

# Proficiency Testing Trends and Method Performance

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# Overview

1. Reasons to enroll in PT for Waived Methods
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# Reasons for Enrolling in PT if Method is Waived

- Accreditation requirements more stringent than CLIA '88:
  - ✓ CAP's Laboratory Accreditation Program (LAP)
  - ✓ COLA
  - ✓ Certain states (CA, GA, MD, NJ, PA, etc)
- Organizational commitment to a QA plan which includes PT for all lab testing regardless of certificate.

# Reasons, cont.

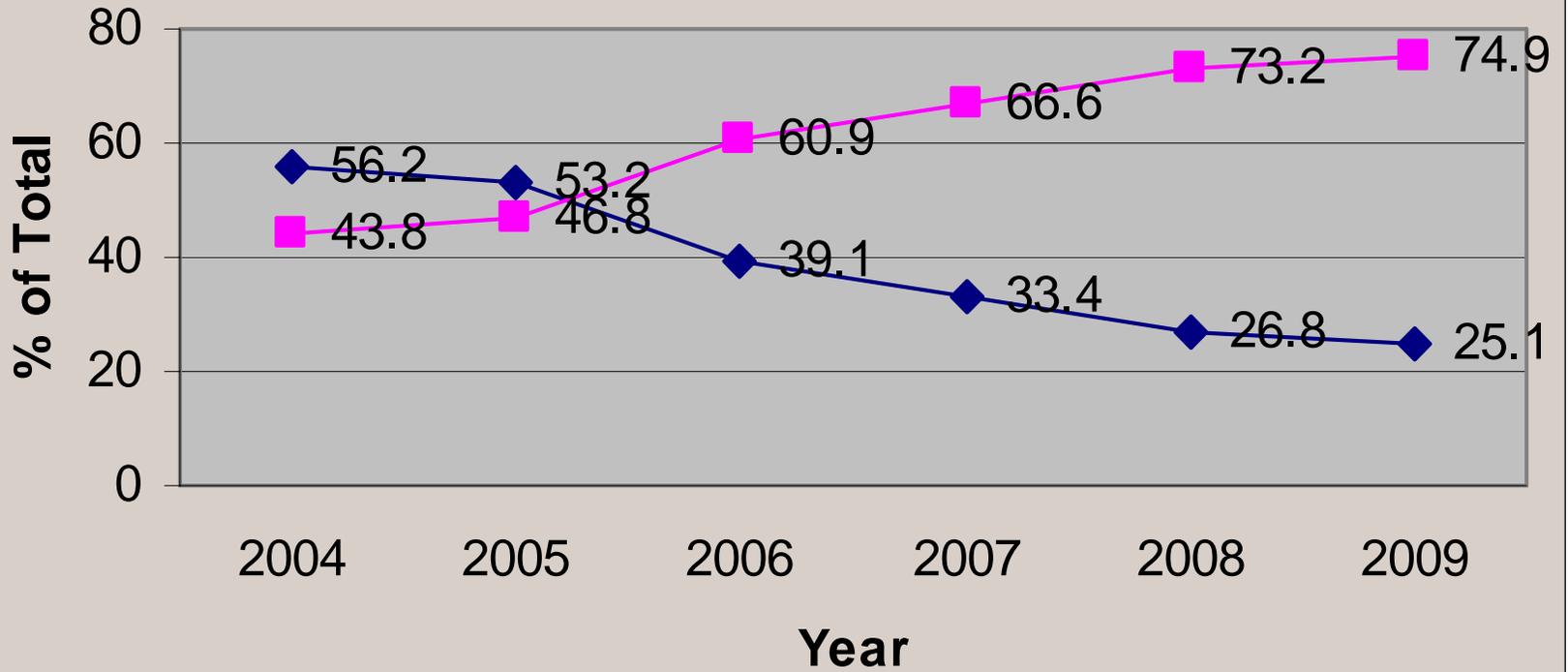
- Risk Management
- Customer confusion: moderately complex certificate = PT required even if waived method
- Convenient process to document competency

# “Regulated” vs “Waived” WSLH PT Configurations

- “Regulated” = 5 samples; 3 shipments/yr
- “Waived” = 2 or 3 samples; 2 shipments/yr
- Wherever possible the waived and regulated configurations ship together and use the same samples.
- Same scoring criteria is applied.
- Some customers enroll in a “regulated” module but will report a waived method because they prefer 5 samples.

