

# Thailand Experiences on Implementation of Quality Assurance and Quality System

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# Presentation Outline

- From QC to QMS
- Implementation of QMS in Thailand
- Model Development of Comprehensive QA program for HIV Testing

# A Long Way From QC to QMS

1975: Implementation of QC program in Clinical Chemistry

1982: First exercise of EQA for Clinical Chemistry

1985: Establishment of Division of Laboratory Quality Control

- External Quality Assessment
- In-service Training for Clinical Chemistry, Hematology, Bacteriology, Microscopy, Immunology and Blood Banks

1994: Implementation ISO guide 25 to clinical laboratory

1998: Establishment of National Accreditation Body for Clinical Laboratory

2000: Implementation of Hospital Accreditation Program

# Implementation of QMS into Clinical Laboratory

- National Accreditation Body was designated
- Since 1994, nation-wide continuation intensive training program for
  - ISO guide 25 and certain technical requirements such as
    - Equipment calibration
    - Method validation
    - Auditing

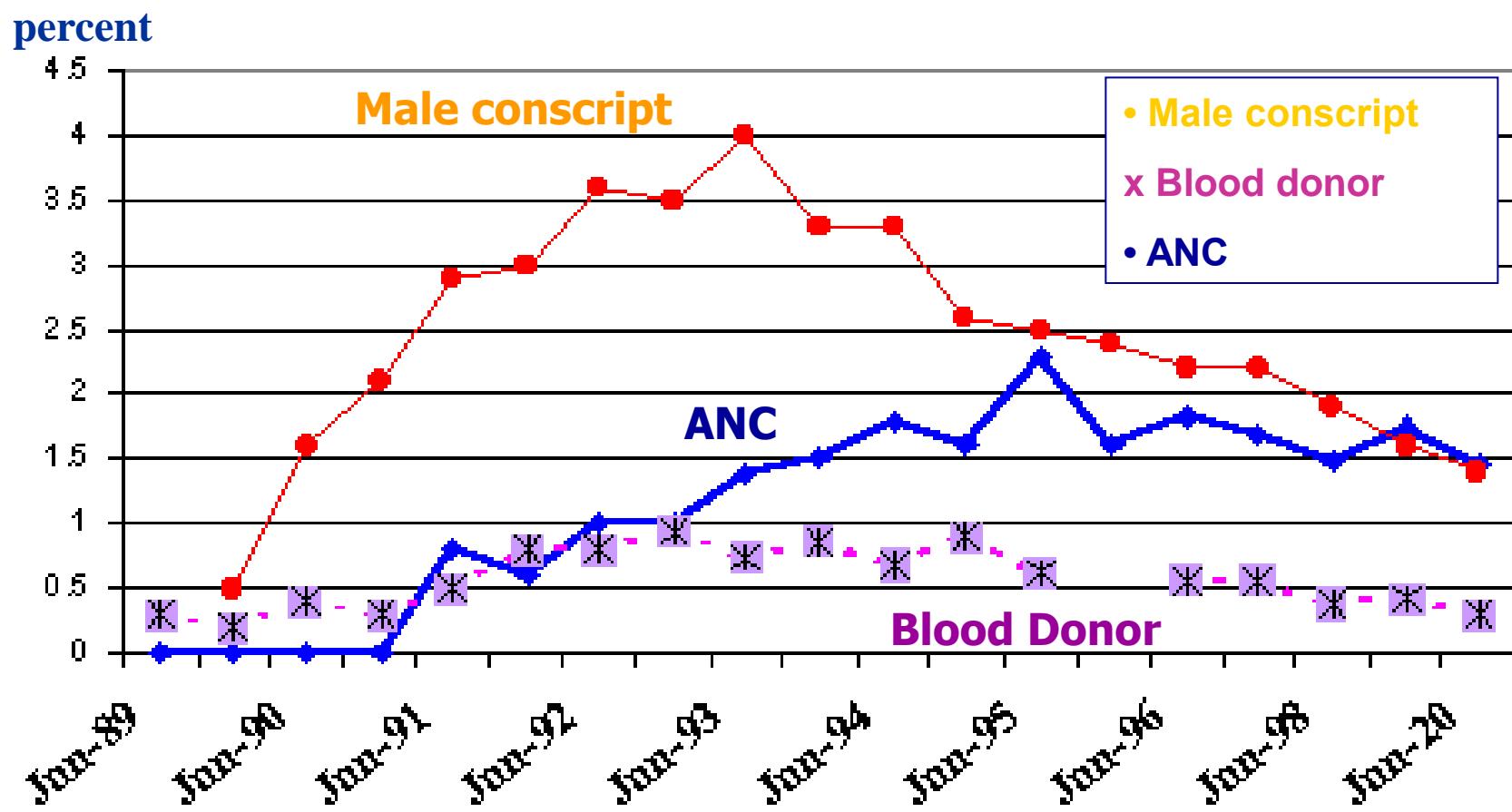
# Clinical Laboratory Accreditation Programs

