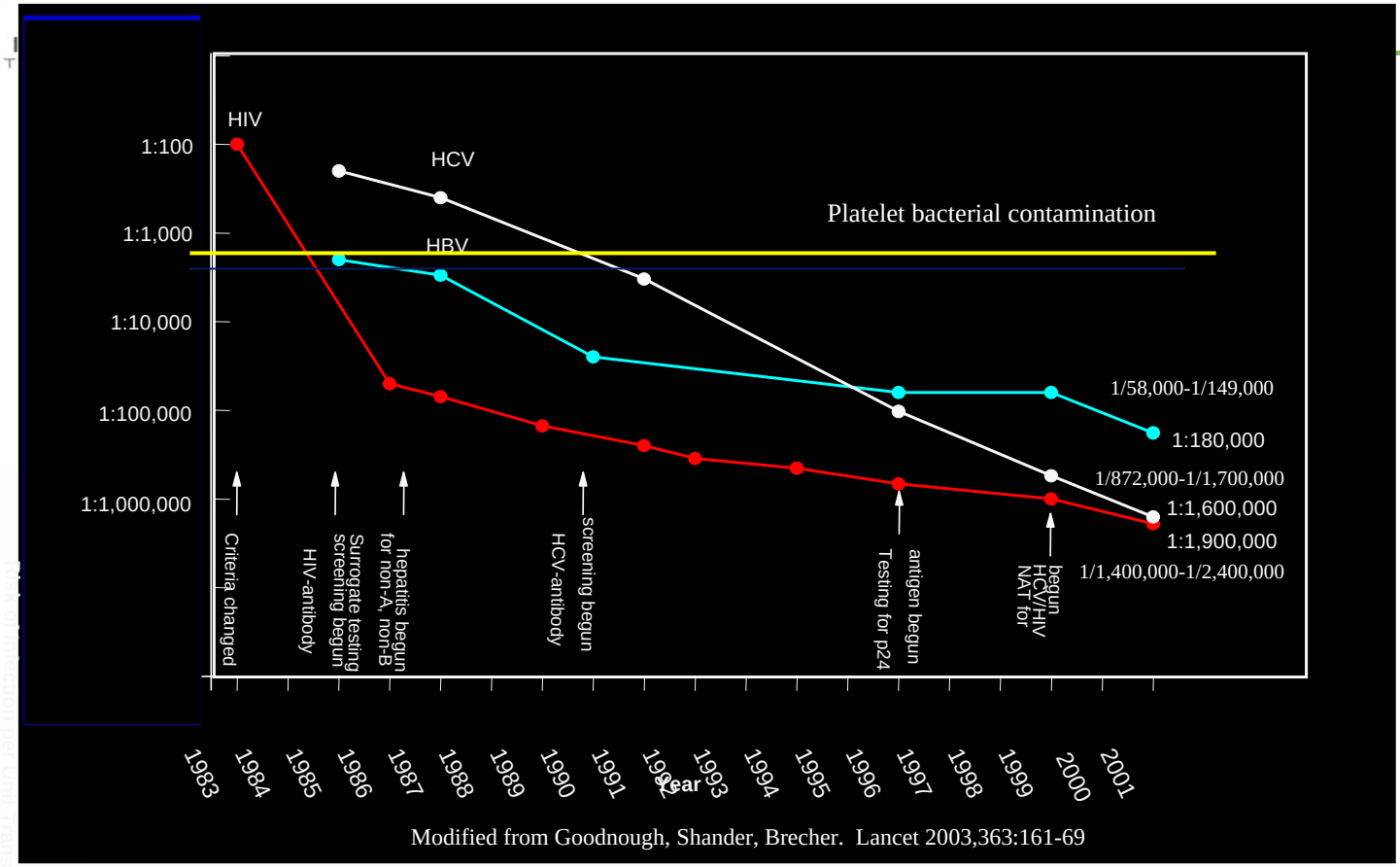
BacT/ALERT Microbial Detection System

A.C. Marchionne, BS, MS
National Sales and Marketing Manger
Blood Bank / Tissue Bank



Modified from Goodnough, Shander, Brecher. Lancet 2003,363:161-69

Platelet transfusions in the United States

4 million platelet bags transfused/year

1:1000 - 1:2000 bacterially contaminated
(N = 2000 - 4000 bags)

