The ’moving window”

A new approach to food safety

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MICROBIOLOGICAL PRODUCT TESTING

When is product testing for microbial content useful?

When information of content is needed and not otherwise available

- Foods of **unknown/dubious quality or history**
- **Documentation** for a claimed safety status

When routine testing is a useful tool for the verification of:

- the **design** of the food safety control system
- the **daily operation** of the food safety control system

Focus on the

Focus on the

METHODS FOR THE VERIFICATION OF CONTROL SYSTEMS

- Review and evaluation of the **records and documents**
- **Measurements and evaluation activities** to ensure that a PRP or process is operating within defined parameters
- Internal and external **audits**
- On-site **inspections**
- (End-)product sampling and **testing**

Approach to testing

- **The performance of a HACCP system depends on the effectiveness of PRPs & the degree of commitment**
- **Testing in a processing plant is carried out at various locations:**
  - Incoming materials
  - Along the process
  - Processing environments
  - End of manufacture
  - Durability assessment
- **Any testing procedure is normally governed by an MC**

MICROBIOLOGICAL CRITERIA (MC)

Organism	*n*	*c*	*m*	*M*	
L. monocytogenes	5	0	100 cfu/g	-	2-Cla MC
	5	0	Absent in 25g	-	
	5	0	100 cfu/g	-	
E. coli	5	2	100 cfu/g	1.000 cfu/g	3-Cla MC
Coagulase positive Staphylococci	5	2	100 cfu/g	1000 cfu/g	
Staphylococcal enterotoxin	5	0	Absent in 25g	-	

THE ”N/C/m/M” SYSTEM

- **Developed prior to the HACCP era**

ICMSF Book 2 (first ed. 1970)

- **Designed for lot-by-lot testing**

Used to sort between acceptable and non-acceptab food lots/batches

(the 15 ICMSF cases)

- **Not designed for today's primary application:**

Verification of the ongoing performance of HACCP based systems

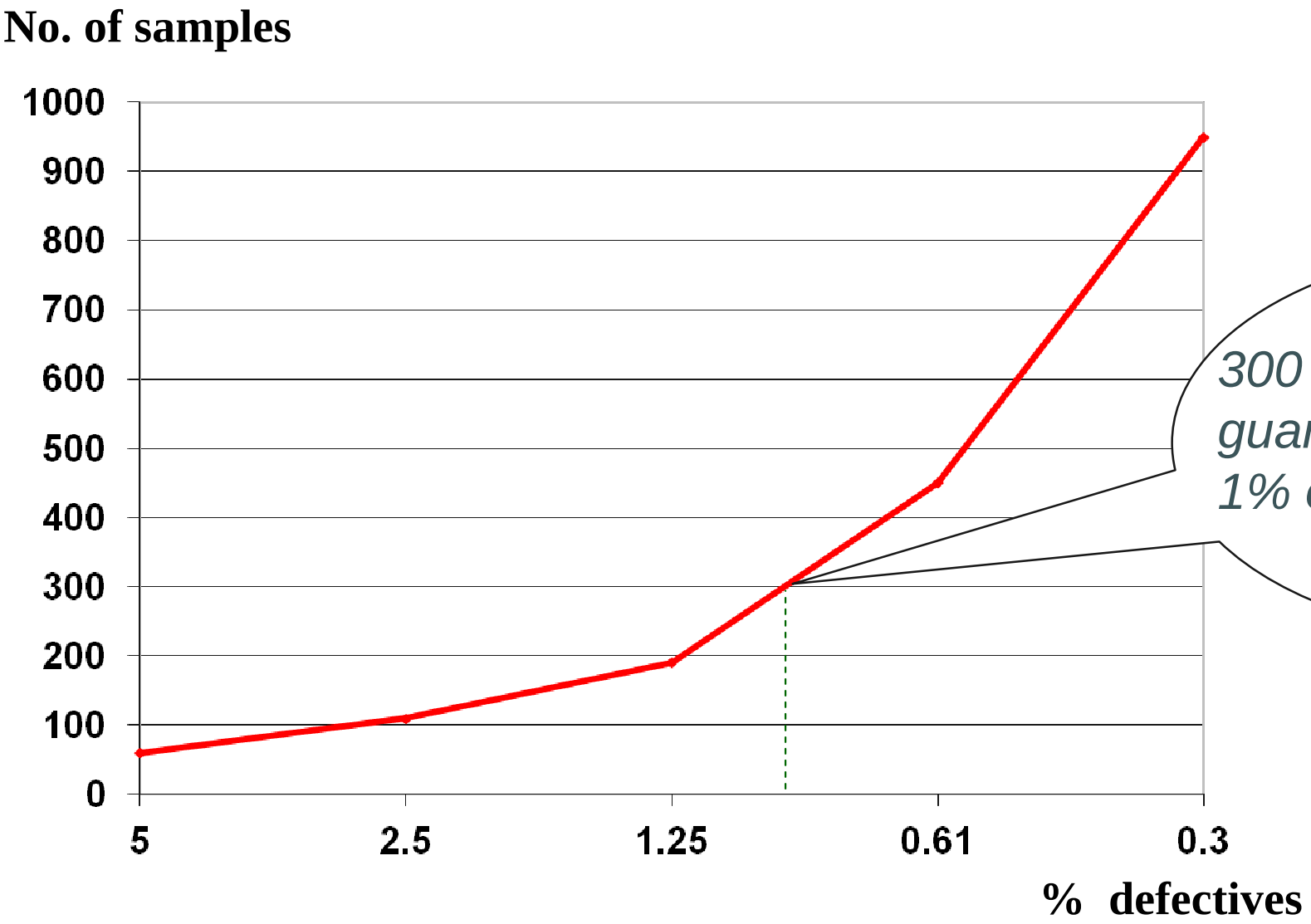
LOT-BY-LOT TESTING

Possibility of not detecting a contaminated lot

Sample size	1% contaminated	5% contaminated	10% contaminated
5	0.95	0.77	0.59
10	0.90	0.60	0.35
15	0.86	0.46	0.21
20	0.82	0.36	0.12
30	0.74	0.21	0.04
40	0.67	0.13	0.01
50	0.61	0.08	0.01