- Laboratory Accreditation by National Accreditation Body
  - ISO 17025 and ISO 15189
- Laboratory Certification by Association of Medical Technologists of Thailand (AMTT)
  - Medical Technology Standard
    - Using 100 item-checklist
- Hospital Accreditation Institute by Institute of Healthcare System Development
  - Developed guideline for Lab survey

# Model: Development of a Comprehensive Program for QA-HIV

# THE THAI HIV EPIDEMIC

- The first AIDS case in Thailand was reported in 1984.
- Trend on HIV prevalence among risk groups, 1989-2001.



Source: AIDS Division, Thai MOPH

# NIH QA Program for HIV/AIDS

- 1994 Kit Evaluation (HIV test)
- 1997 EQA for anti-HIV
- 2000 Re-evaluation
- 2001 Reference Testing
- 2002 Quality Control
- 2003 EQA p24
- 2003 EQA viral load
- 2004 Information Network
- 2005 Kit batch testing

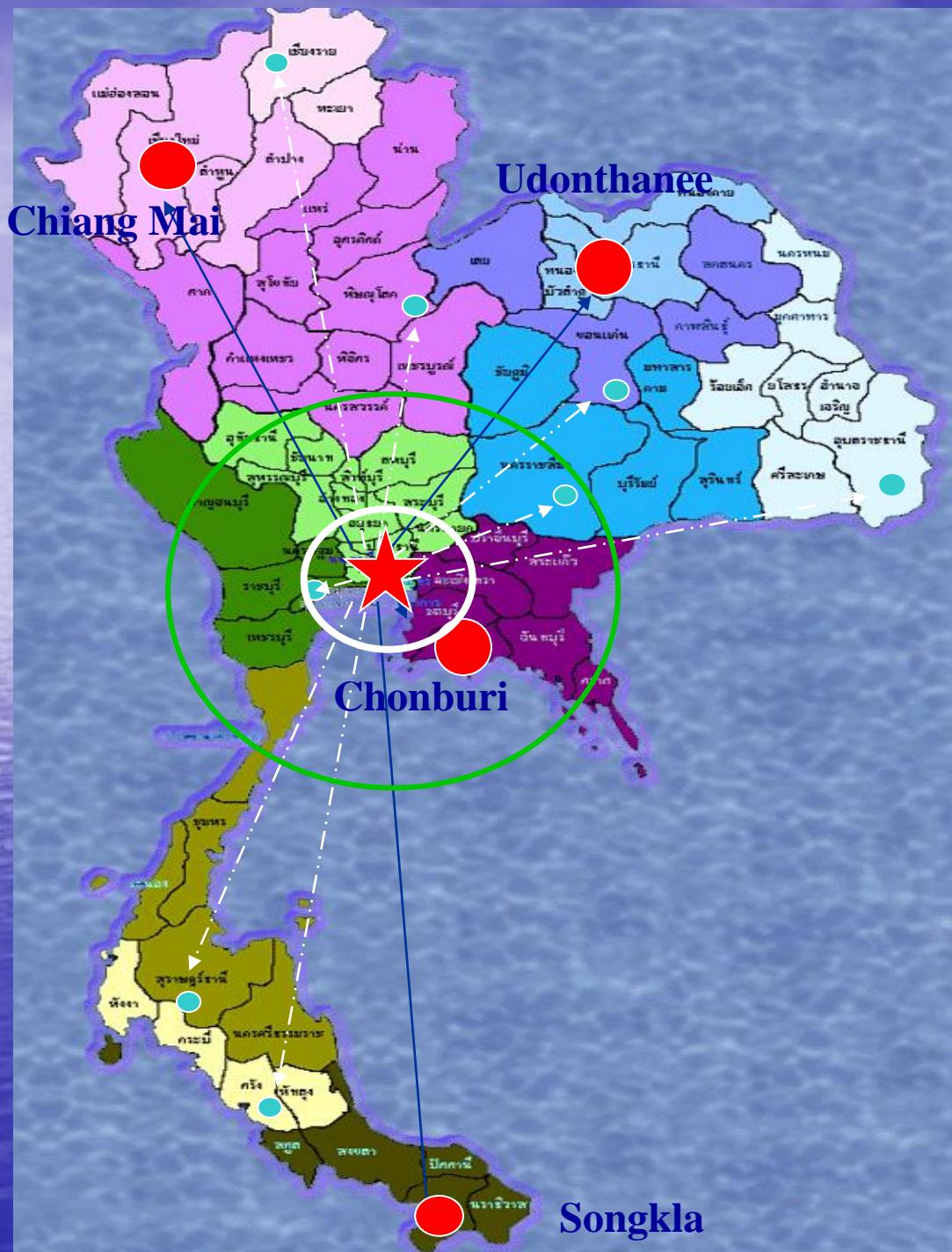
# Implementation of National External Quality Assessment Scheme (NEQAS) for HIV Testing

