
Recall

ThermoGenesis AXP Bag Sets 8-5101

DATE RECALL INITIATED:

February 19, 2008

PRODUCT / LOT NUMBER/EXPIRATION DATE:

Disposable Processing Set for the AXP System 8-5101 (Box of 24)

Lot Number Expiration

25128-0674-05 Oct-08

25128-0674-04 Oct-08

25128-0671-03 Oct-08

25128-0669-02 Oct-08

25128-0667-01 Sep-08

24455-0666-04 Aug-08

24455-0665-03 Aug-08

24455-0663-02 Sep-08

24452-0661-05 Aug-08

24452-0659-04 Sep-08

24452-0655-02 Jul-08

24452-0653-01 Aug-08

24452-0000-03 Aug-08

22455-0661-01 Aug-08

22129-0640-04 Jul-08

22129-0639-03 May-08

22129-0633-01 Apr-08

22128-0633-04 Apr-08

22128-0631-03 Apr-08

22128-0625-01 Mar-08

22127-0623-04 Apr-08

22127-0621-03 Mar-08
22127-0619-02 Apr-08
22127-0617-01 Apr-08
21504-0617-03 Apr-08
21504-0615-02 Mar-08
21504-0614-01 Mar-08
20684-0613-16 Mar-08
20684-0611-15 Mar-08
20684-0609-14 Mar-08
20684-0607-13 Feb-08
20684-0605-12 Feb-08
20684-0603-11 Feb-08
20684-0601-10 Feb-08
20684-0599-09 expired
20684-0597-08 expired
20684-0595-07 expired
20684-0593-06 expired
20684-0588-02 expired
20684-0586-01 expired
20338-0586-02 expired
20337-0000-03 expired
20337-0000-02 expired
20337-0000-01 expired
19863-0000-04 expired
19863-0000-03 expired
19863-0000-02 expired
19863-0000-01 expired
19329-0584-03 expired
19329-0000-06 expired
19329-0000-05 expired
19329-0000-04 expired

19329-0000-03	expired
18279-0000	expired
17882-0000E	expired
16988-0000	expired
16978-0000	expired
16359-0000	expired
16357-0000	expired
15500-0000	expired
15357-0000	expired
15118-0000	expired
15021.00	expired

MANUFACTURER:

ThermoGenesis Corporation
Rancho Cordova, CA

REASON:

ThermoGenesis has discovered that some lots of its AXP Bag Sets 8-5101 were distributed prior to the performance of endotoxin (pyrogen) testing. These lots were not assayed for endotoxins with Limulus Amebocyte Lysate (LAL) as a manufacturing release test. Therefore, the absence of pyrogens in the bag sets comprising these lots cannot be assured.

Empty Bag Set Inventory:

ThermoGenesis Corporation is asking customers to determine if you have any of the recalled lot on hand and to follow the "Steps for Voluntary Recall" instructions to return the recalled bag sets to ThermoGenesis Corporation.

Stored Cord Blood Units:

If you have already processed cord blood with AXP 8-5101 bag sets from the affected lots listed on the attachment, you should be aware that if endotoxins are present in the bag sets, there could be a significant adverse health outcome (e.g., fever, sepsis) which would necessitate medical intervention. The probability of endotoxins being present in the bag sets in significant amounts is low.

FDA believes that the distribution of cord blood products processed with AXP 8-5101 bag sets from recalled lots should only occur when no comparable cord blood product is available. We recommend that information about the reason for the recall of the AXP 8-5101 bag sets used to process and store the cord blood product be prominently displayed, i.e. "Tagged", in the registry listing for these cord blood products.

Although currently there is no testing available for cryopreserved cord blood units, ThermoGenesis is in the validation phase of a post-thaw endotoxin screening protocol using an FDA licensed test system. ThermoGenesis will provide more information on this screening protocol when it becomes available.

FDA does not believe that notification of those patients who have received cord blood processed with an AXP

8-5101 bag set from an affected lot is required at this time.

The information in this listing reflects CBER's best efforts to communicate information that has been reported to FDA. Its accuracy and comprehensiveness cannot be guaranteed.

Updated: February 20, 2008