



America's Blood
Centers

SERVING COMMUNITIES NATIONWIDE

The Impact of Implementing Bacterial Detection

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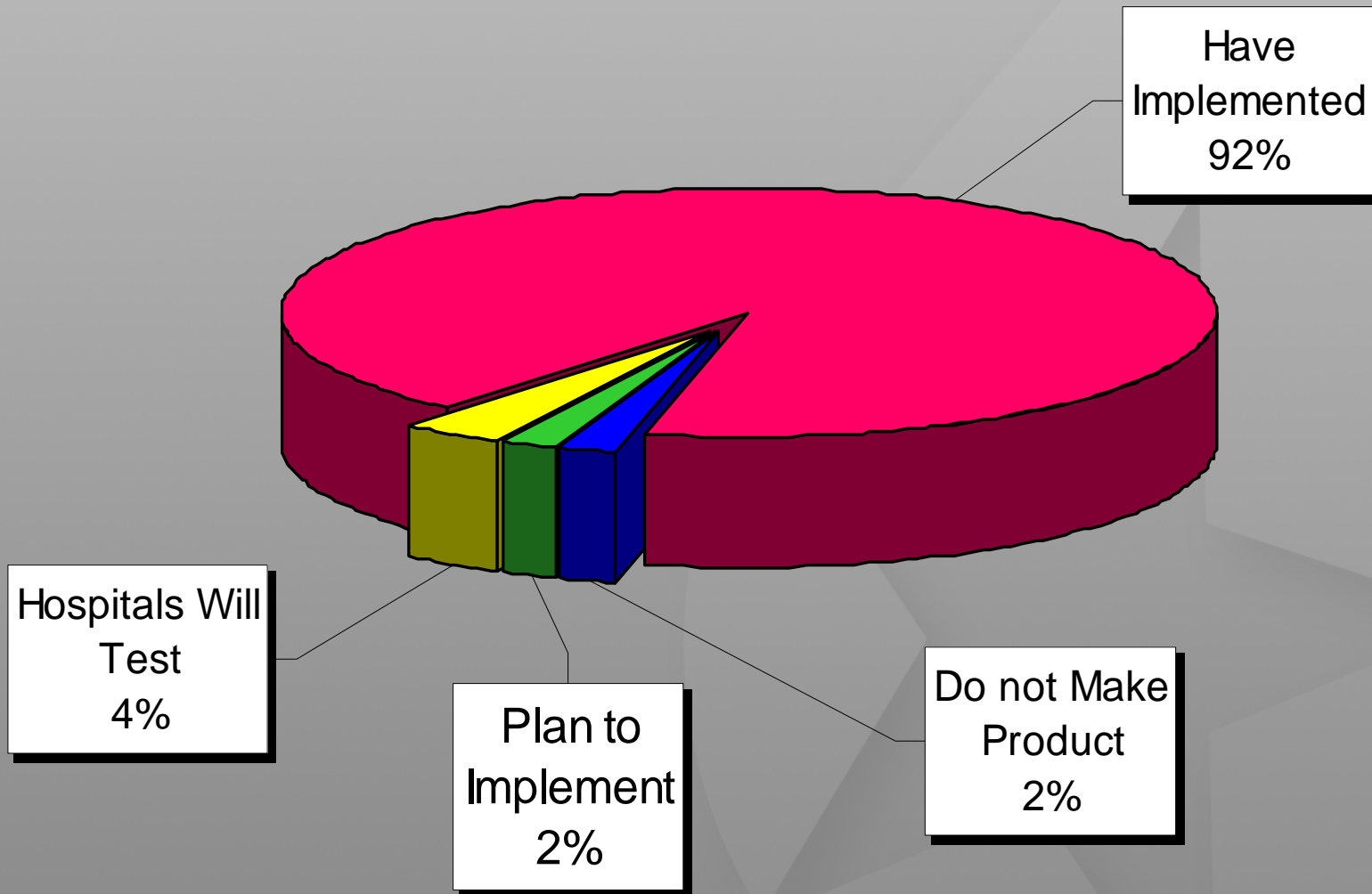
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April 8, 2004

