DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Amy Levin
Sr. Regulatory Affairs Specialist II
Roche Molecular Systems, Inc.
4300 Hacienda Drive
PO Box 9002
Pleasanton, CA 94566

OCT 30 2008

Re: P060030
COBAS AmpliPrep/COBAS TaqMan HCV Test
Filed: December 20, 2006
Amended: December 14, 2006; December 19, 2006; December 20, 2007;January 5, 2008; January 17, 2007; August 6, 2007; February 19, 2008;September 12, 2008; September 24, 2008; October 27, 2008, October 28, 2008, October 30, 2008

Procode: MZP

Dear Ms. Levin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the COBAS AmpliPrep/COBAS TaqMan HCV Test. This device is an in vitro nucleic acid amplification test for the quantitation of hepatitis C viral (HCV) RNA in human plasma or serum of HCV-infected individuals using the COBAS AmpliPrep Instrument for automated specimen processing and the COBAS TaqMan Analyzer or the COBAS TaqMan 48 Analyzer for automated amplification and detection. Specimens containing HCV genotypes 1 – 6 have been validated for quantitation in the assay.

The COBAS AmpliPrep/COBAS TaqMan HCV Test is intended for use as an aid in the management of HCV-infected individuals undergoing anti-viral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and non-sustained virological response to HCV therapy. The results from the COBAS AmpliPrep/COBAS TaqMan HCV Test must be interpreted within the context of all relevant clinical and laboratory findings.

Assay performance characteristics have been established for individuals treated with peginterferon alfa-2a plus ribavirin. No information is available on the assay's predictive value when other therapies are used. Assay performance for determining the state of HCV infection has not been established." We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic

Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at 24 months at 2-8°C when unopened. Once opened HCV CS1, HCV CS2, HCV CS3, PG WR, and HCV CS4 are stable for 28 days at 2-8C. The controls HCV H(+)C, HCV L(+)C and CTM (–) C once opened should be discarded.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

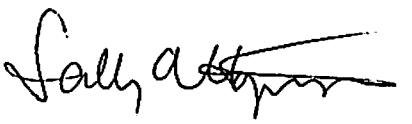
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Kathleen B. Whitaker, Ph.D. at 240-276-0723.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure