

APPROVAL ORDER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sarah Parsons
Associate, Regulatory Affairs
Immunodiagnosics Systems
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

SEP 15 2004

Re: P030026
Vitros Immunodiagnostic Products Anti-HBc IgM Reagent Pack
Vitros Immunodiagnostic Products Anti-HBc IgM Calibrator

Dear Ms. Parsons:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) and issued an approval order on March 4, 2004. We inadvertently made an error in the Indications for Use in your approval order. The Indications for Use should read as follows:

1. *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack:

For the *in vitro* qualitative detection of IgM antibody to hepatitis B core antigen (anti-HBc IgM) in human adult and pediatric serum and plasma (heparin, EDTA and citrate) and neonate serum using the VITROS ECi Immunodiagnostic System. Assay results, in conjunction with other serological and clinical information, may be used for the laboratory diagnosis of individuals with acute or chronic hepatitis B.

2. *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator:

For use in the calibration of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of IgM antibody to hepatitis B virus core antigen (anti-HBc IgM) in human adult and pediatric serum and plasma (EDTA, heparin and citrate) and neonate serum using *Vitros* Anti-HBc IgM Reagent Packs.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact me at (301) 594- 2096.

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