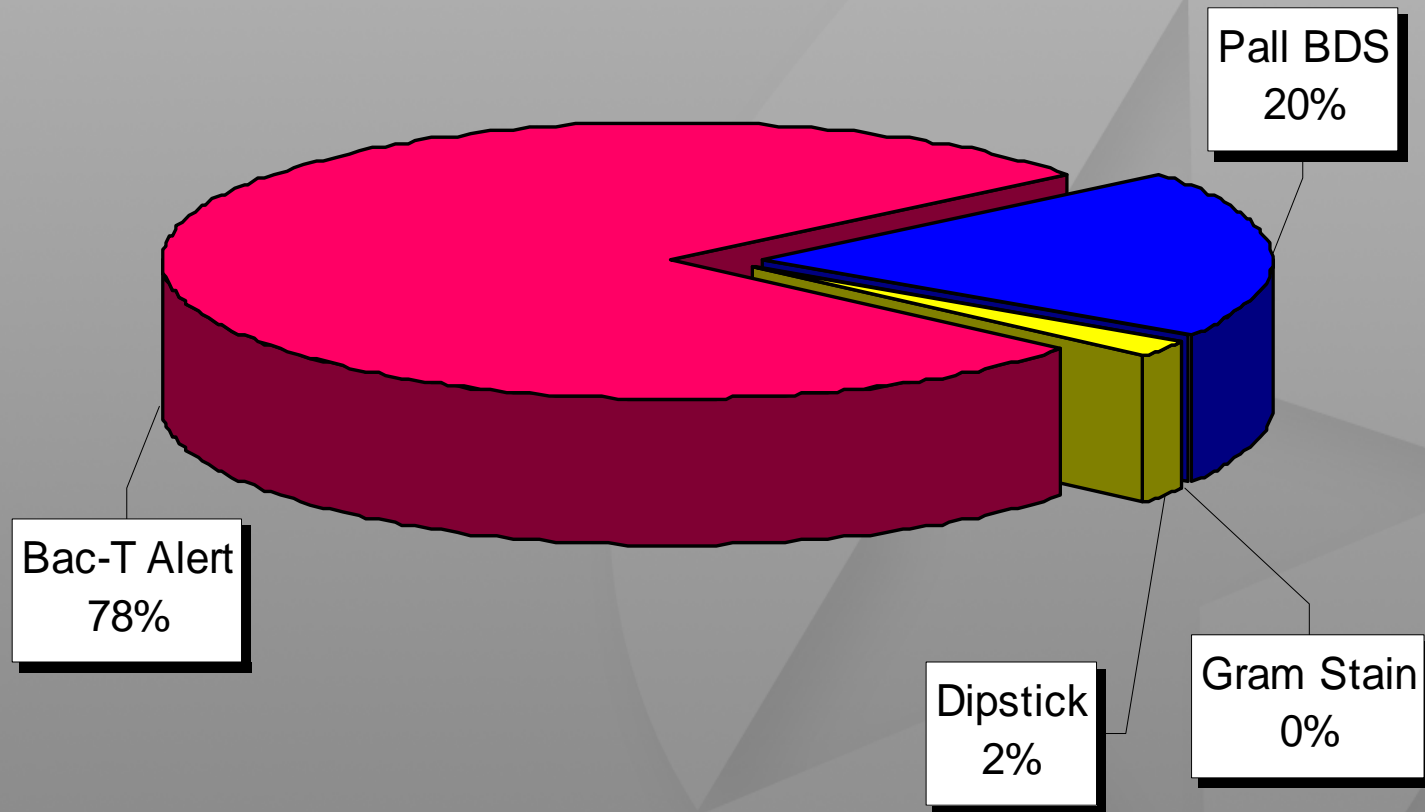
ABC SURVEY RESPONDENTS

- As of Tuesday
- 54 of ABC's 77 centers had responded
- These centers collect 80 percent of ABC's blood supply.
- 39 or about 75% of the responding centers produce WB platelets and 85 % produce apheresis platelets.
- About 70 % of these centers produce double apheresis platelets and 33% produce triples.