LOT-BY-LOT TESTING

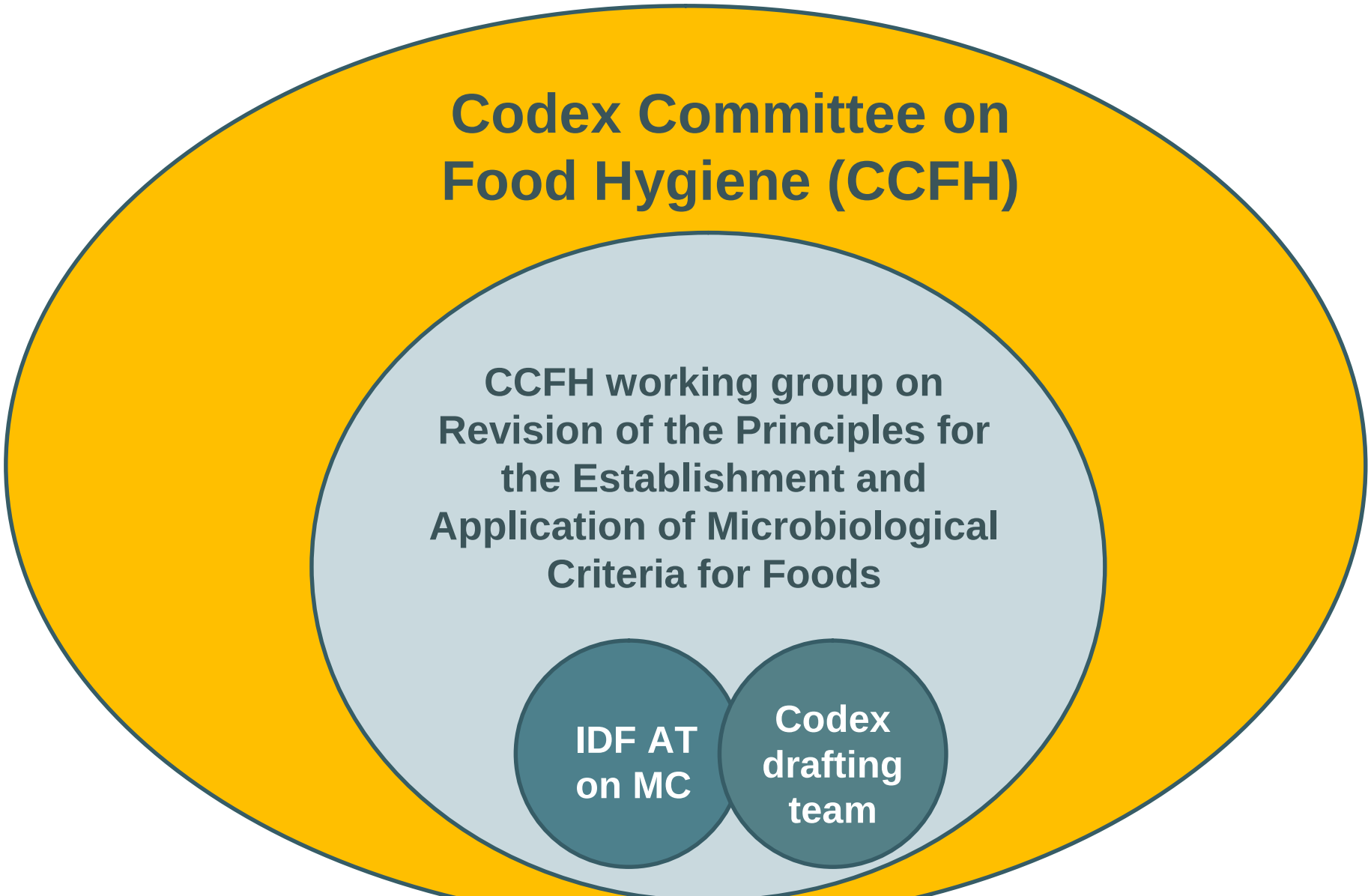
No. of samples required to find defect lots



OBTAINING SAFE FOODS

- **Safe food is obtained through preventive control, i.e.**
  - Verified PRPs
  - Validated control measures
  - HACCP
- **Lot-by-lot testing is not an effective tool to provide nor document safe foods**
- **Product testing can be useful to assist in verifying the continuous performance of the food safety control system**

