

K O P I E

March 27, 2006

Karin McDonough
VIVA Diagnostika GmbH
Horbeller-Str. 33
D-50858 Köln
Germany

RE: Complaint # 06088

Dear Karin,


This letter is in response to your complaint received by ACON Labs on February 21, 2006. The complaint claim is for misassembled cassettes for product number DOA-1105, lot number DOA5020322 (photographs of the affected device were provided).

The cassettes should have contained the following strips: AMP / COC / THC / BZO / TCA / BAR / MET / MOP / MTD/MDMA. One of the cassettes had a PCP strip in lieu of the MDMA strip and the strip in the far right channel of the device was incorrect. Our investigation showed that the error occurred during the assembly process in a specific workshop (workshop #2). Based on the photographs you provided and our investigation we have confirmed your complaint. In response to this confirmed complaint, we initiated a product recall (0602-001) for the complained lot of 2,250 pieces. You have already been provided a copy of the recall and the associated recall accountability form.

In July 2005, a quality plan to address misassembly issues was initiated for workshop #2. This lot was manufactured prior to the initiation of the quality plan and no similar complaints regarding product assembled in workshop #2 have been received since the quality plan was put into place. No new corrective action/preventive action will be initiated at this time however; we will continue to monitor the database for any future misassembly complaints.

Thank you for bringing this to our attention. ACON Labs is committed to providing safe and quality products to the marketplace. If you should have further questions, please don't hesitate to contact me.

Sincerely,



Frazier C. Sullivan
Quality Assurance Technical Representative
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ACON