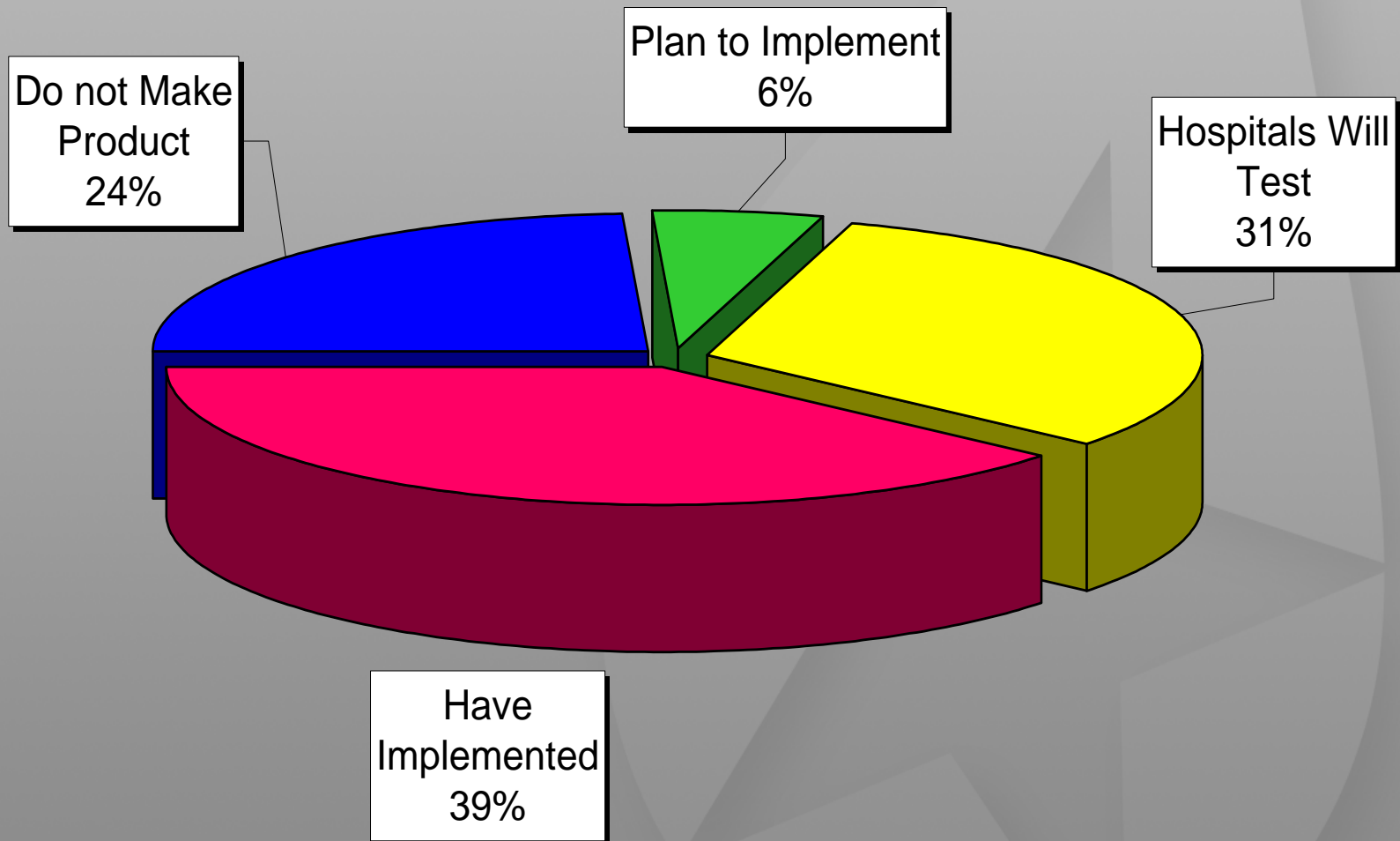
Testing Apheresis Platelets for Bacterial Contamination