MOWING WINDOWS
A new approach for system verification



Changed definition of MC

The old

A microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot

The new

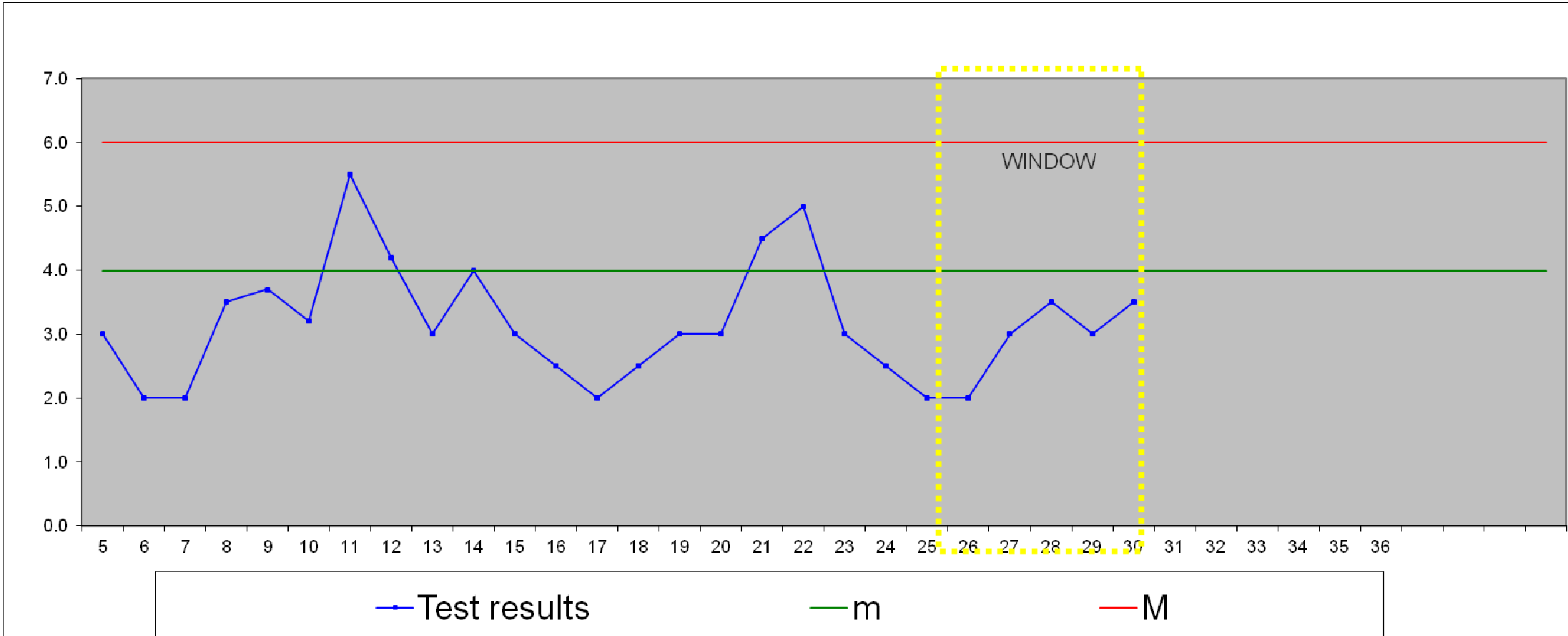
A microbiological criterion is a risk management metric, which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for

