



# UKNEQAS Toxoplasma Serology

It is the fault of the kits – or is it?

# Purpose of the Schemes

The Toxoplasma subschemes consist of IgG and IgM and are designed to:

- Provide information allowing participants to gain an insight into their performance in the detection of Toxoplasma antibodies.
- To take individual action to investigate and remedy any discrepancies.

# Scheme Operation

- Operated from the department of Clinical Parasitology, Hospital for Tropical Diseases, London.
- Collaboration with the Toxoplasma Reference Laboratories in Inverness and Swansea and the Department of Medical Microbiology, St George's Hospital, London

# Scheme Information

	<b>Toxoplasma IgG/Total antibodies</b>	<b>Toxoplasma IgM</b>
<b>Year subscheme recognised as UKNEQAS</b>	1993	1999
<b>Examinations requested</b>	Detection of toxoplasma IgG or total antibodies	Detection of toxoplasma IgM antibodies
<b>Material distributed:</b>	Human serum	Human serum
<b>Number of distributions per annum:</b>	3	2
<b>Number of specimens per distribution</b>	6	4
<b>Performance assessment criteria:</b>	The ability to confirm or exclude the presence of IgG or total antibodies	The ability to confirm or exclude the presence of IgM

# Information provided for participants

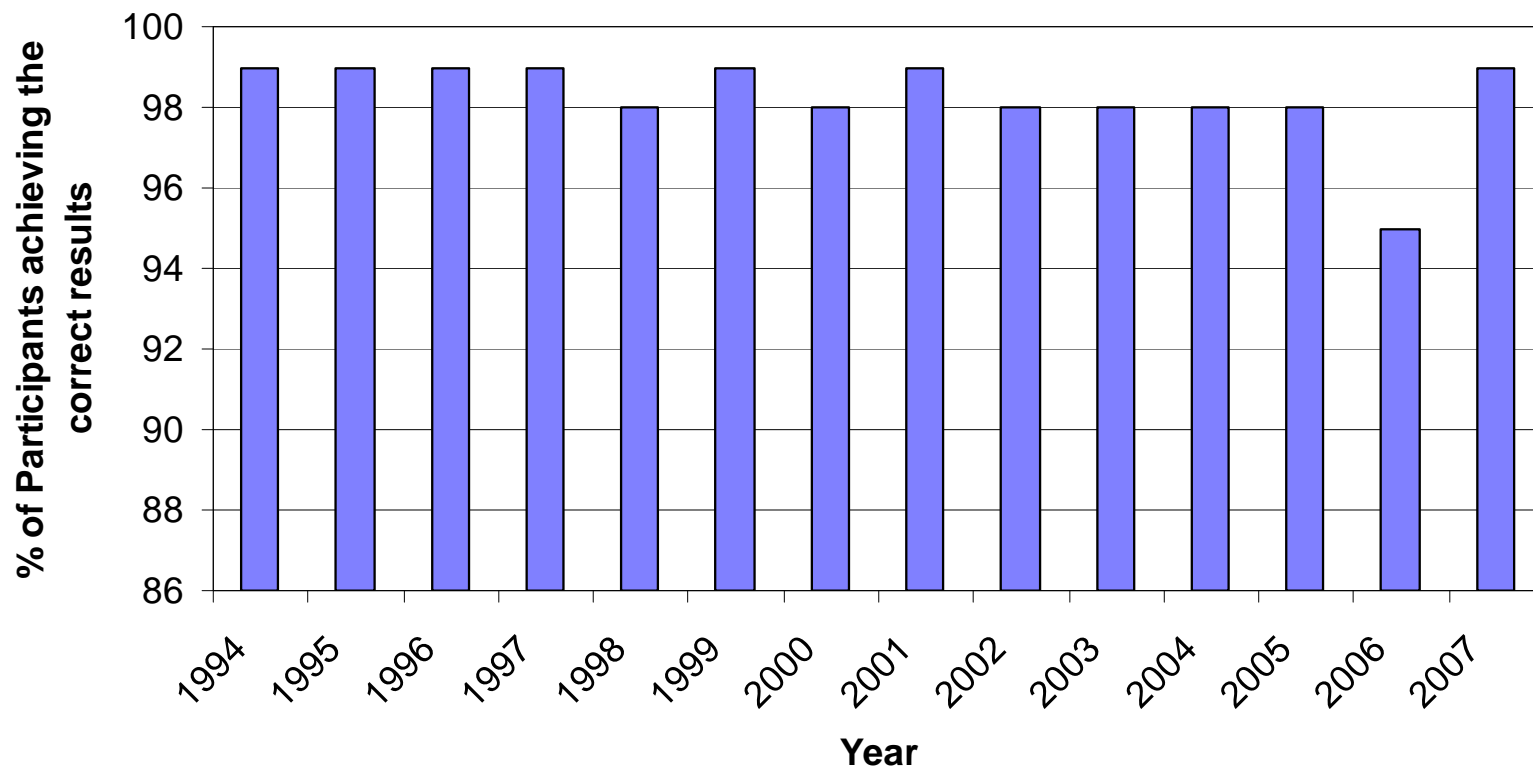
- Participants are allowed 3 weeks to examine the sera and report their results.
- Following analyses of results, a report is provided to all participants.
- This includes specific comments on the Toxoplasma specific antibody content of each specimen and, for one specimen, its relevance to the clinical details.

