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IN-VITRO DIAGNOSTICS ♦ CONTRACT R&D ♦ OEM ♦ FDA-REGULATED

Dear Valued Distributor of the Alfa Scientific Oral-View® Saliva Tests:

June 3, 2011

In our ongoing effort to ensure full compliance with Federal Regulation we are sending this reminder to all of our distributors of the current status of the Oral-View® Saliva Tests. While a submission for FDA clearance of the Oral-View® test is currently pending, it remains a product that is clearly labeled and must be sold **FOR FORENSIC USE ONLY**.

Based on our understanding of the definition of “Forensic Use”, we feel that it is appropriate to sell such devices to court systems, police departments, probation/parole offices, juvenile detention centers, prisons, jails, correction centers and other similar law enforcement entities, or to laboratories performing forensic testing for these entities.

Therefore, following this definition, it is not appropriate to sell such devices for in vitro diagnostic applications, workplace testing or over the counter use. Alfa Scientific Oral View® Saliva Tests are not 510(k) cleared for in vitro diagnostic use, therefore “510(k) clearance”, or “FDA approval” should not be directly stated or implied on any of your labeling or promotional materials, through any promotional practices, or in any interactions with current or potential customers (including websites). Statements and marketing practices inconsistent with a “Forensic Use Only” intended use could result in possible FDA enforcement action as well as Alfa Scientific Design’s refusal to fulfill future orders.

Please continue to follow this guidance regarding the sale of Oral-View® Saliva tests. We will notify you immediately following the announcement of an FDA clearance. We value your business and hope that this information assists you in promoting and selling Alfa Scientific Design’s Forensic Use Only products in an appropriate manner.

To confirm your receipt of this communication please sign and date a copy of this letter and return to Alfa via e-mail attachment, fax or standard mail. We appreciate your cooperation. If you have any further questions please feel free to call either myself or Ms. Suni Dungan, our QA/RA Director.

Sincerely,

Jim Mc Menamy
Vice President/General Manager

I acknowledge receipt of this letter:

Printed Name: _____

Date: _____

Signature: _____

Title: _____

Company Name: _____