Moving windows

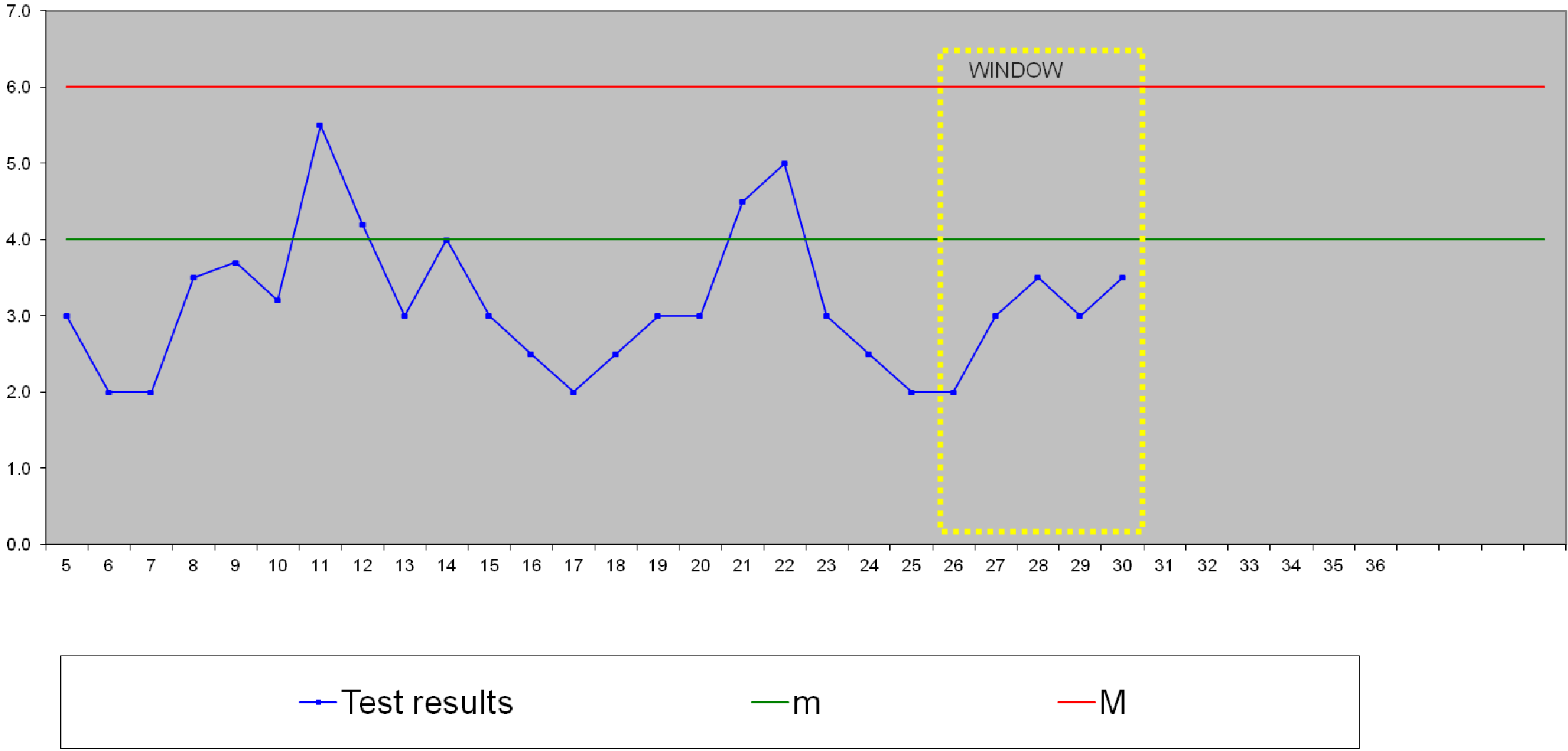
A series of sampling occasions → = *n*

with a specified sampling frequency → = *e.g. one/week*

within a defined time frame → = *n * frequency*



A MOVING WINDOW



n=5; c=2; m=10,000; M=100,000

A MOVING WINDOW

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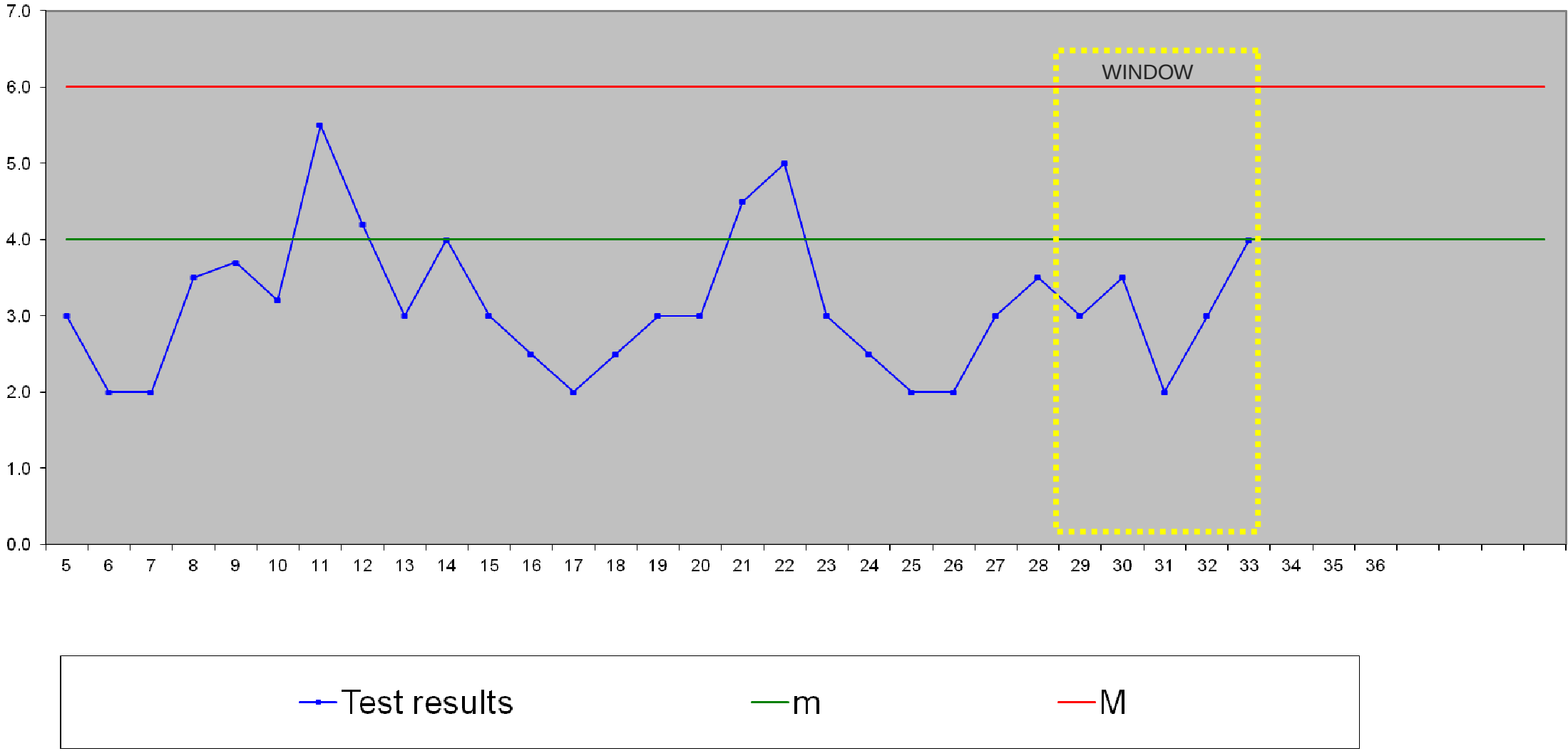

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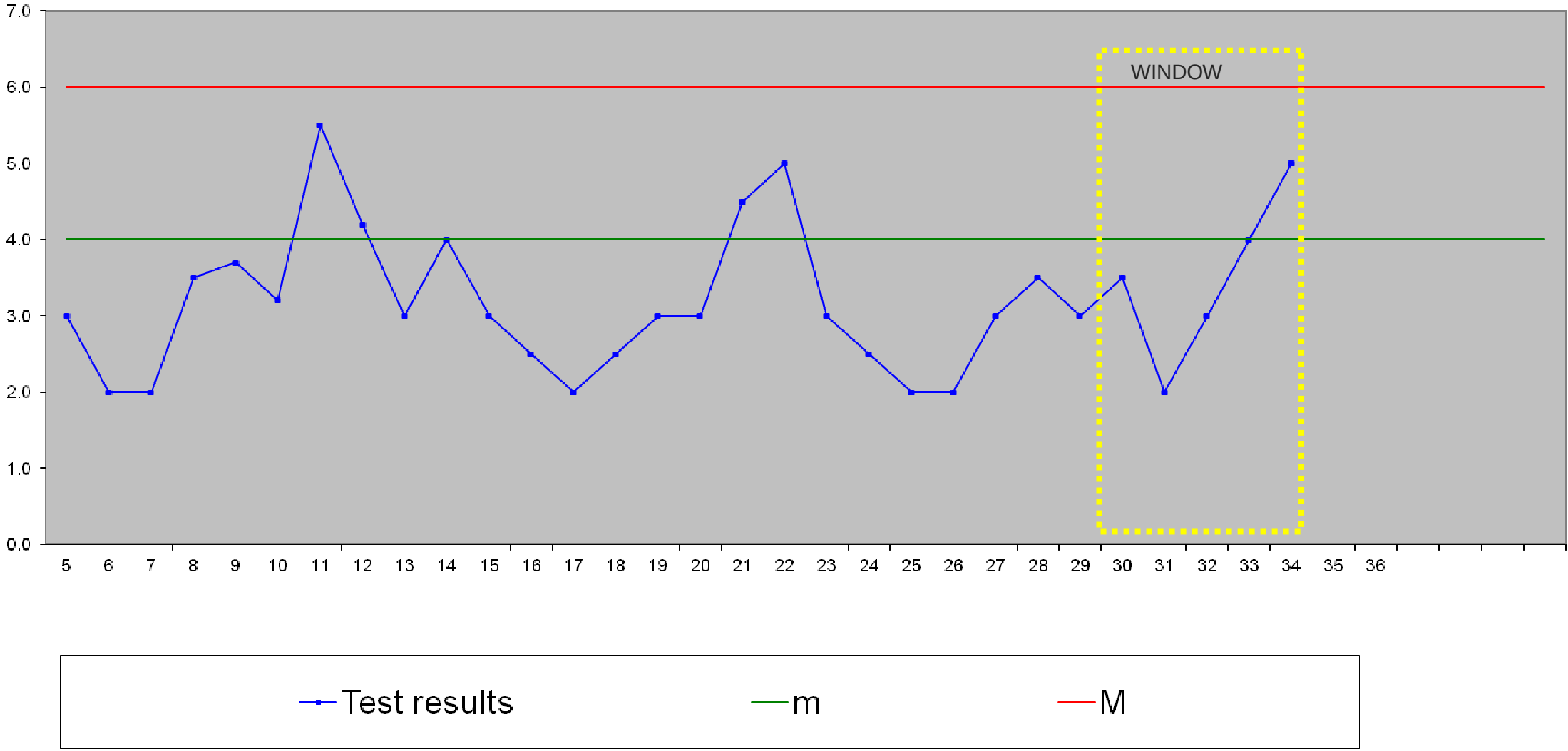