# Participation in Schemes

	UK	Portugal	Total Overseas
Toxoplasma Serology	149	39	173
Toxoplasma IgM Serology	45	39	175

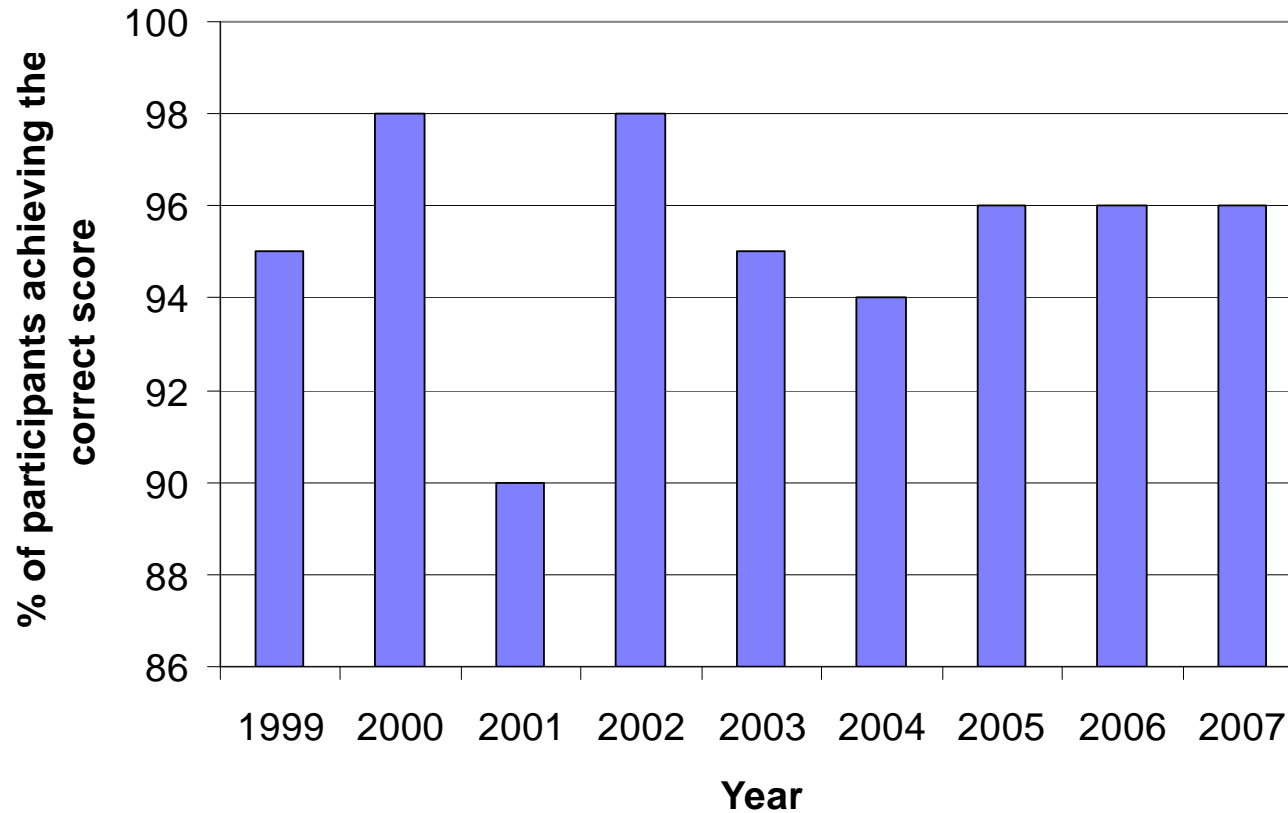
# Performance: Toxoplasma IgG

Toxoplasma IgG: Participants performance



# Performance: Toxoplasma IgM

Toxoplasma IgM: Participants' results



# Range of Kits

**Abbott AxSYM**

**Toxo IF bioMérieux**

**Biokit Launch**

**Bouty ELISA (IHA)**

**Cobas Core Roche**

**Diamedix**

**DPC Immulite Toxo-**

**In House tests**

**Mast Latex Agglutination**

**Radim EIA**

**Toxospot bioMérieux**

**Abbott IMX Antigene**

**Beckman Access**

**Biorad**

**Captia Toxo-G Select**

**(EIA)Dade Behring**

**Diasorin ETI Toxo-**

**Eurogenetics**

**ISAGA bioMérieux**

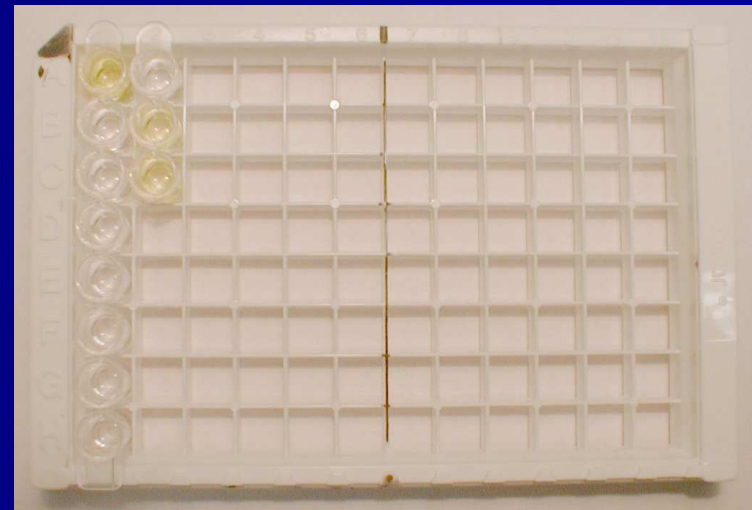
**Organon Toxnostika**

**Sabin Feldman Dye Test**

**Vidas bioMérieux**

# Participants have experienced problems with:

- Screening kits
- Low level titres
- Toxoplasma IgM detection



