



QUALTEXSM
LABORATORIES

Infectious Disease Testing of
Source Plasma Donations: Past
and Future

Agenda

- Serological testing (VMT)
- Nucleic Acid Testing (NAT)
- Future
- Summary
- Questions



Serological Testing Data

- December 2013 – May 2017
- San Antonio & Atlanta labs
- Source plasma testing
 - 25,723,740 donations
 - Mixture of applicant and repeat donors
 - Repeat reactive donations

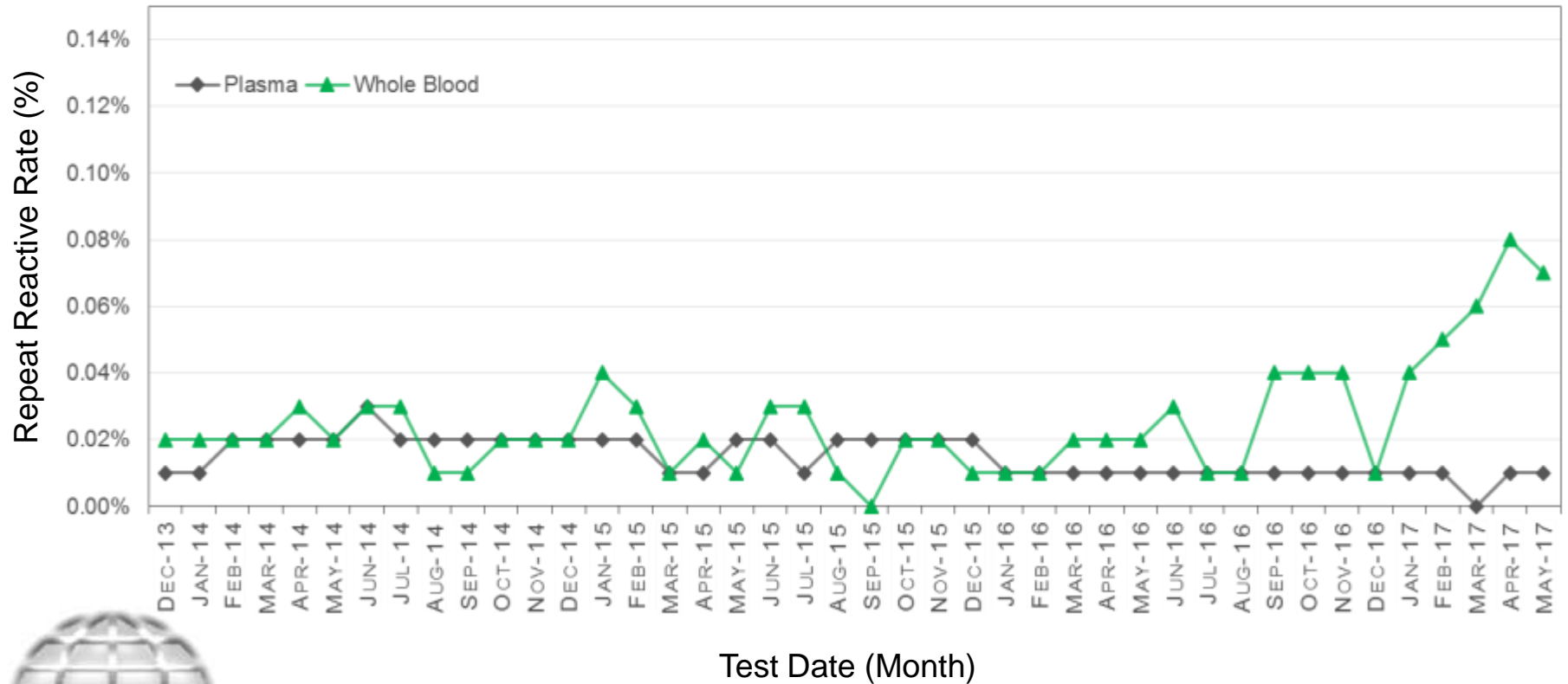


Serological Testing Data

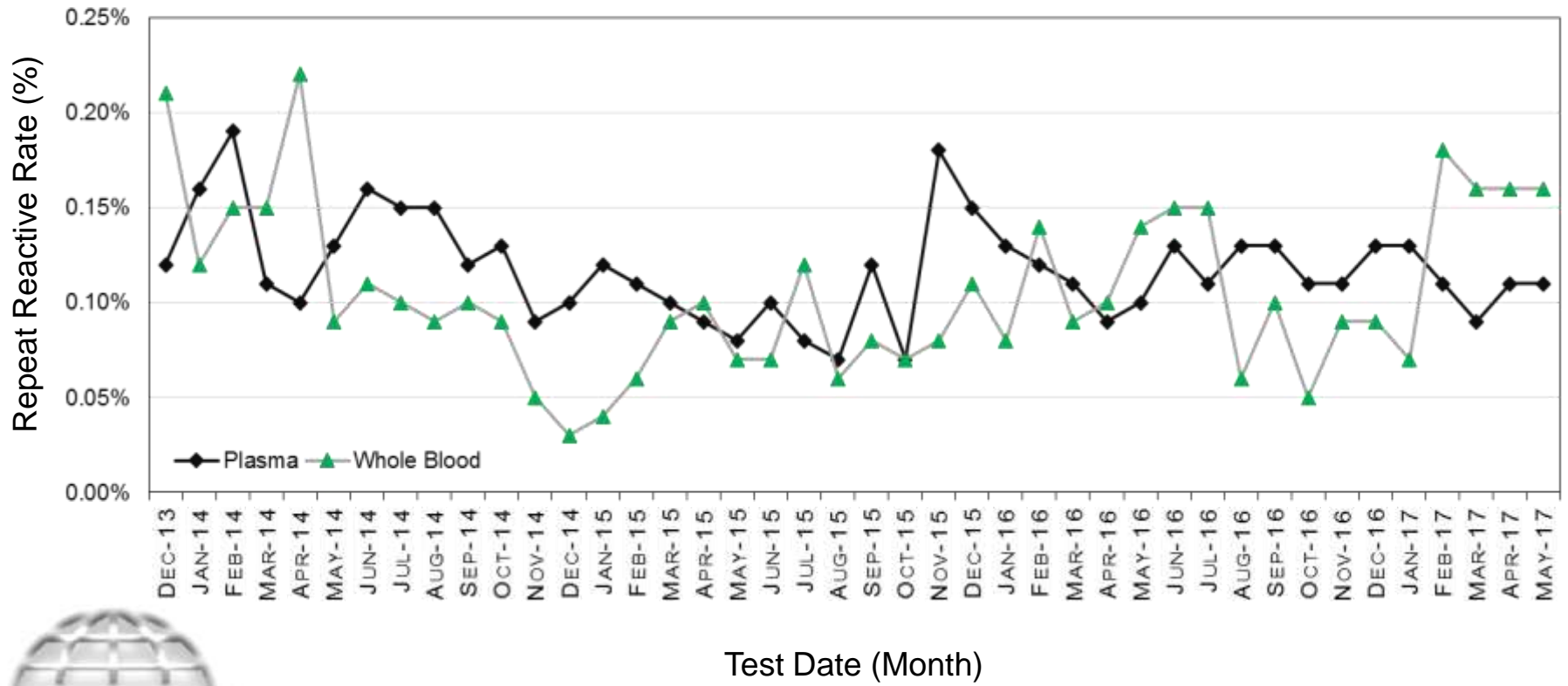
- Whole blood donations
 - 1,859,361 donations
 - Repeat reactive donations
- **ABBOTT PRISM**
 - HBsAG Assay (HBsAg)
 - HIV O Plus Assay (anti-HIV-1/2)
 - HCV Assay (anti-HCV)