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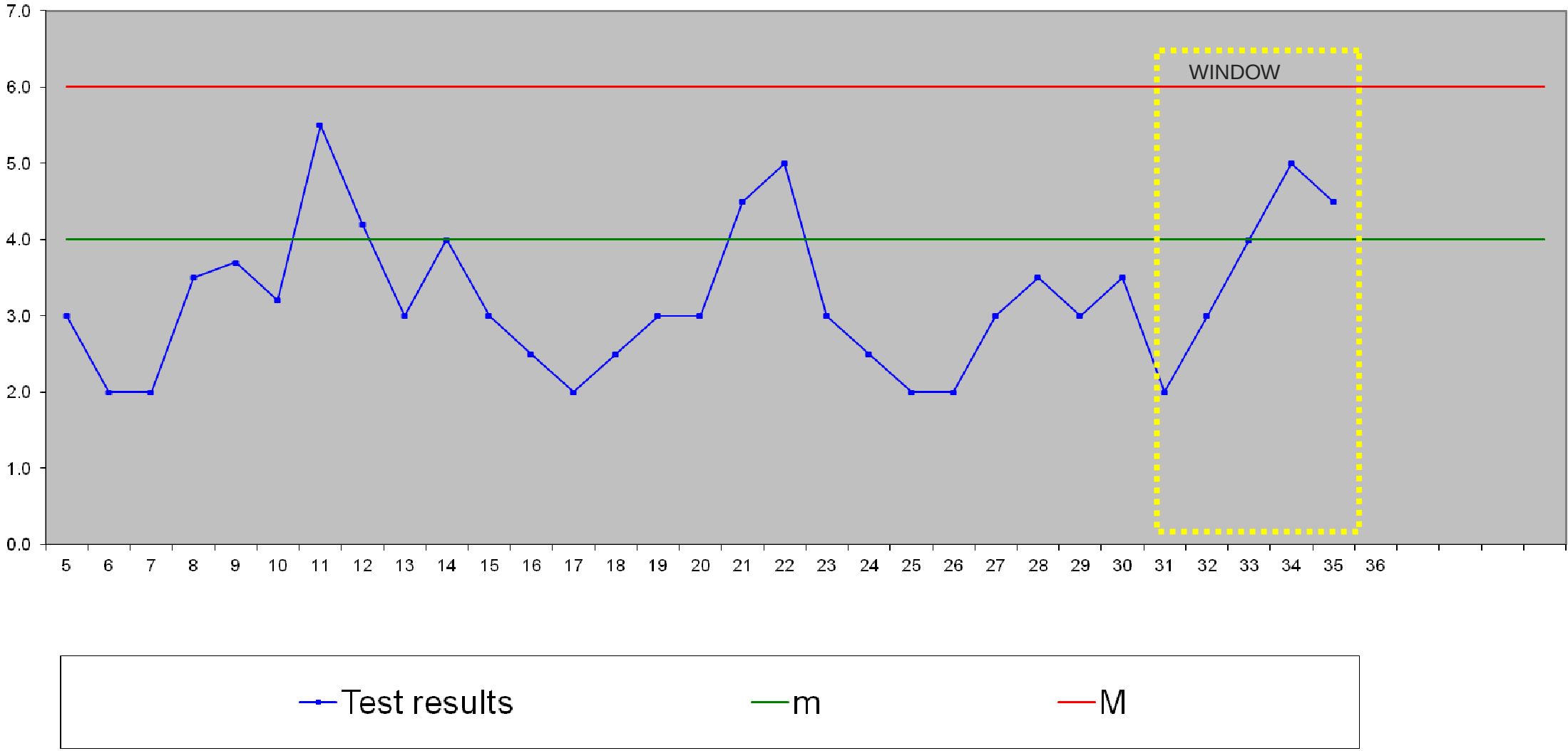