# How National EQA for HIV Serology was Established in Thailand

- Skill building of organizer
- A pilot program was initiated in 1998 to 1999
- It was expanded to the nation-wide program by year 2000
  - Plan and propose to get approval.
  - Select co-organizer to run sub-scheme in the regions.

# Selection Criteria for EQAS Co-organizer Laboratory

- Technical competence (on particular test)
- Resources e.g. staff, data management equipment etc....
- Representative of the country region
- Technical consultant (university) available in the local area.



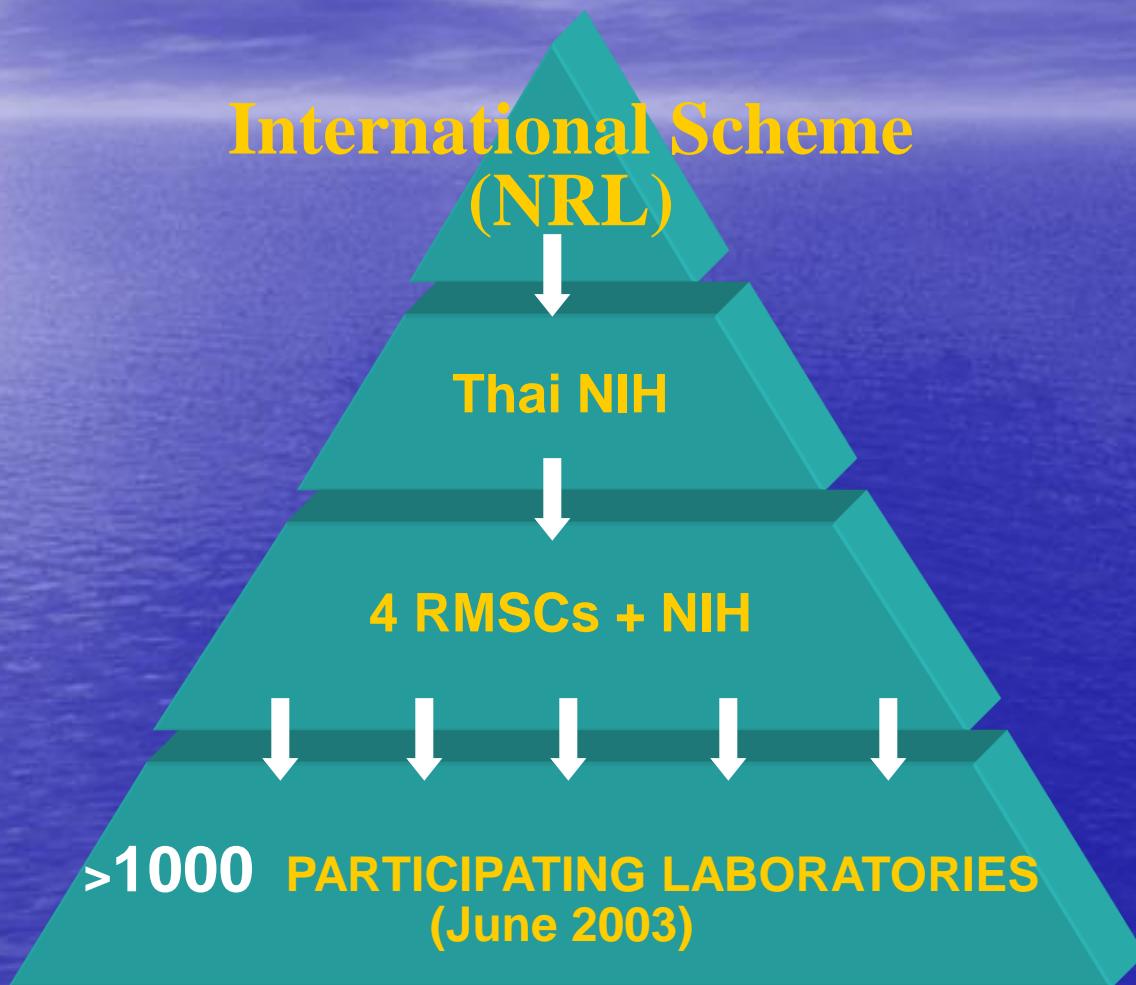
# The Royal Kingdom of Thailand

Area (Km <sup>2</sup> )	513,115
Populations	61,661,701

# Preparation steps

- Research (e.g. information required, stability of test item)
- Training workshop for co-organizer
  - Develop harmonized protocol
  - Sample preparation
  - Data analysis
  - Performance evaluation
  - Provide feedback
- Funding support for scheme operation
- Sharing the required materials

