

February 20, 2017

Product: Panocell®-20

LOT 52872

2017-03-03

REF ₀₀₀₅₀₂₀

UDI 10888234001843

Product Notification

Issue:

Immucor is issuing this product notification regarding the V antigen typing for donor E1011, Cell #11 of Panocell-20, Lot 52872. Additional DNA testing of donor E1011 has confirmed the donor as V-, instead of V+ as indicated on the Master List.

Impact to Results:

Since donor E1011 is V-, Cell #11 will be nonreactive with specimens that may contain anti-V. V (RH10) is a low prevalence antigen in the RH system. You can evaluate the impact on any previous testing results using these lots per your procedures.

Required Action:

A corrected Master List for Panocell-20, lot 52872 is attached to this notification; it is identified with an "A" in the upper-left corner. Please replace your original Master List with this corrected Master List.

Please acknowledge your receipt of this notification by completing the response form below and returning it to us by facsimile +49 (0) 610380566390 or per email: vigilance.eu@immucor.com.

If you have questions or require additional information, please contact Immucor Technical Support at 855-IMMUCOR (855-466-8267).

We apologize for the inconvenience this issue may have caused your laboratory.

Sincerely,

Howard Yorek Senior Director, Regulatory Affairs

RESPONSE FORM

I acknowledge that our facility is aware of the product notification for Panocell-20 , lot 52872 (FA-17-02)
Name:
Position:
Facility/Institution
Account number
City/State
Telephone