Ortho-Clinical Diagnostics
a Johnson & Johnson company

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December 23, 2003

IMPORTANT USER NOTIFICATION

ORTHO® Antibody to HBsAg ELISA Test System 3 and ORTHO® Antibody to HBsAg ELISA Test System 3 Confirmatory Test

Dear Customer,

Ortho-Clinical Diagnostics Inc., (OCD) after consulting with the Food and Drug Administration (FDA), is notifying you of reports of increased initial reactive (IR) and repeat reactive (RR) rates obtained with our Antibody to HBsAg ELISA Test System 3 donor screening assay with false repeat reactive results being confirmed using the Antibody to HBsAg ELISA Test System 3 Confirmatory Test.

We are currently examining available information as to the causes of these events. While our investigation continues, we recommend that you consider implementing the following measures to mitigate the problems noted for the donor screening assay:

- Prepare only enough substrate for use within two hours or less.
- Where feasible, use the semi-automated wash method for initial and/or repeat testing.
- If you are using the Ortho Summit Processor (OSP):

  Daily maintenance should also include running the Weekly Maintenance software function. Complete only the procedures performed automatically by the software.

  The Weekly Maintenance software function is accessed by selecting the following choices from the software menu:

  1. Main menu – select Services/Maintenance
  2. Maintenance menu – select Procedure/Weekly
     Allow the instrument to run through the three phase rinse cycles of the OSP system and tubing.

To minimize the potential for false-positives using the Confirmatory Test, the following changes are being made to the instructions for use of the Antibody to HBsAg ELISA Test System 3 Confirmatory Test kit:

- **Quality Control Procedures**

  Section 5. Calculation of Percent Reduction Results

  b. Calculation of Percent Reduction of the Specimen

  The following text has been added to explain how to calculate the percent reduction of the specimen:

  Calculate percent neutralization for each pair of control and test wells. Confirm only when % neutralization calculations are ≥ 50%.

  Consistent with the addition of the above instructions, the note quoted below that is in the current labeling for the product is no longer applicable and will be deleted:

  "Note: Cross control and test values until neutralization of ≥ 50% is obtained or until all four possible calculations are performed."

- **Specimen Dilution/Repeat Testing and Interpretation**

  Summary

  In order for a specimen to be considered confirmed positive:

  a. *The optical density values of both control wells must be greater than or equal to the confirmatory test cutoff.*
  b. *Confirmation is achieved only when both test wells reduce the reactivity of the specimen by at least 50%.*

Should you have any questions, require additional information, or wish to have a semi-automated washer for use in the interim, please contact OCD Customer Technical Services at 1-800-421-3311 (Options 2, 2, 1). We will keep you informed with regard to the outcome of our investigation. We thank you for your cooperation and compliance with the above interim measures during this time.

Sincerely,

Andrea Casper
Director of Worldwide Regulatory Affairs