1/10 to 2/5 result in clinical sepsis
(N = 200 - 1600 cases)

Perhaps 1/5 to 1/3 result in fatalities
(N = 40 - 533 deaths)
or
(1:7,500 to 1:100,000 fatalities/unit)

BIOMÉRIEUX INDUSTRY

BacT/ALERT 3D

Colorimetric Technology

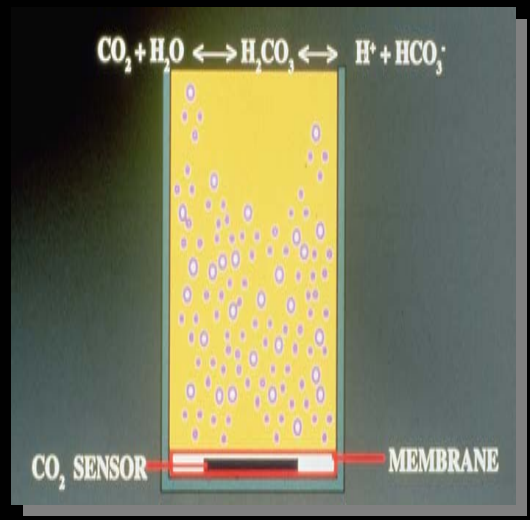
Growth chemistry

Organisms grow in media and produce CO_2