# Screening Kits: False negatives

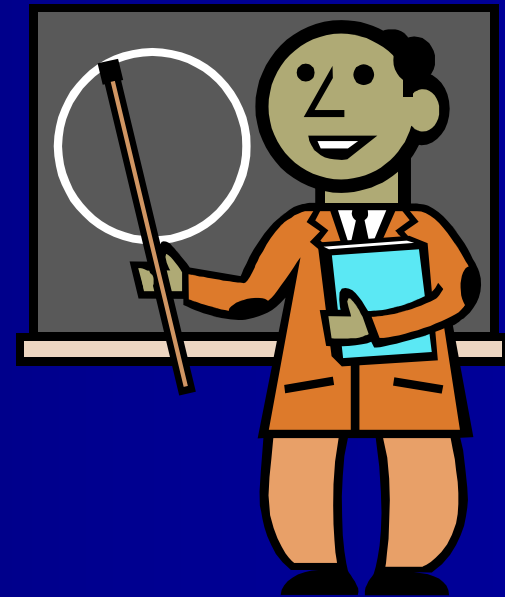
- Intended results: Dye Test 16IU/mL, Latex agglutination 1:16, IgG ELISA positive
- Range of results: <1:16 – 1:256
- Cut off titres reported by participants ranged from 1:8 to 1:32.
- Equivocal results reported by participants ranged from 1:8 to 1:32.

# Manufacturers results

- The manufacturers found a titre of 1:16 with the specimens and they reported no apparent problems with batch to batch variation.
- Further tests were done to prove that the result of 1:16 was a specific reaction against toxoplasma antibody and this led to the conclusion that the original test result of 1:16 was specific.

# Advice

- Do not deviate from the manufacturer's instructions



# Comment from UKNEQAS

- The educational element of UKNEQAS is of primary importance and there is danger of reducing this emphasis if the results were to be amended to "not-scored".