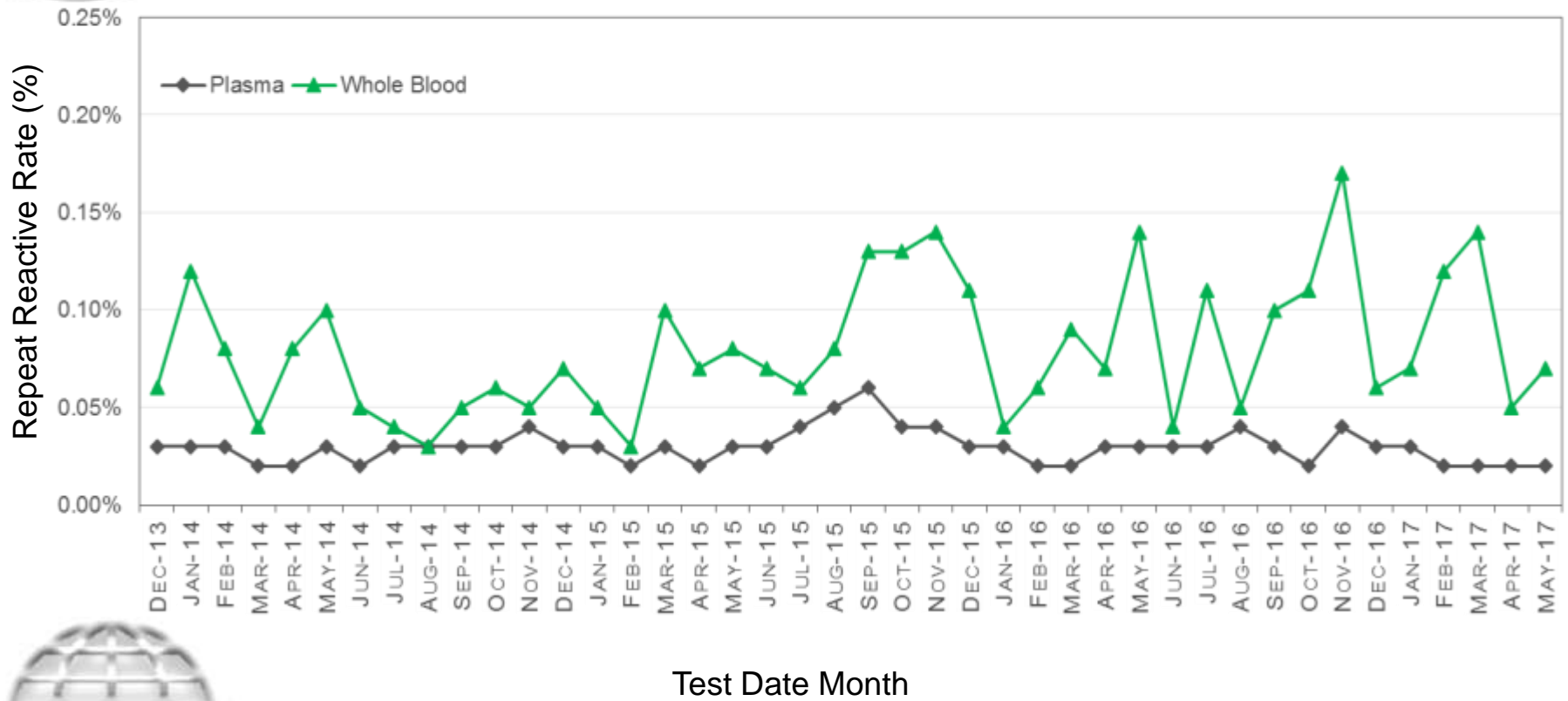
HBsAg Testing



anti-HCV Testing



anti-HIV Testing

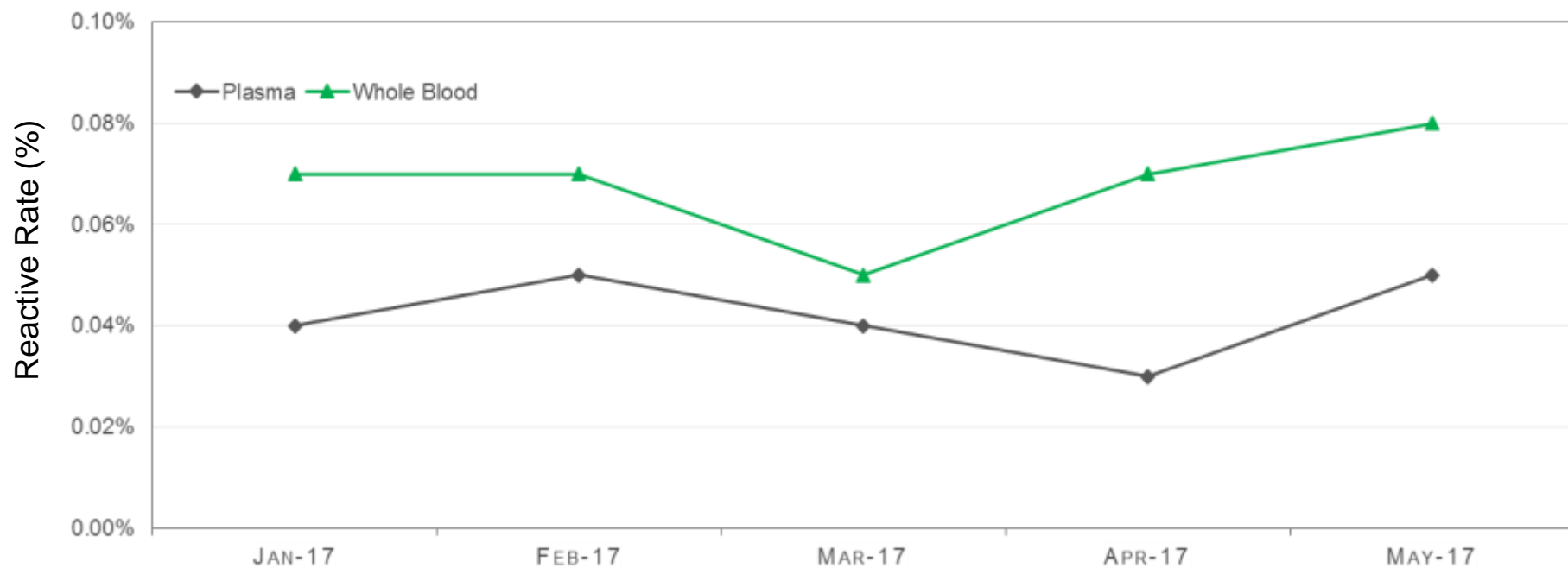


NAT Assays

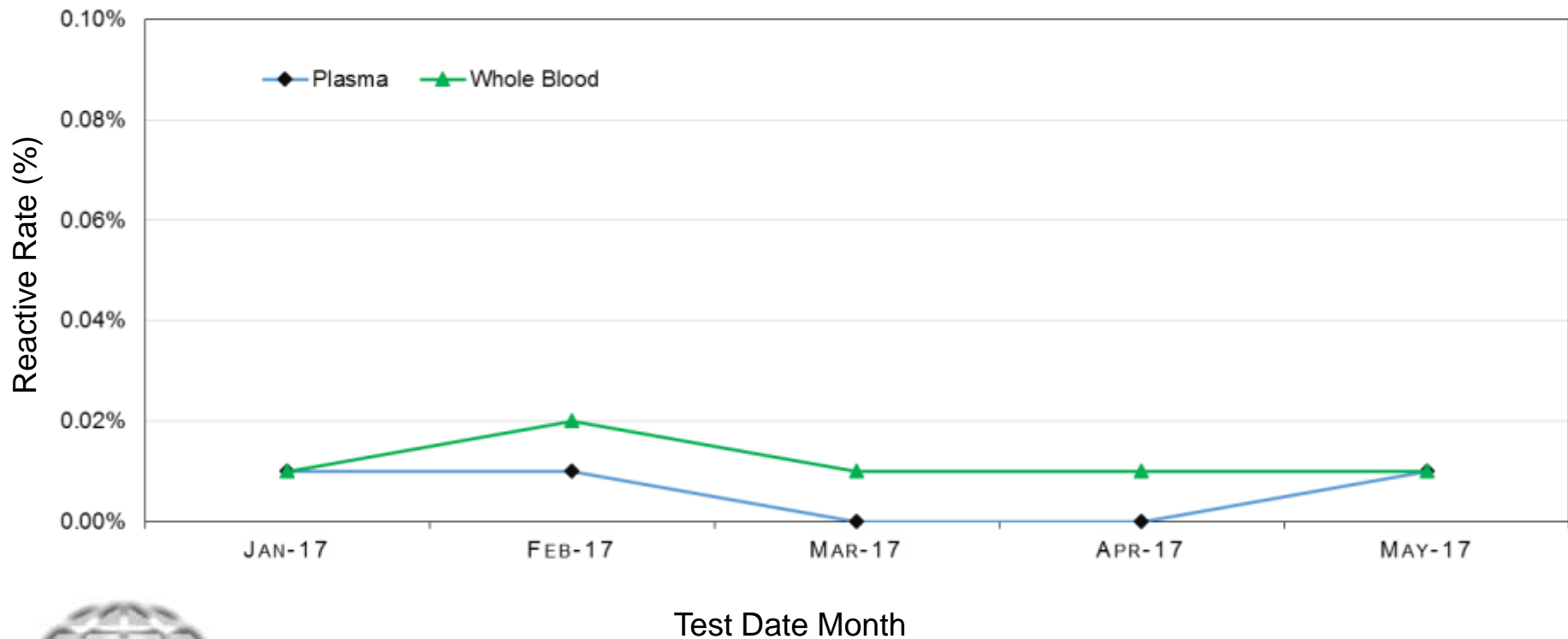
- January 2017 – May 2017
- Source plasma testing
 - 2,003,431 donations
 - Mixture of applicant and repeat donors
 - Reactive
- Whole blood donations
 - 136,398 donations
 - Only tested on Roche platform
- Roche cobas TaqScreen MPX version 2.0 Assay