# Strep A Antigen

◆ SA "Regulated"    ■ WS Waived

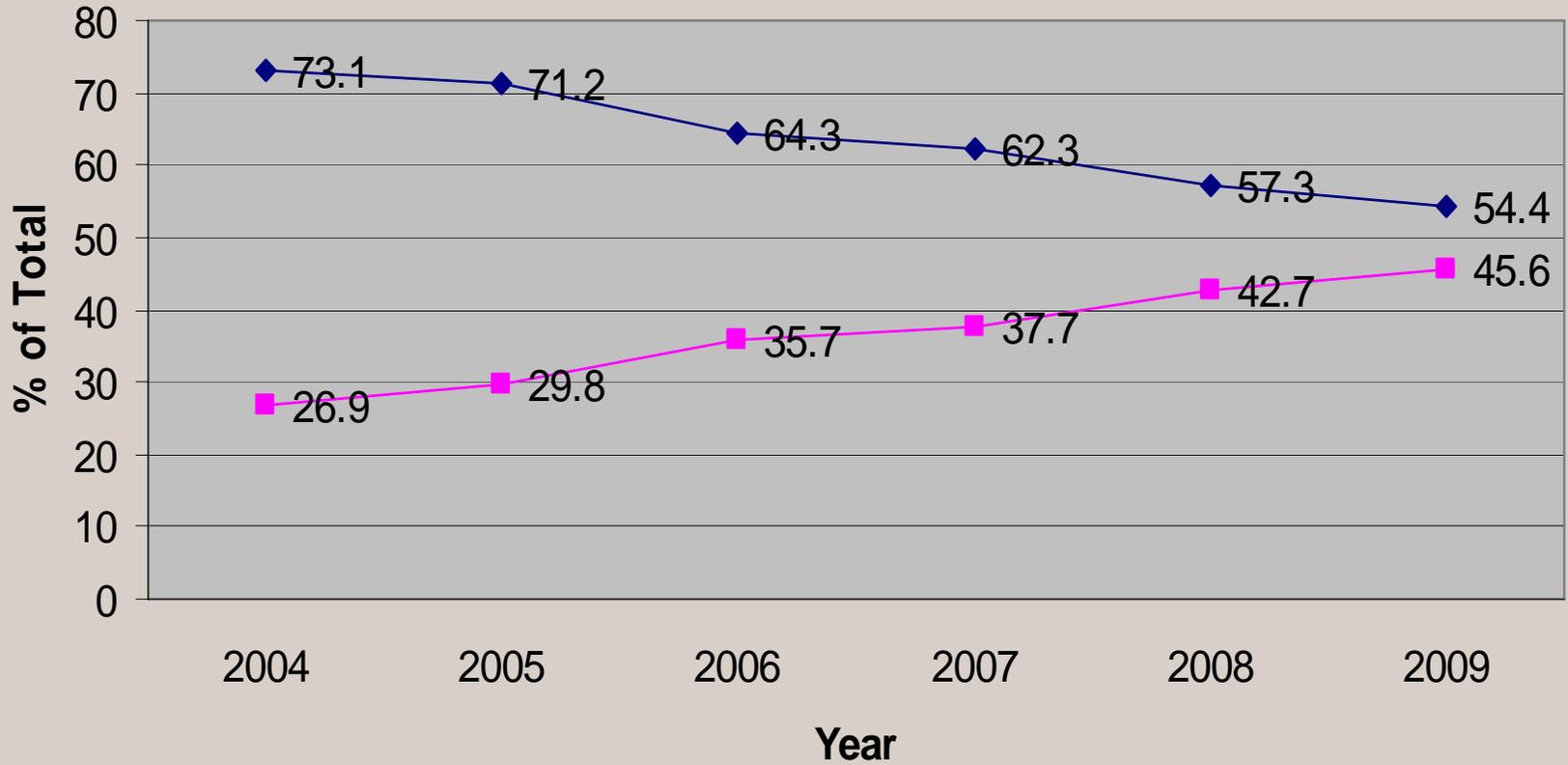


# Additional Data

- Total enrollment for all Strep A antigen PT increased by 40% over the same time period.
- Over 20% of customers enrolled in the “regulated” module report waived methods.
- Passing rates (moderately complex; waived) were similar.