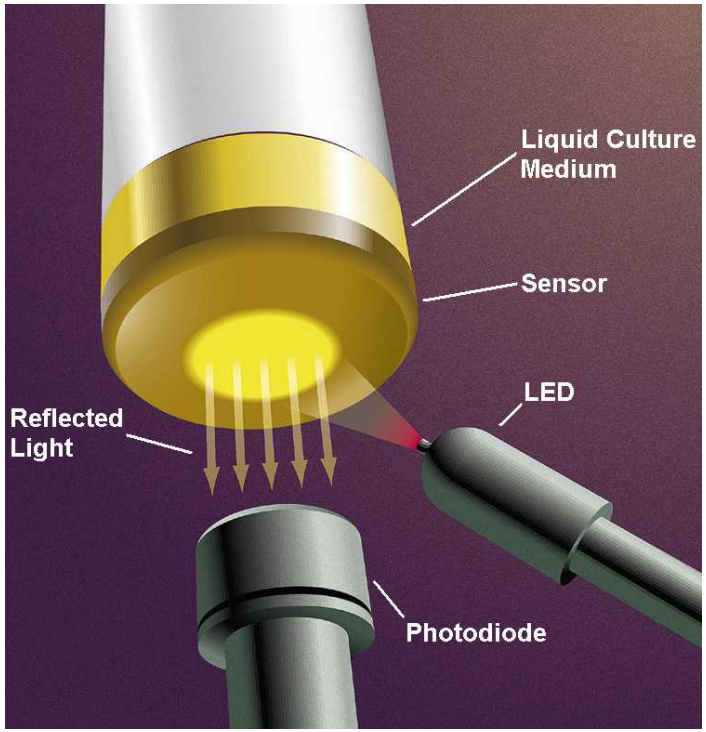
CO_2 traverses semi-permeable membrane

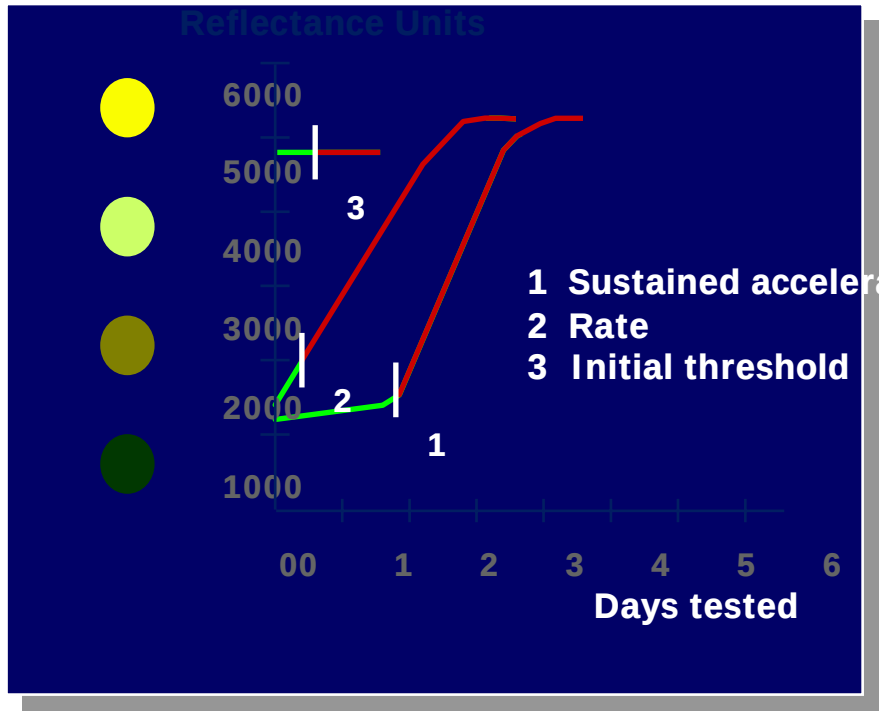
Sensor changes from

green to yellow



Schematic View of Detection

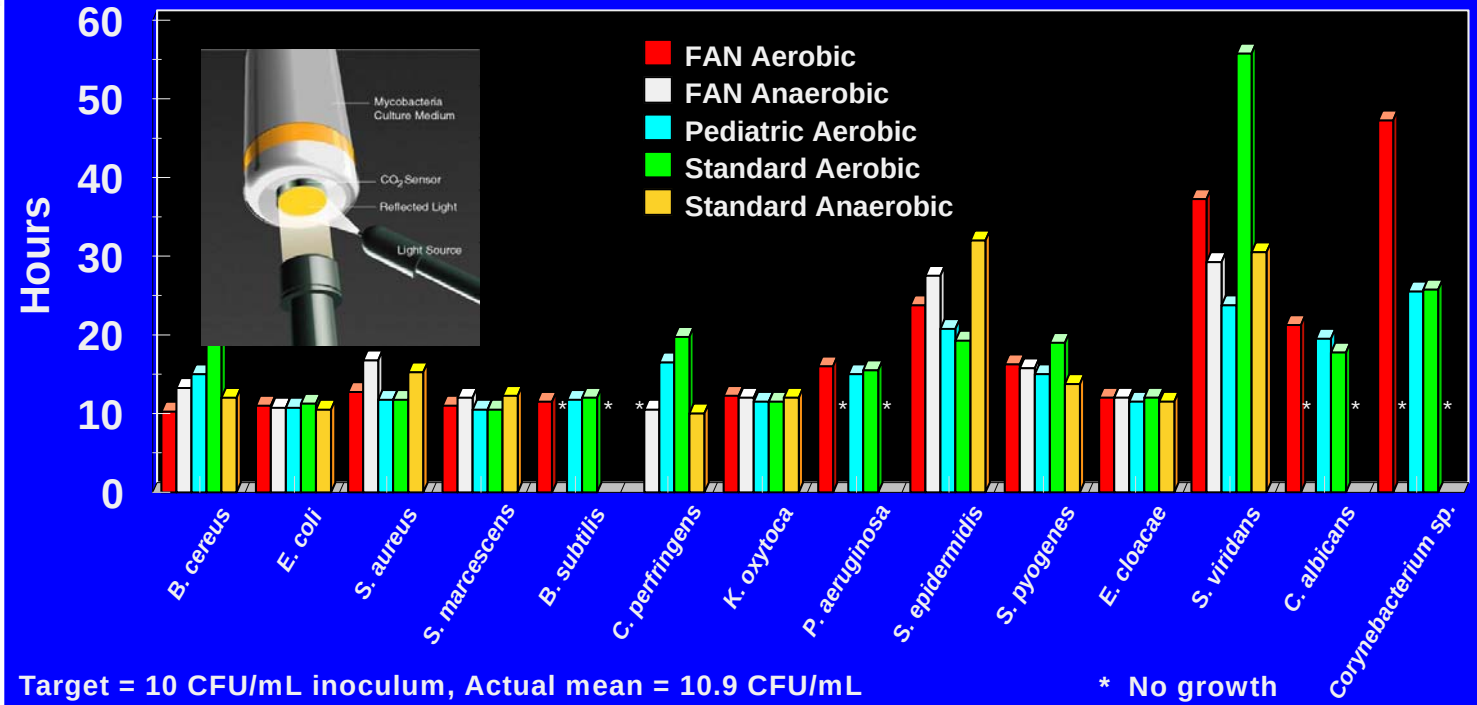




Sampling Devices

Sampling & Loading

Automated Culture (BacT/ 3D Alert)



