



OraSure Technologies, Inc.

January 09, 2015

Ms. Melissa Ervin
Laboratory Manager
City Of Columbus
Public Health Department
240 Parsons Avenue
Columbus, OH 43215

SUBJECT: Sole Source Letter for OraQuick[®] HCV Rapid Antibody Test & OraQuick ADVANCE[®]
Rapid HIV-1/2 Antibody Tests

Dear Ms. Ervin:

OraSure Technologies, Inc. (“OraSure”) is the only licensed manufacturer of the OraQuick[®] HCV Rapid Antibody Test (the “OraQuick[®] Test”), PMA P080027, product numbers 1001-0180, 100 count, 1001-0181, 25 count, 1001-0182, Controls and OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test (the “OraQuick[®] Test”), PMA BP010047, product numbers 1001-0079 (25 count), P/N 1001-0078 (100 count) and P/N 1001-0077, OraQuick *ADVANCE*[®] Controls.

OraSure is the Sole Source distributor of the aforementioned products to Public Health Departments. The above listed products are not available for resale or distribution to Public Health Departments from any other source including web sites. Sales of these products by other vendors are not authorized by OraSure Technologies, Inc. and they will not be able to provide you with product.

If you need any further information, please contact Pat Reis at 916-782-3119 or e-mail preis@orasure.com.

Sincerely,

Tony Zezzo
EVP, Marketing and Sales

CITY OF COLUMBUS - SOLE SOURCE INFORMATION FORM

TO ACCOMPANY LEGISLATION WHICH WAIVES
ANY PROVISIONS OF COLUMBUS CITY CODE CHAPTER 329.
(LIMIT YOUR RESPONSE TO THIS SHEET)

1. Verification of sole source: (Why no other individual or business entity is capable of supplying the needed item/service.)

- Sole source manufacturer/distributor.
- Sole distributor authorized for this territory.
- Patented product purchased for owner/developer.
- Sole company offering this unique service.
- Other:

2. Describe any effort to bid for alternate item (service or product) that is not provided by a sole source that would meet this need:

This is the only rapid HIV and test (FDA approved and CLIA waived) that is available for oral fluid testing. It will serve as the secondary supplemental test for preliminary positive HIV tests. This is also the only rapid 20 minute test for hepatitis C.

3. Describe efforts to determine/verify that the company is the sole source:

This is a proprietary item and Orasure is the sole manufacturer. They are the only company that can distribute it to the Health Department

4. Indicate how the price or fee structure was determined:

Pricing sheet attached

Ordinance No.: _____

Approved By: Authorized Approval on Corresponding Legislative File