# Infectious Mono

◆ "Regulated"    ■ Waived

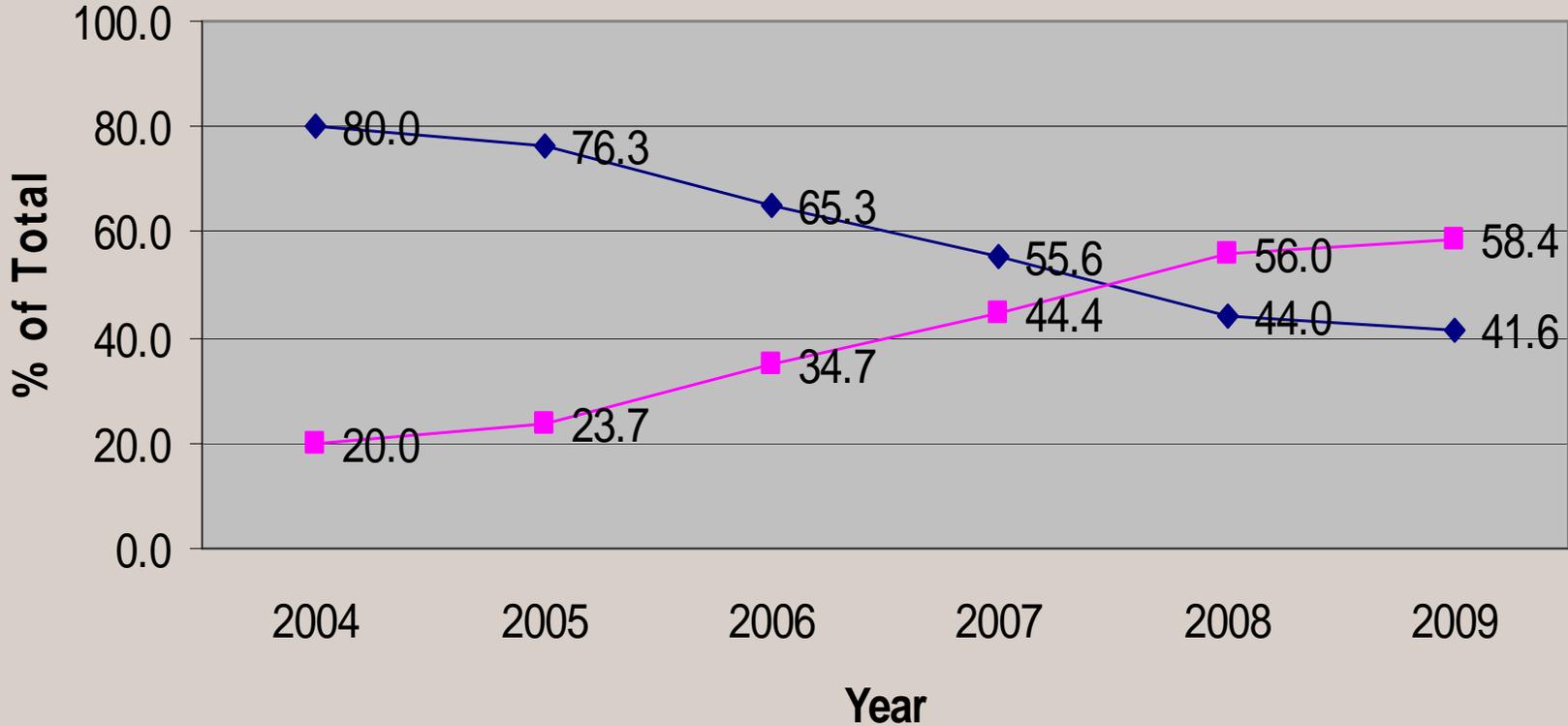


# Additional Data

- Total enrollment for Infectious Mono PT increased by over 11% during the same time period.
- Passing rates were similar.