Target = 10 CFU/mL inoculum, Actual mean = 10.9 CFU/mL

* No growth

Brecher ME, Means N, Jere CS, Heath D, Rothenberg S, Stutzman LC. Evaluation of the BacT/ALERT 3D® Microbial Detection System for platelet bacterial contamination: An analysis of 15 contaminating organisms. Transfusion 2001;41:477-482.

BIOMÉRIEUX INDUSTRY

BacT/ALERT 3D

TRANSFUSION COMPLICATIONS

Evaluation of an automated culture system for detecting bacterial contamination of platelets: an analysis with 15 contaminating organisms

Mark S. Brecher, Norreen Mamus, Charlotte S. Jacy, Hazel Barth, Steve Pechenberg, and Lee C. Stutzman

TRANSFUSION COMPLICATIONS

Evaluation of a new generation of culture bottle using an automated bacterial culture system for detecting nine common contaminating organisms found in platelet components

M.E. Brecher, D.G. Beach, S.N. Hay, S.J. Krekenberg, and L.C. Stutzman

TRANSFUSION PRACTICE

Evaluation of a new generation of plastic culture bottles with an automated microbial detection system for nine common contaminating organisms found in PLT components

M.E. Brecher, S.N. Hay, and S.J. Krekenberg

BIOMÉRIEUX INDUSTRY

BacT/ALERT 3D

ORIGINAL PAPER

Evaluation of the BacT/Alert automated blood culture system for detecting bacteria and measuring their growth kinetics in leucodepleted and non-leucodepleted platelet concentrates

Vox Sanguinis

Introduction

ORIGINAL ARTICLE

Operational feasibility of routine bacterial monitoring of platelets

A. Macauley, A. Chandrasekar, G. Geddis, K. G. Morris and W. M. McClelland

MATERIALS AND METHODS

ORIGINAL ARTICLE

Evaluation of the 3D BacT/ALERT automated culture system for the detection of microbial contamination of platelet concentrates

BIOMÉRIEUX INDUSTRY

BacT/ALERT 3D

<u>BacT/ALERT BPA</u> culture bottles are used with the BacT/ALERT Microbial Detection Systems for quality control testing of leukocyte reduced

apheresis platelet (LRAP) units

single units of whole blood platelet concentrates (WBPC).