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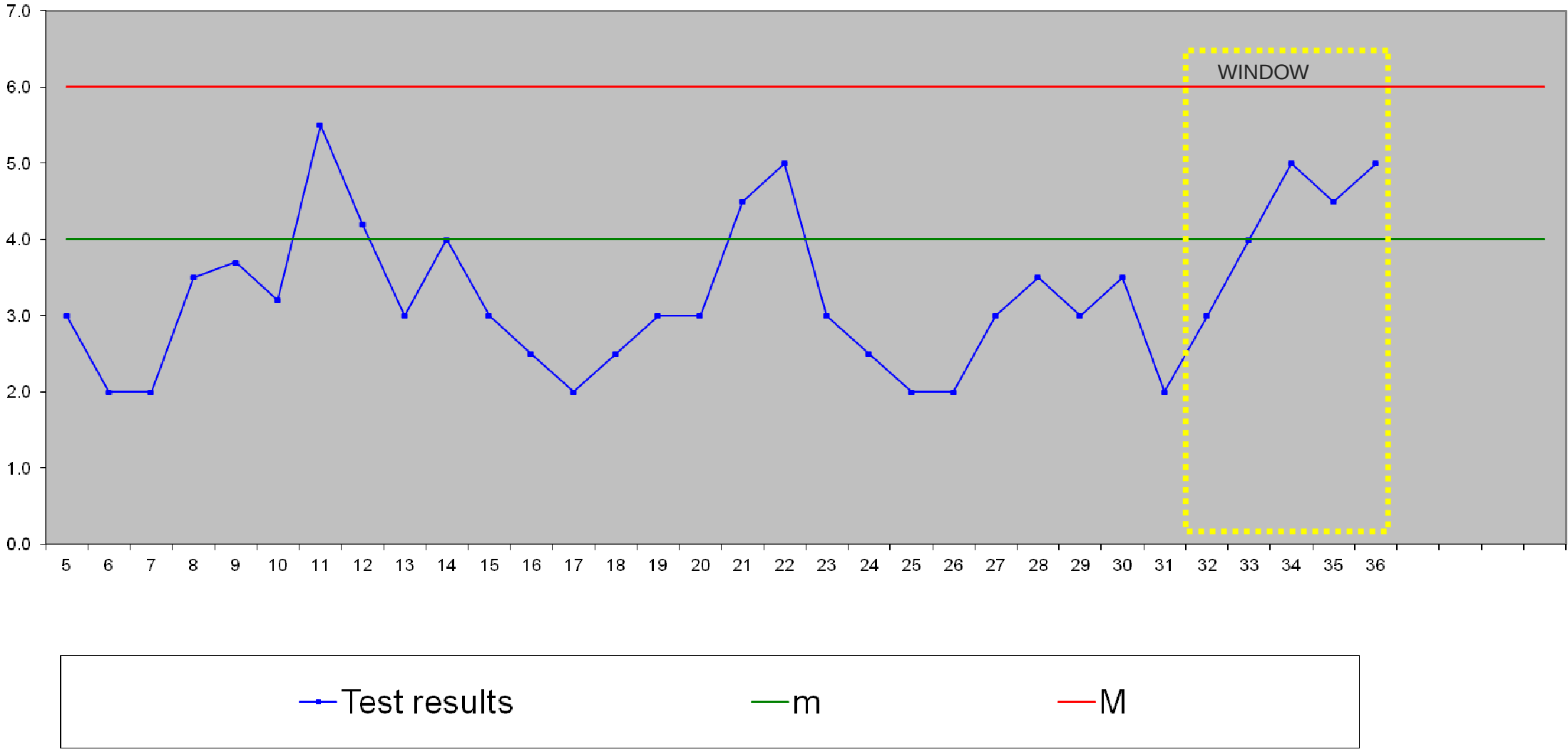


n=5; c=2; m=10,000; M=100,000

Corrective action

When?

Last ”n” results (n=5, 10 or 30):

- **When ”M” is exceeded (action on individual results)**
- **When ”c” is exceeded within the sampling period**

What?

Targeted actions based on review of data, source tracking & root cause analysis, e.g.:

Implementation	Design	Affected lot, if require
Restore control of control measures	Revalidation	Rework
	Improve PRPs	Containment & recall
Improve monitoring	Change intended level of	

Moving windows: Why?

- **Shift in focus towards system performance**
- **Excellent as feed-in to trend analysis**
- **Cost-effectiveness**
  - Generates more data and information from operations
  - Maximizes output of analytical sampling & testing
  - Reduces analytical costs in well performing HACCP based systems

"The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system (Codex Alimentarius 2013 - CAC/GL 21)

Moving windows: When?

Routine verification

- ✓ Daily
- ✓ Weekly
- ✓ Bi-weekly

Type of microbiological criteria

- ✓ 3-class (n;c;m;M)
- ✓ 2-class (n;c;m)

Well performing HACCP based systems

IS IT LEGALIZED IN EU?

EU Definition of MC*

*Microbiological criterion means a criterion **defining the acceptability of a product, a batch of foodstuffs or a process**, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.*

**) Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs*

The new Codex definition

*A microbiological criterion is a risk management metric, which **indicates the acceptability of a food, or the performance of either a process or a food safety control system** following the outcome of sampling and testing for microorganisms at a specified point of the food chain.*

IS IT LEGALIZED IN EU?

Art 5.1

The analytical methods and the **sampling plans** and methods **in Annex I sh**
be applied as reference methods.

Art 5. 3

The **number of sample units** of the sampling plans set out in Annex I **may b**
reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

Art. 5.5

Food business operators may use **other sampling and testing procedures**,
they can demonstrate to the satisfaction of the competent authority that these procedures provide **at least equivalent guarantees**. Those procedures may include use of alternative sampling sites and use of trend analyses.