# Influenza

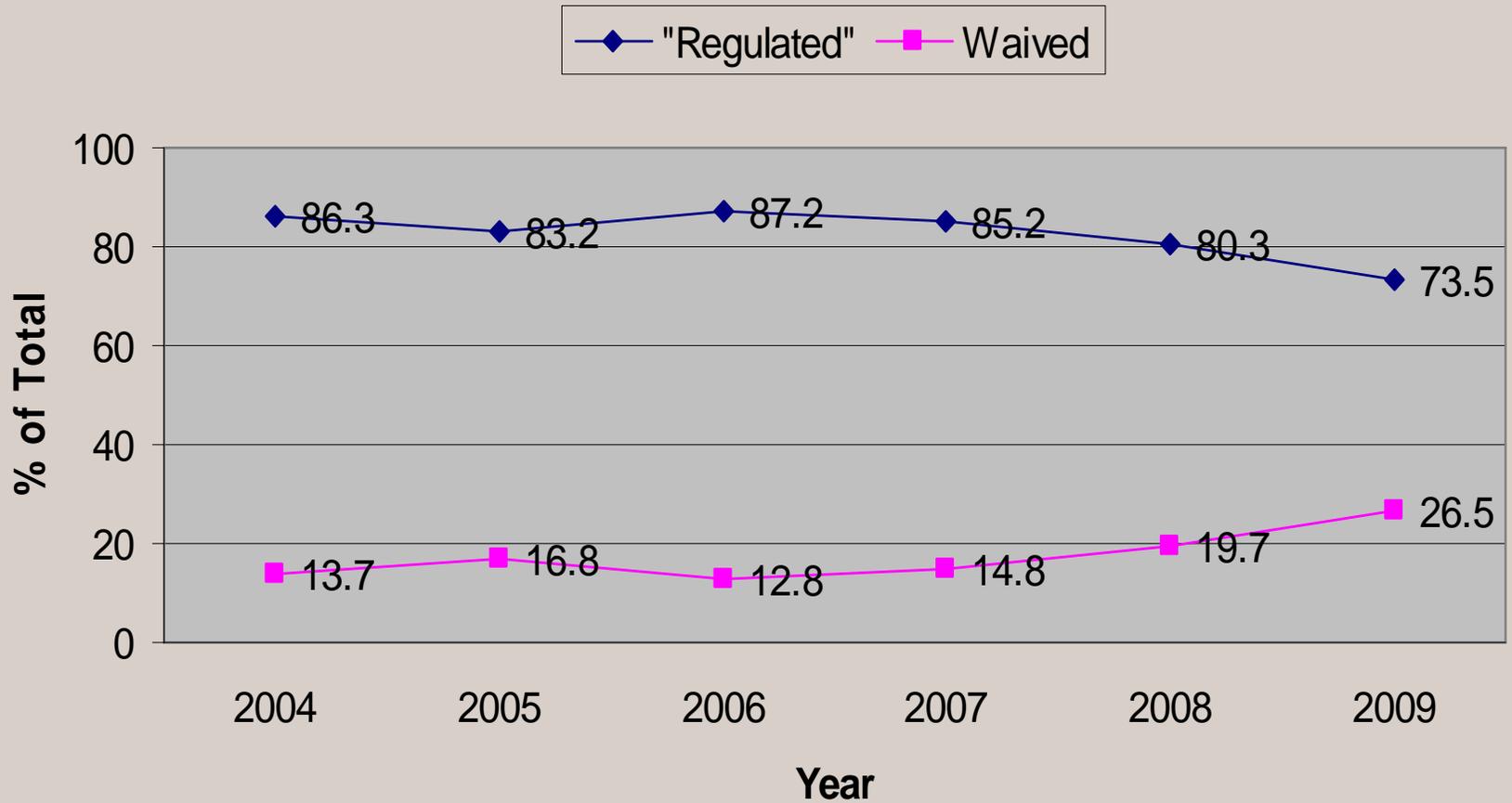
◆ "Regulated"    ■ Waived



# Additional Info

- Total enrollment for viral antigen PT doubled over this time period.
- Over 25% of customers enrolled in the “regulated” module report waived methods.
- Passing rates were similar.
- Non-waived kits had a slightly higher incidence of non-consensus.