BPA culture bottles – aerobic bacteria

BIOMÉRIEUX INDUSTRY

BacT/ALERT 3D

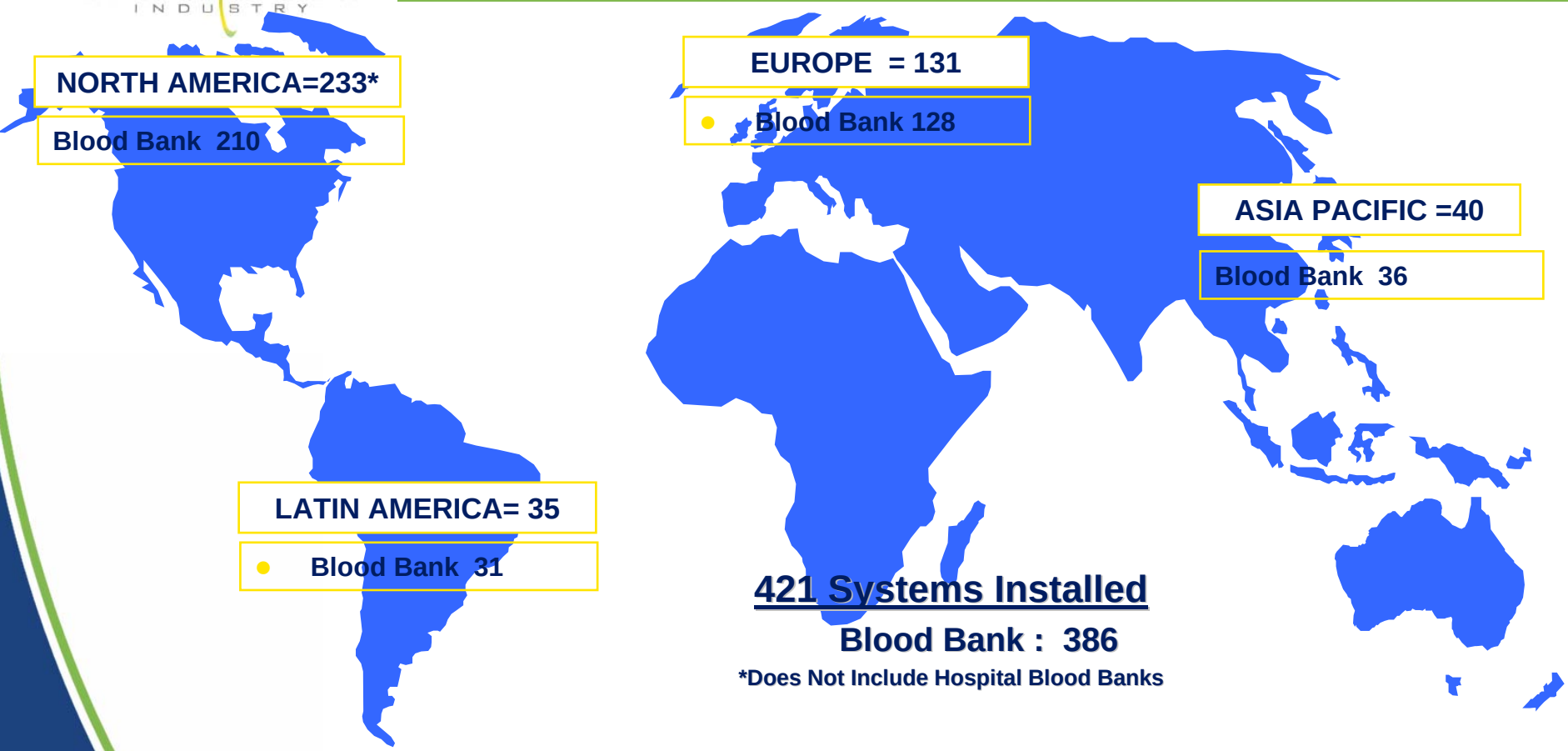
<u>BacT/ALERT BPN</u> culture bottles are used with the BacT/ALERT Microbial Detection Systems for quality control testing of leukocyte reduced

apheresis platelet (LRAP) units

single units of whole blood platelet concentrates (WBPC).

BPN culture bottles - anaerobic & facultative anaerobic bacteria.

BacT/ALERT Worldwide Placements for Platelet Testing



421 Systems Installed

Blood Bank : 386

*Does Not Include Hospital Blood Banks

BacT/ALERT 3D

TRANSFUSION COMPLICATIONS

Monitoring of apheresis platelet bacterial contamination with an automated liquid culture system: a university experience

M.E. Brecher, S.N. Hay, and S.J. Rothenberg

BACKGROUND: With 4 million platelet units transfused per year in the United States and with the current estimate of bacteria contamination rate in PLT units, it would be expected that 2000 to 4000 bacterially contaminated units are transfused and associated with 333 to 1000 cases of clinical sepsis.

STUDY DESIGN AND METHODS: Apheresis platelets were sampled on Day 2 of storage (collection day = Day 0) and issue (or following outdate, Days 5-6) using a sterile connection device (SCD) to attach a sampling bag. Using aseptic technique and a laminar flow hood, bottles were inoculated and placed onto an automated liquid culture system (BacT/ALERT 3D Microbial Detection System) for 7 days.

RESULTS: A total of 2397 apheresis PLT units were sampled. A triple apheresis collection was reactive within 14 hours of the Day 2 sampling (aerobic bottles) and the bags were removed from inventory. *Staphylococcus epidermidis* was identified in all three contaminated bags. Two double apheresis collections were found to be contaminated with *Propionibacterium* sp. after 6 days of incubation but had been transfused to four patients without discernible clinical sequelae. There was one false-positive aerobic bottle and one false-positive anaerobic result due to inadvertent contamination of a bottle. Thus, the overall true-positive rate was 7 of 2397 apheresis units (0.29%) with a true-positive rate for aerobic organisms of 0.13% and an anaerobic true-positive rate of 0.17%. The false-positive rate was 2 out of 4794 samplings (0.04%) or 2 out of 9588 bottles (0.02%).

