



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Grace LeMieux
Sr. Regulatory Affairs Administrator
Diagnostics Division
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6092

NOV 6 2007

Re: PMA P060035
ARCHITECT[®] CORE-M[™] Reagent Kit
ARCHITECT[®] CORE-M[™] Calibrators
ARCHITECT[®] CORE-M[™] Controls
Filed: December 1, 2006
Amended: January 11, February 9, April 12, May 25, October 26, and October 29,
2007
Procode: LOM

Dear Ms. LeMieux:

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 ARCHITECT[®] CORE-M, ARCHITECT[®] CORE-M Calibrators, and ARCHITECT[®] CORE-M Controls. The device is indicated for:

ARCHITECT[®] CORE-M

The ARCHITECT CORE-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human adult and pediatric serum or plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HBc is indicated as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

ARCHITECT[®] CORE-M Calibrators

The ARCHITECT CORE-M Calibrators are used for the calibration of the ARCHITECT *i* System when the system is used for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) using the ARCHITECT CORE-M Reagent Kit. The performance of the ARCHITECT CORE-M Calibrators has not been established with any other IgM anti-HBc assays.

ARCHITECT[®] CORE-M Controls

The ARCHITECT CORE-M Controls are used for monitoring the performance of the ARCHITECT *i* System when used for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) when using the ARCHITECT CORE-M Reagent Kit. The performance of the ARCHITECT CORE-M Controls has not been established with any other IgM anti-HBc assays.

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 6 months when stored at 2-8°C. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

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 Prasad Rao, Ph.D., at (240) 276-0722.

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

TRANSMISSION VERIFICATION REPORT

TIME : 11/06/2007 18:01
NAME : CDRH OIVD
FAX : 2402760644
TEL : 2402760450
SER.# : BROE6J474069

DATE, TIME
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11/06 18:00
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FDA



*Office of In Vitro Diagnostic Device Evaluation and
Safety*

Center for Devices and Radiological Health

Food & Drug Administration

2098 Gaither Road, HFZ-440

Rockville, Maryland 20850

Office Director's # 240-276-0484

Chemistry & Toxicology Division # 240-276-0443

Microbiology Division # 240-276-0496

Immunology & Hematology Division # 240-276-0493

FAX # 240-276-0652 or 240-276-0663

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of this communication is not authorized. If you have received this document in error, please
immediately notify us by telephone and return it to us at the above address by mail. Thank you."*

To: *Grace Lemieux*

From: *Patricia Beverly for Dr. Sally Hojvat*

Total Pages: 4

Comments:

CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations that require a PMA supplement cannot be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
 - a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
 - b. reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.
2. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:
 - a. has not been addressed by the device's labeling; or
 - b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.

The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Additional information on MDR is available at <http://www.fda.gov/cdrh/devadvice/351.html>

October 25, 2007

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

Re: PMA Number: **P060035**
Device Trade Name: **ARCHITECT CORE-M Reagents, Calibrators and Controls**

To Whom It May Concern:

We have received your form electronically dated October 24, 2007, and

We concur with the "Conditions of Approval" which were attached to the email dated October 24, 2007

We do not concur with the "Conditions of Approval" which were enclosed with the approvable letter or other restrictions as stated in the approvable letter and have attached our suggested revisions/comments.

We did not have postapproval study requirements

We agree to these postapproval study requirements.

We disagree with the proposed postapproval study requirements and have attached our comments.

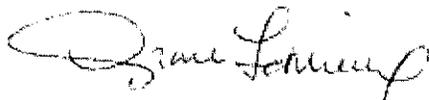
Attached is the postapproval study protocol.

We did not have any additional deficiencies to address as a result of the approvable letter

We did not have any additional information provided in this response that is not identified above.

Sincerely,

ABBOTT LABORATORIES



Grace LeMieux
Sr. Regulatory Affairs Administrator

Abbott

XII. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Microbiology Advisory Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

FDA issued an approval order on November 6, 2007.

The applicant's manufacturing facility was inspected on 5/2/07 (Abbott Park), & 7/20/07 (Puerto Rico) and found to be in compliance with the Quality Systems Regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

Post-approval Requirements and Restrictions: See approval order.

Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION:

Device Generic Name: IgM Antibody to Hepatitis B Core Antigen
(Anti-HBc IgM)

Device Trade Name: ARCHITECT[®] CORE-M[™] Reagent Kit
ARCHITECT[®] CORE-M[™] Calibrators
ARCHITECT[®] CORE-M[™] Controls

Name and Address of Applicant: Abbott Laboratories
Abbott Diagnostics Division
100 Abbott Park Road
Abbott Park, IL 60064-3500

Premarket Approval Application (PMA) Number: P060035

Date of Panel Recommendation: None

Date of Notice of Approval to the Applicant: November 6, 2007

II. INDICATIONS FOR USE:

Reagent Kit

The ARCHITECT CORE-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human adult and pediatric serum or plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HBc is indicated as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

Calibrators

The ARCHITECT CORE-M Calibrators are used for the calibration of the ARCHITECT *i* System when the system is used for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) using the ARCHITECT CORE-M Reagent Kit. The performance of the ARCHITECT CORE-M Calibrators has not been established with any other IgM anti-HBc assays.

Summary of Safety and Effectiveness Data

Controls

The ARCHITECT CORE-M Controls are used for monitoring the performance of the ARCHITECT *i* System when used for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human adult serum and plasma when using the ARCHITECT CORE-M Reagent Kit. The performance of the ARCHITECT CORE-M Controls has not been established with any other IgM anti-HBc assays.

III. CONTRAINDICATIONS: None known.

IV. WARNINGS AND PRECAUTIONS: For *in vitro* diagnostic use only.

Warnings and precautions for ARCHITECT CORE-M Reagent Kit, ARCHITECT CORE-M Calibrators, and ARCHITECT CORE-M Controls are stated in the respective product labeling.

V. DEVICE DESCRIPTION:

Kit Configurations and Components

For detection of IgM antibody to hepatitis B core antigen, the ARCHITECT CORE-M Reagent Kit is composed of the following two components:

- o ARCHITECT CORE-M Microparticles: 1 or 4 Bottle(s) (5.6 mL)
Anti-human IgM (mouse, monoclonal) coated microparticles in TRIS buffer with protein (1.0% bovine serum albumin and 2.5% goat IgG) additives. Minimum concentration: 0.12% solids. Preservatives: antimicrobial agents.
- o ARCHITECT CORE-M Conjugate: 1 or 4 Bottle(s) (5.9 mL)
Acridinium-labeled hepatitis B virus core antigen (*E. coli*, recombinant) conjugate in succinate buffer with protein (2.5% bovine serum albumin and 2.0% bovine calf serum) additives. Minimum concentration: 0.4 µg/mL. Preservatives: antimicrobial agents.

Summary of Safety and Effectiveness Data

In addition, the following components are required for the ARCHITECT CORE-M Reagent Kit:

- o ARCHITECT *i* System is an analyzer designed to perform automated immunoassay tests based on the use of CMIA detection technology.
- o ARCHITECT CORE-M Calibrators, which consists of calibrator 1 and calibrator 2 for the calibration of the instrument.
- o ARCHITECT CORE-M Controls (or other control material), which consist of a negative control and a positive control.
- o ARCHITECT *i* Pre-Trigger Solution contains 1.32% (w/v) hydrogen peroxide.
- o ARCHITECT *i* Trigger Solution contains 0.35N sodium hydroxide.
- o ARCHITECT *i* Wash Buffer contains phosphate buffered saline solution with preservative.

The ARCHITECT CORE-M Calibrators contain:

- o 1 Bottle (4 mL) of Calibrator 1, which is recalcified IgM anti-HBc negative human plasma.
- o 1 Bottle (4 mL) of Calibrator 2, which is IgM anti-HBc positive human plasma in recalcified IgM anti-HBc negative human plasma.
- o ProClin[®] 950, ProClin 300, and other antimicrobial agents are used as preservatives in Calibrator 1 and Calibrator 2.

The ARCHITECT CORE-M Controls contain:

- o 1 Bottle (4 mL) of Negative Control, which is recalcified IgM anti-HBc negative human plasma.
- o 1 Bottle (4 mL) of Positive Control, which is IgM anti-HBc positive human plasma in recalcified IgM anti-HBc negative human plasma.
- o The positive control is blue and contains Acid Blue No. 9 dye.
- o ProClin 950, ProClin 300, and other antimicrobial agents are used as preservatives in the Negative Control and Positive Control.