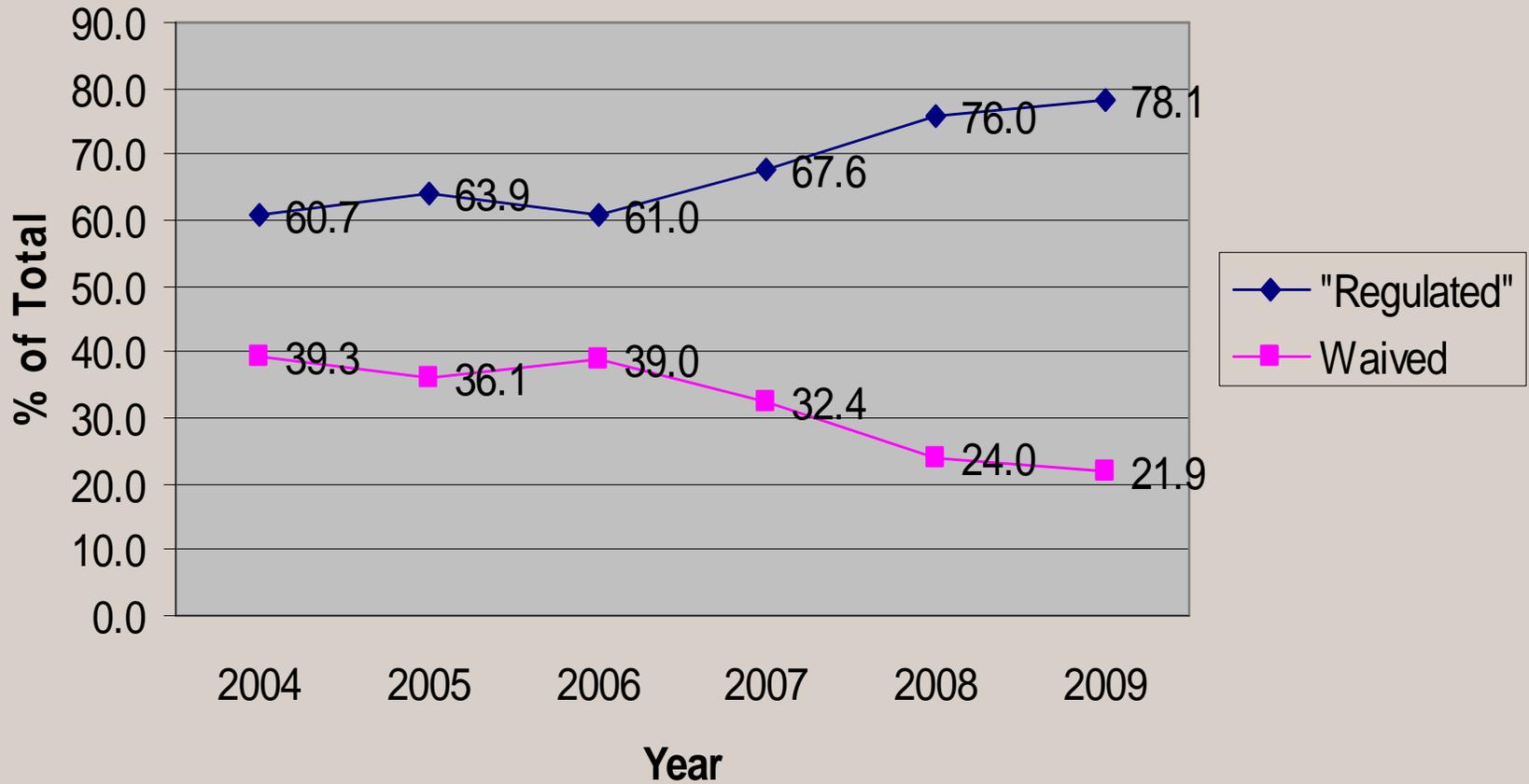
# Anti HIV



# Additional Info

- Total enrollment for anti-HIV PT remained at the same level over this period of time.
- Over 27% of customers enrolled in the “regulated” module report waived methods.
- Waived methods have a higher incidence of non-consensus for some kits and there have been “failures”.

## Coagulation (Protime/INR)



# Additional Info

- Total enrollment for protime/INR PT have dropped by 20% over this time period.
- Passing rates were similar.

# Summary

- PT providers offer services for waived testing because there is a need.
- The number of WSLH PT customers using waived methods has increased significantly for some analytes over a 5 year period.
- Data provided reflects performance in the WSLH PT Program.
- Data provided does not reflect performance for all sites using waived methods.

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