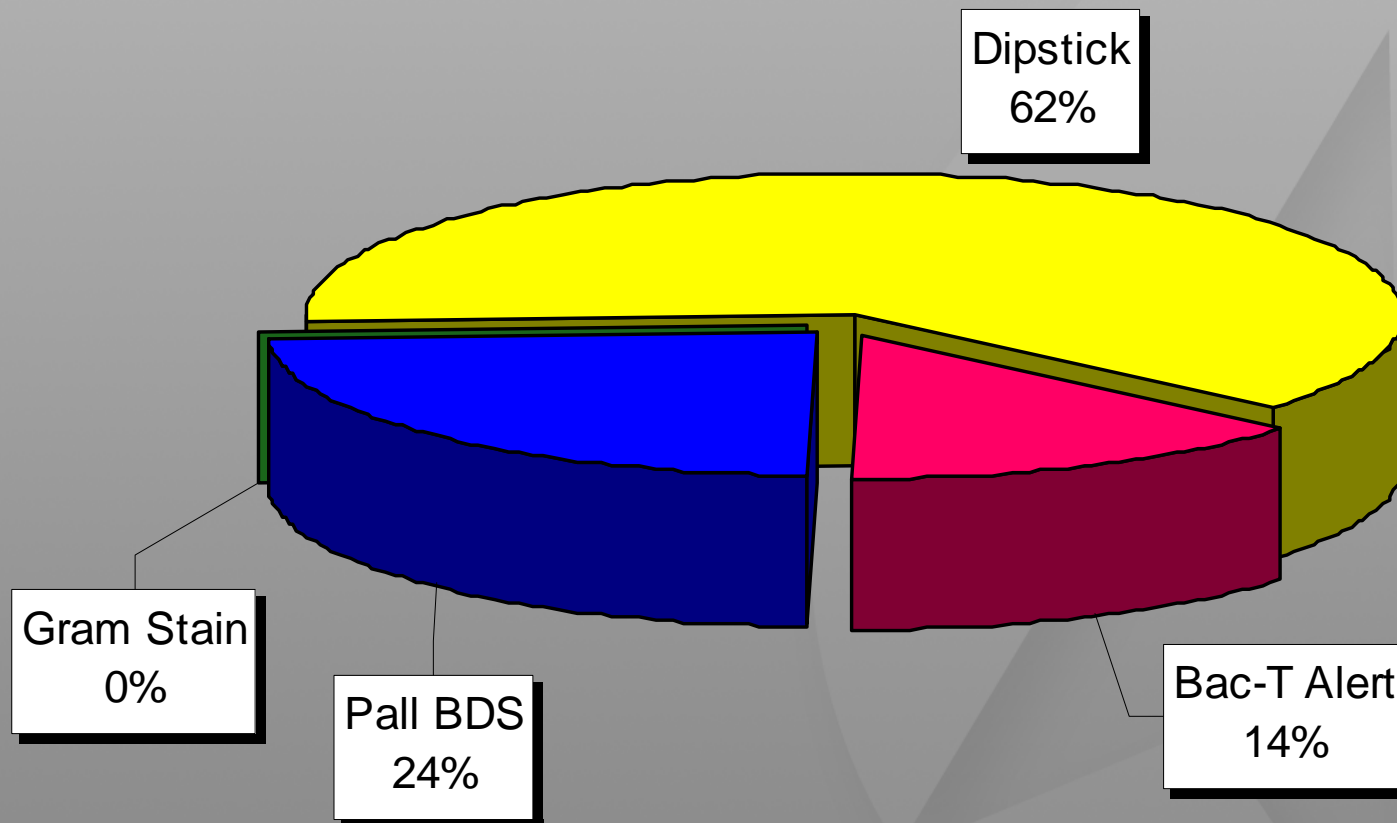
Methods Used to Test Apheresis Platelets for Bacterial Contamination