**Penalise!**

# Low level positives: False negatives

- Intended results: Dye Test 8IU/mL, Latex test 1:32, IgG ELISA Positive
- 50-70% of participants reported positive results
- All Kits were affected

# Reference Laboratories comments

- The likely cause of problems was the low level of specific antibody present.
- Detection of low levels of antibody can be important for patient management.
- Failure to detect low level specific toxoplasma antibody would give false reassurance that there is no risk of reactivated toxoplasma infection with serious consequences for patient management.

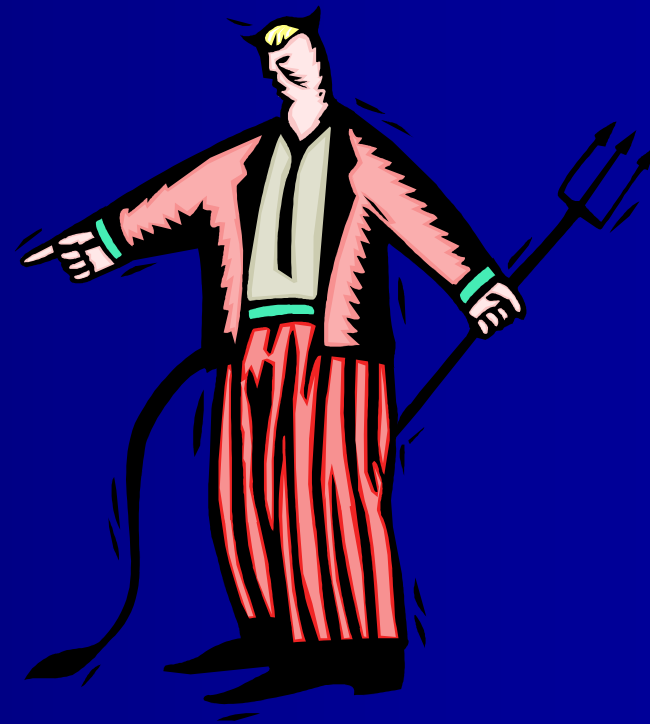
# Advice

- These samples highlight the different sensitivities, specificities and thresholds of the many different tests used for toxoplasma testing.
- Participants (and manufacturers) should be encouraged to evaluate the performance of their kits and their testing strategy.



# Comment from UKNEQAS

- Samples with low level toxoplasma antibody are a reality and this should be reflected in the samples in the NEQAS distributions.
- Such samples will be included occasionally and they will be scored providing the results are confirmed by pre and post distribution testing.

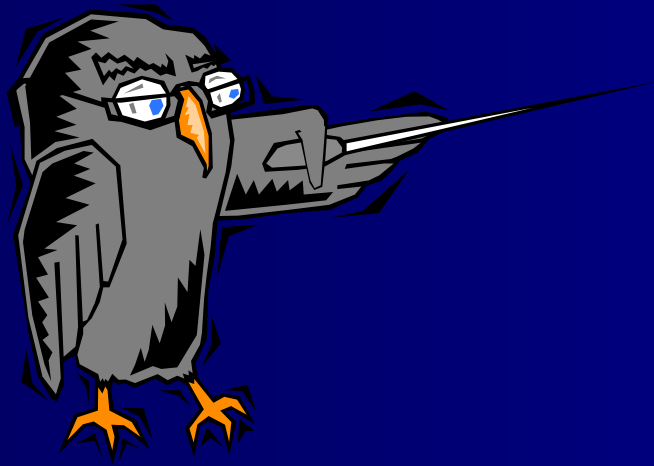


**Yet more punishment!**

# Toxoplasma IgM

- Intended results: Dye Test 65IU/mL, IgM ELISA Borderline positive, IgM ISAGA Positive
- A number of EIA kits failed to detect Toxoplasma IgM antibodies which were detected by more sensitive IgM ISAGA kit.

# Referee Laboratorys' Comments



- These specimens highlighted the importance of choosing the correct assay for the clinical group of interest.

# Advice

- Manufacturers' documentation usually provides information as to which group the kit is appropriate.



# Comment from UKNEQAS

- Participants were not scored for these specimens since not every laboratory uses an IgM ISAGA because of its limitations.



**UKNEQAS is our name**

**Good will is our aim**

# Conclusion

- EQA can provide a valuable educational stimulus to laboratory staff.
- EQA provides an insight to national performance levels
- The problems with kits highlighted the importance of adhering to the manufacturer's instruction and choosing the correct assay for the clinical group of interest.