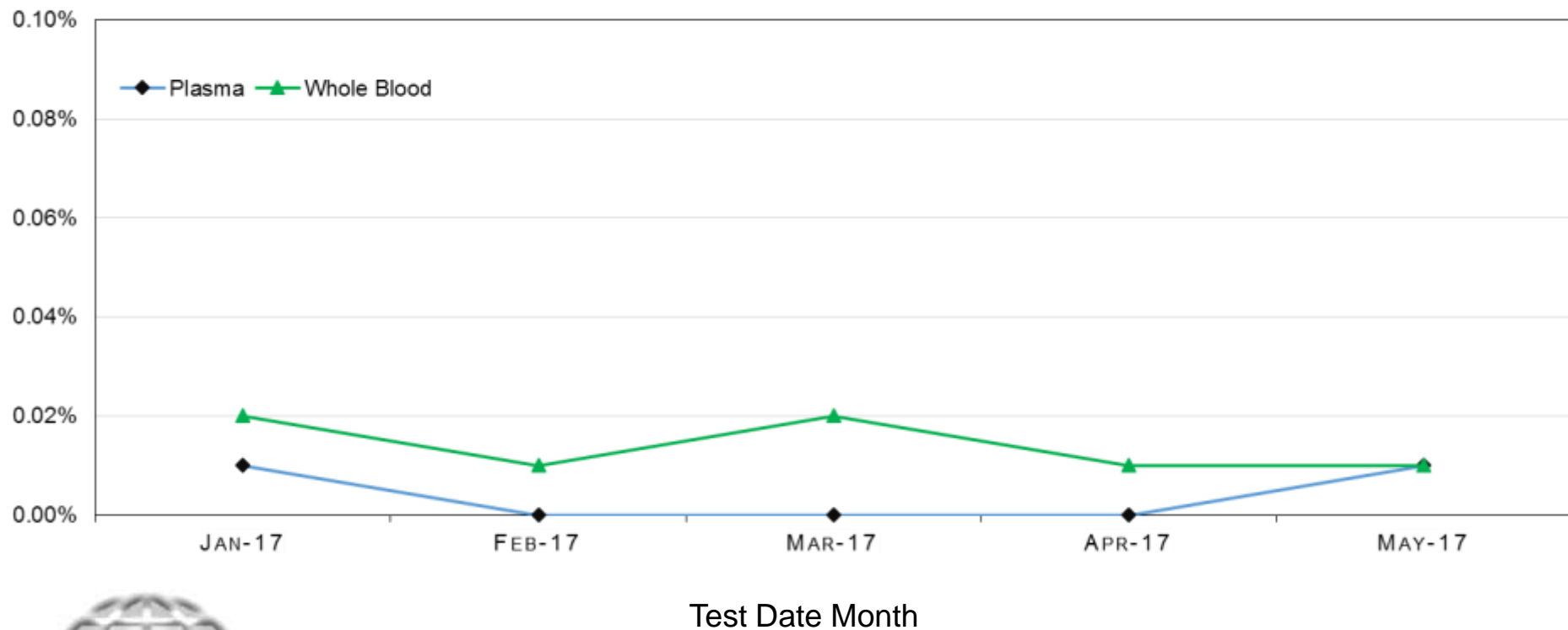
MPX 2.0 HCV Reactive Rate



MPX 2.0 HIV Reactive Rate



MPX 2.0 HBV Reactive Rate



Future Testing

- HEV
 - European Pharmacopeia requirement
 - “The plasma pool is tested using a validated nucleic acid amplification technique (2.6.21). A positive control with 2.5 log₁₀ IU of hepatitis E virus RNA per milliliter and, to test for inhibitors, an internal control prepared by addition of a suitable marker to a sample of the plasma pool are included in the test.”



Future Testing

- Production pool testing
 - Total Protein
 - ABBOTT Biuret Assay
 - Serological Testing (VMT)
 - HBsAg & Anti-HIV-1/2
 - ABBOTT PRISM Assays
 - Validated lower cut-off
 - NAT
 - Roche cobas TaqScreen MPX version 2.0
 - Serological Testing (VMT)



Conclusions

- No statistical significant difference between repeat reactive rates for serological testing of source plasma and whole blood donations
- No statistical significant difference between reactive rates for NAT testing of source plasma and whole blood donations
- Able to perform production pool testing and HEV NAT testing soon



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