



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

September 20, 2007

Alfred F.K. Lui, M.D.  
Focus Diagnostics  
5785 Corporate Ave  
Cypress, CA 90630

PFI 3774: Diagnostic Immunology Limited Exemption

Dear Dr. Lui:

The Wadsworth Center's clinical laboratory reference system has reviewed the application requesting a limited exemption from submission of individual validation packages for review and approval as performed under your permit in Diagnostic Immunology – Diagnostic Services Serology. Based on comprehensive review of your standardized method validation protocol supported by accepted validation packages to date, a limited exemption is hereby granted for the above referenced category for assays using the following specific methodologies:

ELISA/EIA, Western Blot, Multi-Analyte Immunodetection (MAID), Fluorescent Microsphere Immunoassay (FMI), Immunofluorescence Assay (IFA) and Immunoblot (IBL)

Please be reminded of your obligation to notify the Program of each addition to your test menu. Notification must be made using Section I of the Clinical Laboratory Evaluation Program Submission Guidelines for Test Approval, indicate validated specimen types, and must be accompanied by a summary description of the validation performed, including a summary of the data analysis, and sample reports for all possible outcomes, including test interpretation.

Further, a description of any modifications to your approved and exempted tests must be immediately forwarded to this office for evaluation by the program's professional staff. You will be informed if additional validation studies are required to support the modifications of your procedure.

If you have any questions or require further information, please contact either Beth Johansen at 518-402-4064 or Michael Neal at 518-402-4110. Additionally, they can be contacted by e-mail at [CLEPCERT@health.state.ny.us](mailto:CLEPCERT@health.state.ny.us)

Sincerely,

A handwritten signature in black ink, appearing to read 'Adam Nagy'.

Adam N. Nagy, Ph.D.  
Head, Technical Development Unit  
Clinical Laboratory Evaluation Program

MHN

cc: Reviewer  
Joyce Bladel  
Tony Aini