CONCLUSION: This preliminary data suggests that the use of a SCD, aseptic technique, and a laminar flow hood is associated with a low rate of contamination. In no case did an issue (or outdate) detect contamination that was not detected by the Day 2 culture. Additional surveillance is necessary before we can conclude that a Day 2 sterile culture is fully predictive of an issue (or outdate) sterile culture. Bacterial culture surveillance of PLTs would be expected to save lives and may facilitate an extension in PLT storage.

The true positive rate for aerobic organisms was 3/2397 (0.13% or 1/799 units) and 4/2397 (0.17% or 1/599 units) for anaerobic organisms. No positives detected with late culture alone.

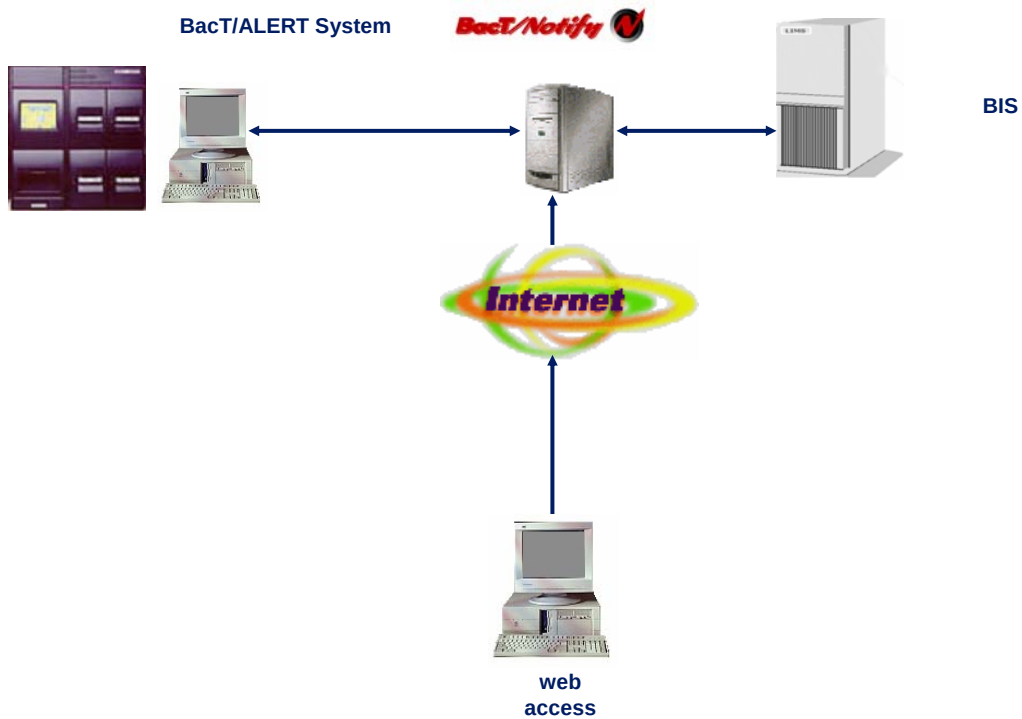
Anaerobic Bacteria and Platelets

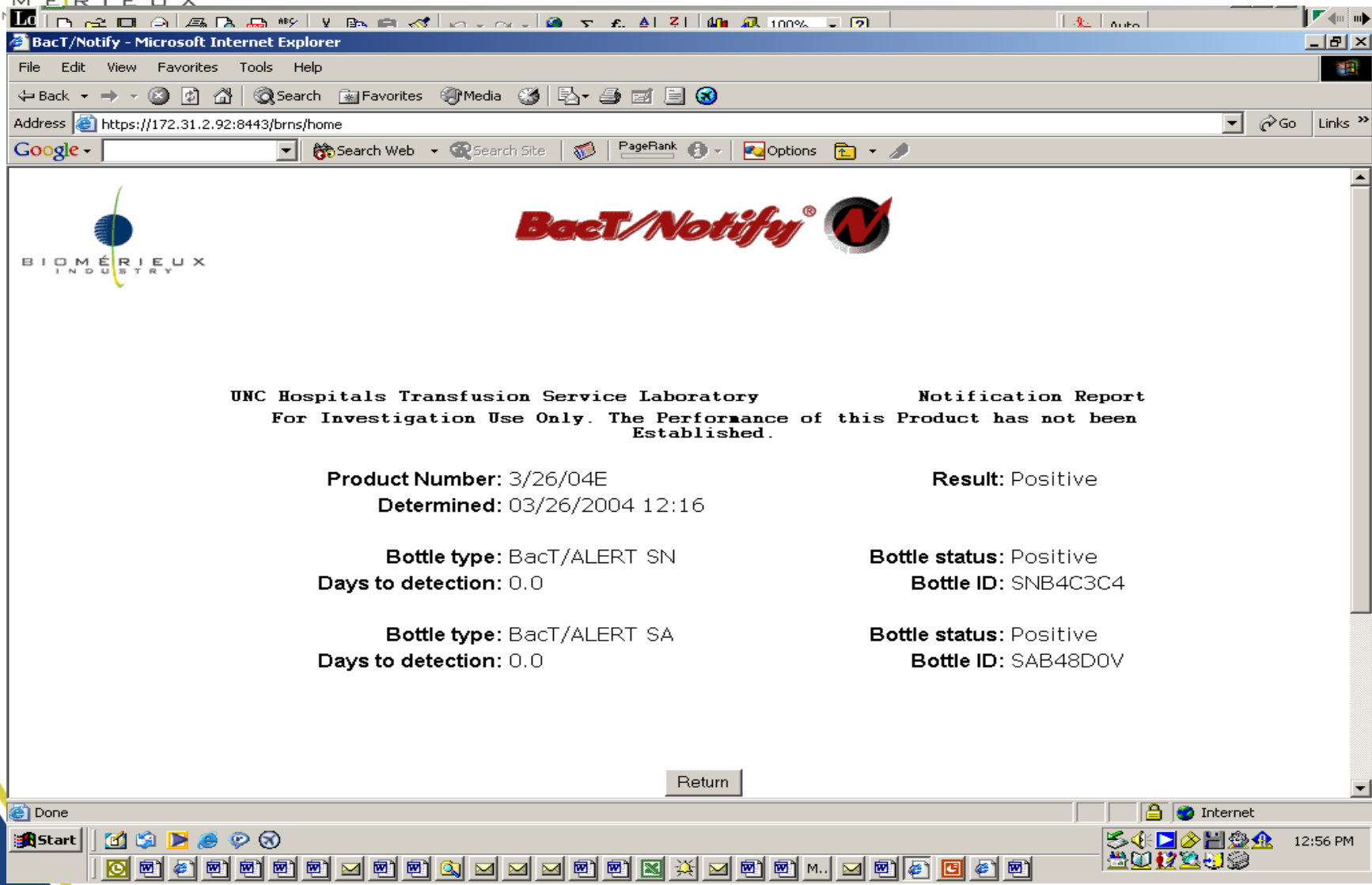
Schneider, Breviere,Taillefer,Pujol-Rey, Huart. Contamination bacterienne de concentres de plaquettes a *Propionibacterium acnes*. Transfus Clin Biol 2000;7:540-6

McDonald, Hartley, Orchard, Hughes, Brett, Hewitt, Barbara. Fatal *Clostridium perfringens* sepsis from a pooled platelet transfusion. Transfusion Medicine 1998;8:19-22

View Latest Available Culture Status Just Before Transfusion!

Transfusion centers will be able to access specific culture results by accessing a webpage.




BacT/Notify - Microsoft Internet Explorer
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Go Links
Google Search Web Search Site PageRank Options
BIOMÉRIEUX INDUSTRY
BacT/Notify®
UNC Hospitals Transfusion Service Laboratory Notification Report
For Investigation Use Only. The Performance of this Product has not been Established.
Product Number: 3/26/04E
Result: Positive
Determined: 03/26/2004 12:16
Bottle type: BacT/ALERT SN
Bottle status: Positive
Days to detection: 0.0
Bottle ID: SNB4C3C4
Bottle type: BacT/ALERT SA
Bottle status: Positive
Days to detection: 0.0
Bottle ID: SAB48D0V
Return
Done
Internet
Start
12:56 PM