statements provided in the attached letter for the products manufactured and distributed by ZeptoMetrix Corporation. We understand the current regulatory requirements with respect to the distribution and use of the referenced products. We agree to comply with the noted requirements, and intend to use the referenced products only for the use(s) specified below. We agree that the referenced products will be used for research purposes only. The referenced products specifically **will not be used** in the diagnosis or prognosis of disease, for donor screening, as a confirmatory test, as a supplemental test, or to counsel donors. We also agree that in the event that we utilize the reference product(s) as a raw material in an assay intended for diagnostic purposes, we take full responsibility for assuring that the subsequent product(s) are **in full regulatory compliance** with all applicable local, state, national, and international requirements. We also understand the Food and Drug Administration has the right and the legal authority to audit our organization with respect to the use(s) of the referenced product(s).

PRODUCTS TO BE  
PURCHASED

ESTIMATED  
12 MONTH TOTAL

BRIEF DESCRIPTION OF USE

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

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For ZMC Office Use Only

Certificate Number: \_\_\_\_\_

Date: \_\_\_\_\_

Follow Up: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_