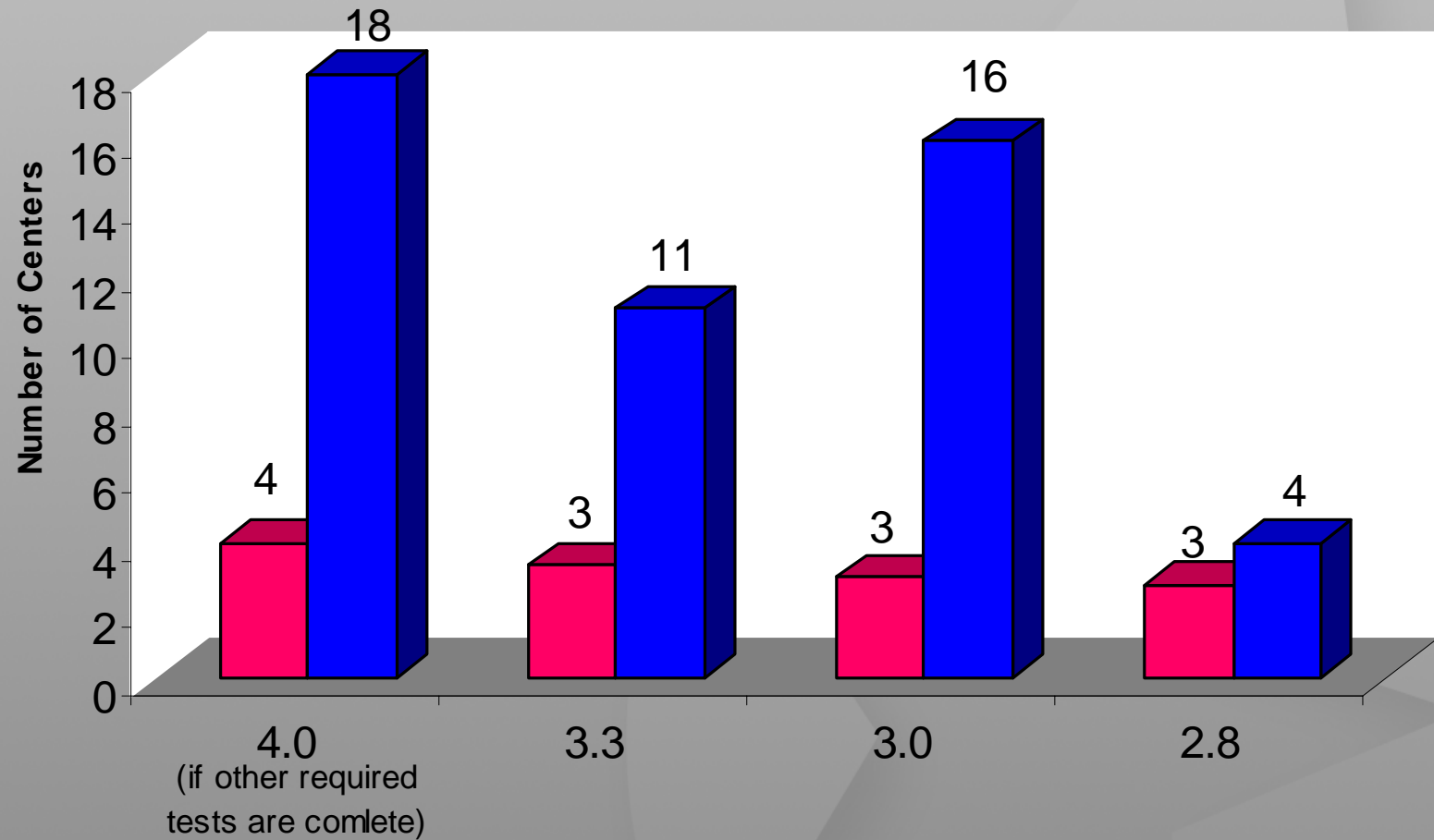
Testing WB Platelets for Bacterial Contamination