Interpretation:

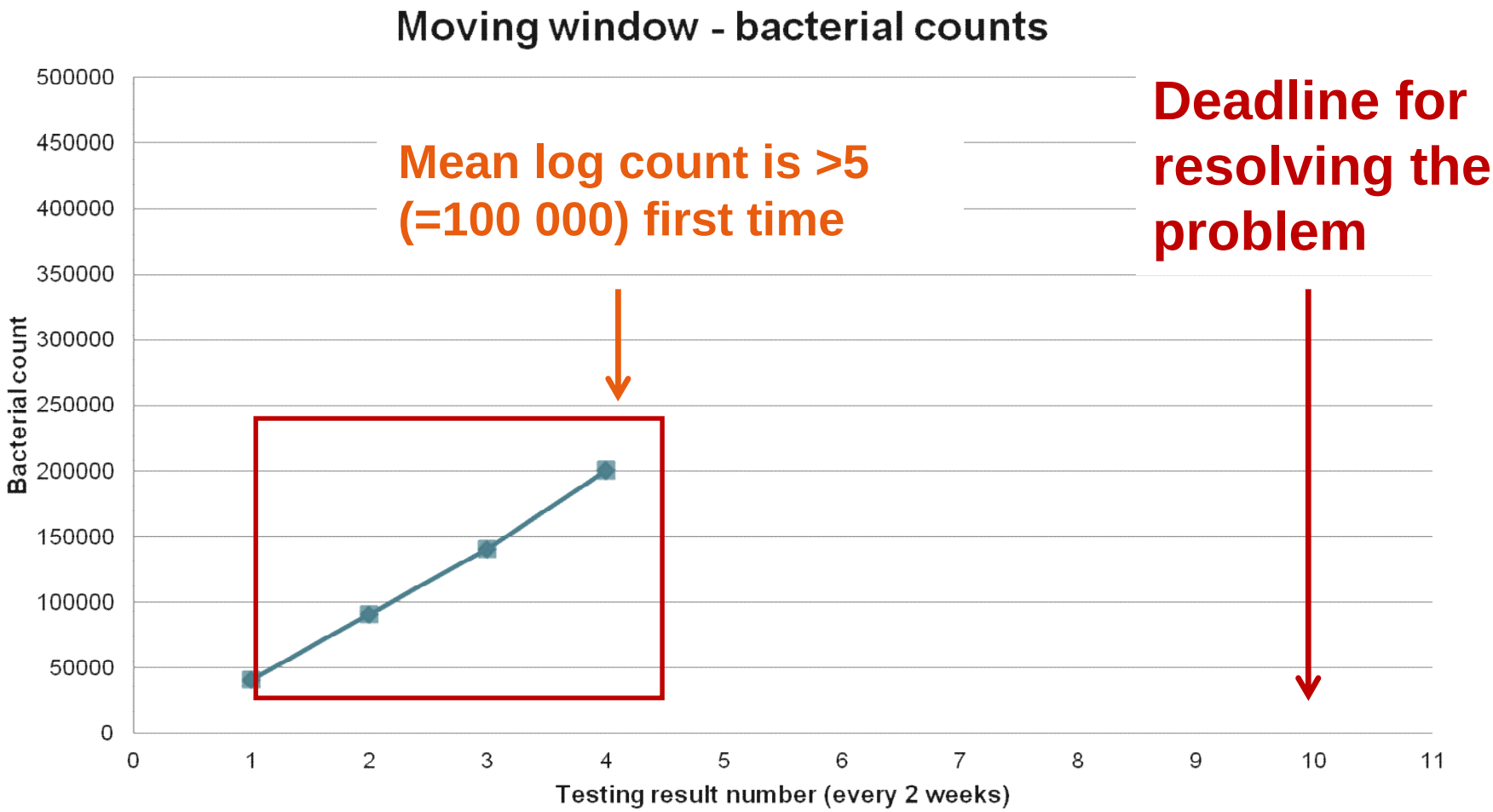
→**Art 5.1:** Typically 1 monthly sampling (n=5)

→**Art 5.5:** Moving window as alternative sampling procedure (n=1 spread over time)

Not a new concept!

Reg 853/2004, Annex III, Section IX, Chapter III

- ≤ 100.000 per ml as rolling geometric average over a two-month period
- In case of non-compliance, the rolling geometric average over a two-month period shall be <100.000 per ml again, before the end of a 3 month period


