

January 8, 2005

URGENT PRODUCT RECALL NOTIFICATION

FETALSCREEN™ Product Code 780540

Lot FS451 (expired on December 21, 2004)

Lot FS452 (expiration date January 18, 2005)

Lot FS453 (expiration date February 15, 2005)

Dear Customer,

Our records indicate that you were shipped FETALSCREEN Lots FS451, FS452, and/or FS453. Ortho-Clinical Diagnostics, Inc. (OCD) has received reports of weak or negative reactivity with the positive control provided in these kits. We have confirmed the complaints and are actively pursuing the root cause to identify corrective and preventive actions.

Our testing has indicated that in the presence of a weakly reactive positive control, patient samples of the same concentration may not show rosetting. This could result in the laboratory not performing subsequent quantitative testing that may be required to determine the extent of fetal maternal hemorrhage.

Therefore, you must immediately discontinue using FETALSCREEN Lots FS451 (expired), FS452, and FS453.

Please do the following until further notice:

- Discontinue using and discard any remaining kits of FETALSCREEN Lots FS451, FS452, and FS453. At this time we are unable to supply you with replacement product.
- Use an alternative method for detection of D (Rh_o) positive fetal red blood cells in the maternal circulation.
- Consult your Medical Director or appropriate Standard Operating Procedure (SOP) for evaluation of results for previously tested patients.
- Complete and return the attached Confirmation of Receipt form. Once we receive the completed form, we will credit your account.
- Forward the information in this notification to other users of these affected products if you have distributed them outside of your facility.

Until a root cause is identified, we will be unable to supply you with replacement product. We will credit your account for any discarded kits.

We apologize for any inconvenience this may cause your laboratory and are committed to provide you with reliable Immunoematology products. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions concerning this letter, please call Customer Technical Services at 1-800-421-3311 (Options 2, 1, 1).

Sincerely,



Donna N. Godward

Vice President, Worldwide Quality, Regulatory, Compliance, Clinical & Medical Affairs