Methods Used to Test Whole Blood Platelets for Bacterial Contamination



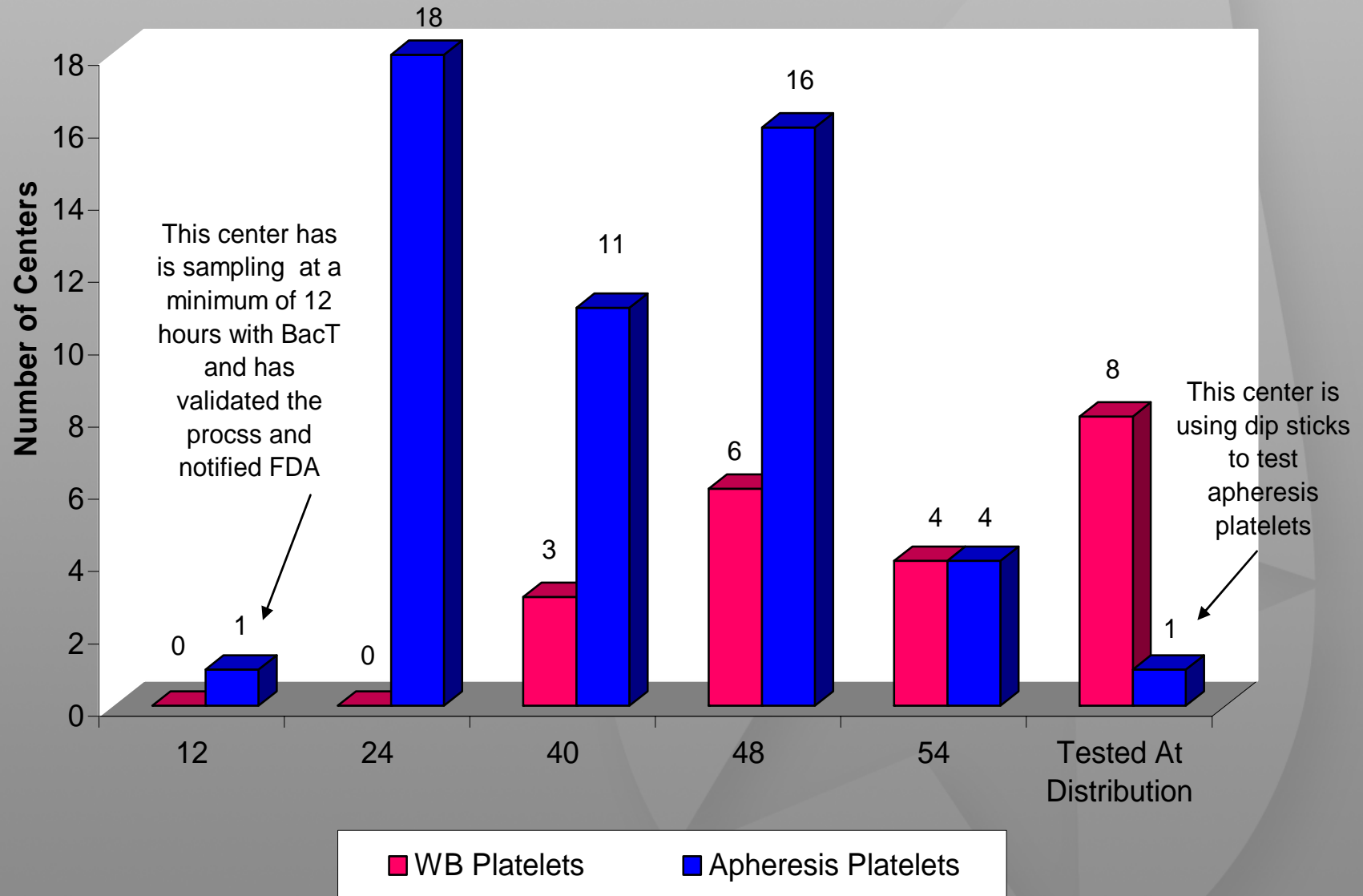
Platelets: Days to Expiration at Distribution