# Thailand EQAS Network

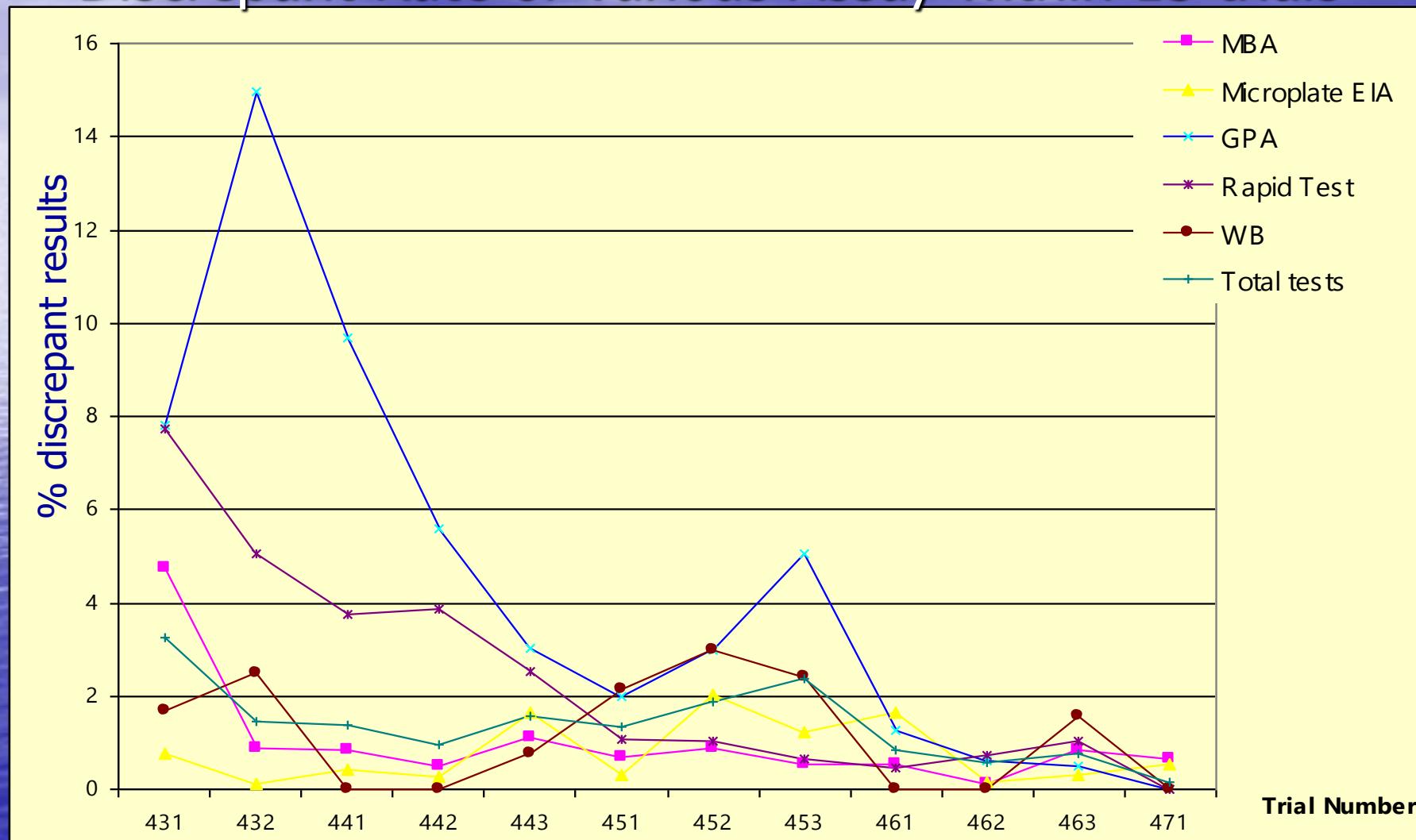


# Quality Assurance of Scheme in Operation

- Homogeneity check of EQA sample
- Recheck stability of returned sample
- Data input and processing will be verified sufficiently
- Participate to other EQA program
- Apply QMS and Auditing by
  - ISO 17025 for sample preparation and laboratory testing
  - ISO/guide 43 for scheme management

# Outcome 1999-2003:

## Discrepant Rate of Various Assay within 13 trials



No. of test varies from 4549 to 9725 tests

# Follow up activities on participants

- Provide consultative visit
- Organize training workshop.
  - Quality Assurance
  - HIV testing.
- Provide Quality Control program

Provide Triple constituents QC sample for  
Anti HIV, HBsAg and Anti HCV



# Pitfalls of our system

- Re-organization of the department did not facilitate the implement of QA program
- Re-engineering of the government organization made program under staffed
- There is no central organization to actually coordinate the QA program

# Next Steps

- Apply for accreditation on ISO 17025 and ISO guide 43 by year 2004
- Expanded the activities to other blood safety screening markers

# Acknowledgement

- Technical consultant
  - NRL Australia
- Funding agency
  - Global AIDS Program
- The network
  - Advisory group
  - The 4 Sub-scheme organizers, Chiang Mai,  
Udorn Thani, Songkla and Chonburi RMSC
- Staff members of QA-HIV Laboratory,  
National Institute of Health

A wide-angle photograph of a sunset over a calm body of water. The sky is filled with dramatic, layered clouds in shades of orange, yellow, and dark grey. The sun is low on the horizon, its light reflecting brightly on the water's surface. In the distance, a dark silhouette of land or trees is visible across the water. The overall atmosphere is peaceful and scenic.

Thank you