■ WB Platelets

■ Apheresis Platelets

Bacterial Detection, Total Time (in Hours) from Collection to Release



Outdates: Centers That Began Testing Apheresis Platelets Before February 2004

	Number of Centers
Total Centers	12
No change in outdates	7
Outdates Increased	5
Average Increase	5.2%
Minimum Increase	3.0%
Maximum Increase	7.0%

COMMENTS RECEIVED FROM CENTERS

- **Impact of AABB Standard on WB Platelets**
 - Four ABC centers reported that they had to stop making WB platelets because it was not feasible for them to implement bacterial detection for this product.
 - We are producing two thirds less WB platelets than previously.”
 - We now produce about a quarter as many WB platelets as before testing. The number we distribute has also been decreased dramatically.
 - Hospitals prefer to order apheresis platelets to avoid testing WBP. WBP platelet orders are down over 25%”

COMMENTS RECEIVED FROM CENTERS

- **Others Reported Little Change in Production of WB Platelets:**
 - **Our hospitals were not willing to change their use of random platelets for apheresis and did not want to be involved in platelet testing at their facilities.**
 - **Most hospitals have converted to apheresis platelets. That conversion was accelerated during the last year. Since the majority of our WB platelets have been made to serve as backups for apheresis platelets, there has been little change.**
 - **Due to the dipstick method, there has been no change in the production and/or distribution of WB platelets.”**

COMMENTS RECEIVED FROM CENTERS

- **Hospital Testing of WB Platelets**
 - Hospitals report numerous false positive WB platelets. We culture all that do not pass. This is a very subjective test and is creating a lot of unnecessary cultures.
 - Hospital agreed last fall to implement a process to test random WB platelets. Our experience has been that 50 percent of our customers have not been able to achieve this goal. For this reason, many customers are refusing to accept WB platelets.
 - We will implement WB testing but only when an approved, cost-effective method is available.

COMMENTS RECEIVED FROM CENTERS

- **Increased Time, Staffing, Expense**
 - At this small blood center, the standard has impacted our production, costs, platelet availability staffing, and ultimately, patient care.
 - Changing blood bags and implementing a new process was a huge undertaking affecting every process, individual, and department.
 - We added four staff to accommodate bacterial QC in production area
 - We have experienced a substantial increase in the deliveries we do as a result of the reduced time left on the product; need to move it around to ensure its use.
 - Additional incubators purchased to facilitate work flow and ensure the separation of in-process platelet products from those not yet sampled
 - We now release apheresis platelets in two batches rather than one; one early afternoon (used to be all) and one 7 to 9 PM”
 - All WB platelets are manufactured as early in the day as possible so that sampling can start by 1:00 PM the next day.

Testing Is Not the Ultimate Solution

- Alternate storage solutions
- Return to refrigerated storage
- Freezing or lyophilizing platelets
- Inactivation methods
- Filtration techniques
- Pre-pooled WB platelets.

Your Continued Support is Needed

- We also encourage this committee to ask HHS to recognize that this is only the first step in the journey to eliminate the risk of bacterial transmission from blood transfusion. Additional research is needed to develop simpler quicker methods of bacterial detection in conjunction with the need to improve storage media and techniques that either inhibit or inactivates bacterial growth or allows time for detection methods to be used as a release measure without impacting availability of these life saving products. Thank You.