Moving window - bacterial counts
Mean log count is >5 (=100 000) first time
Deadline for resolving the problem
Bacterial count
500000
450000
400000
350000
300000
250000
200000
150000
100000
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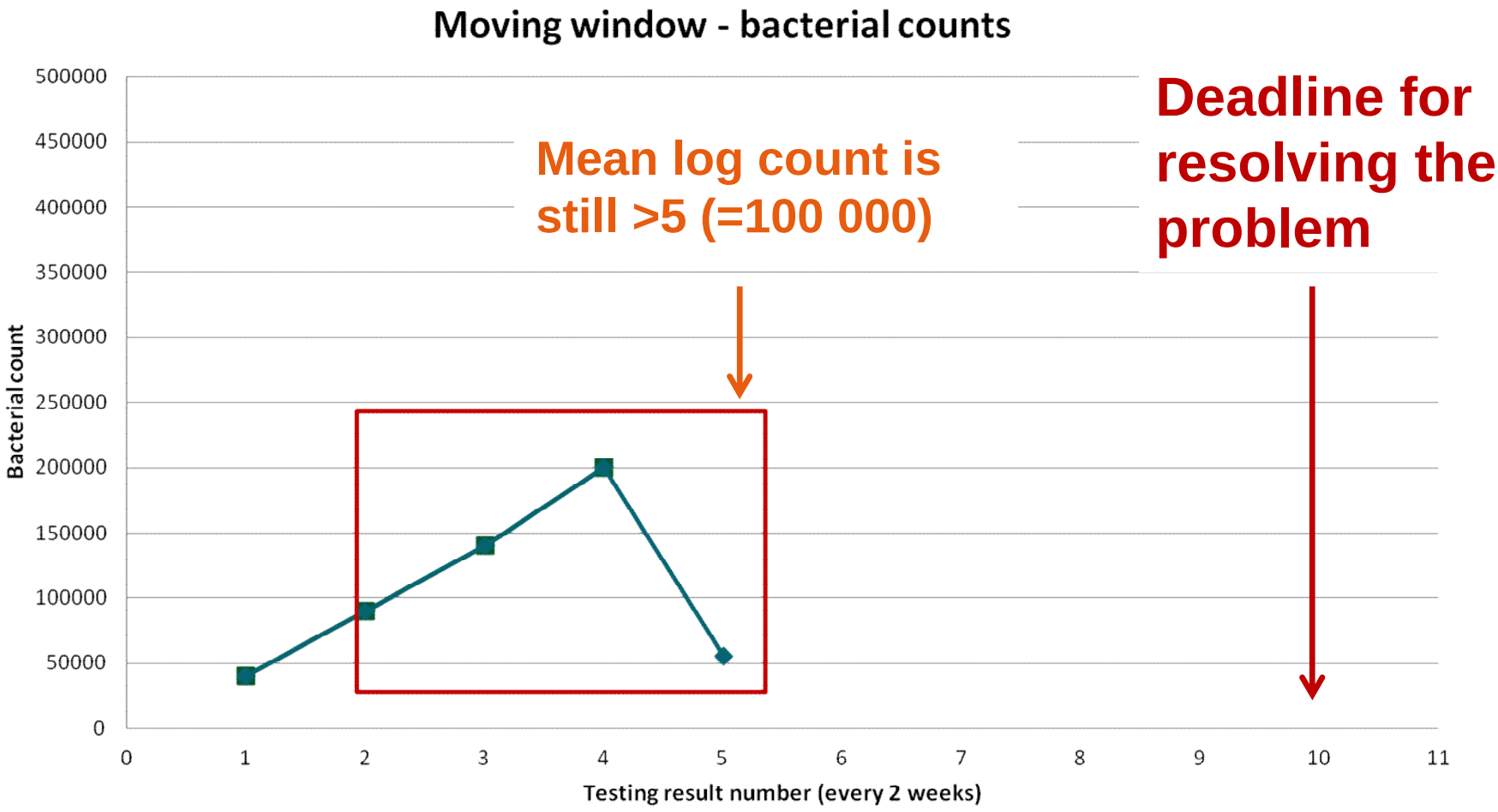
Testing result number (every 2 weeks)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Mean log count is still >5 (=100 000)
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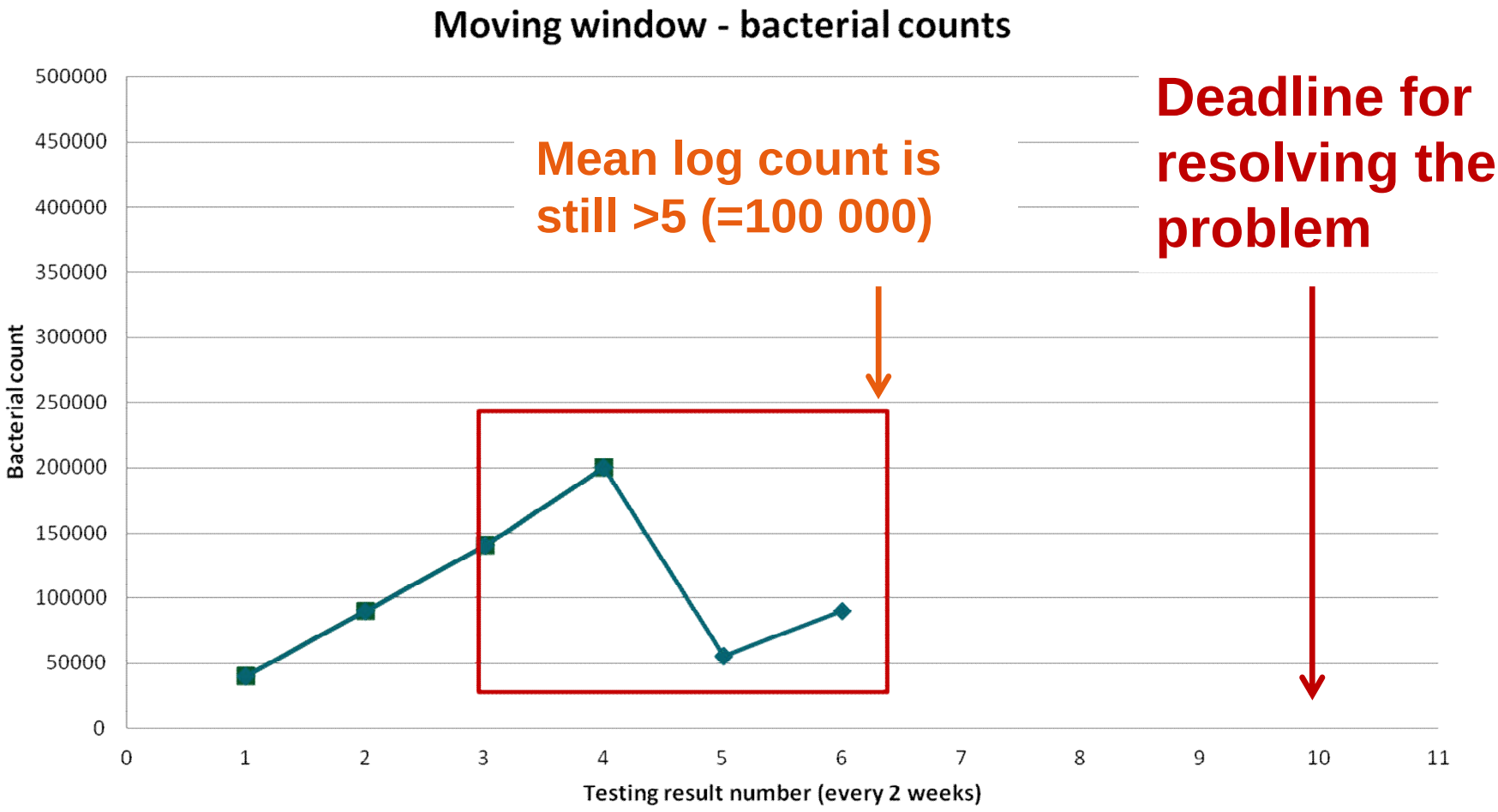
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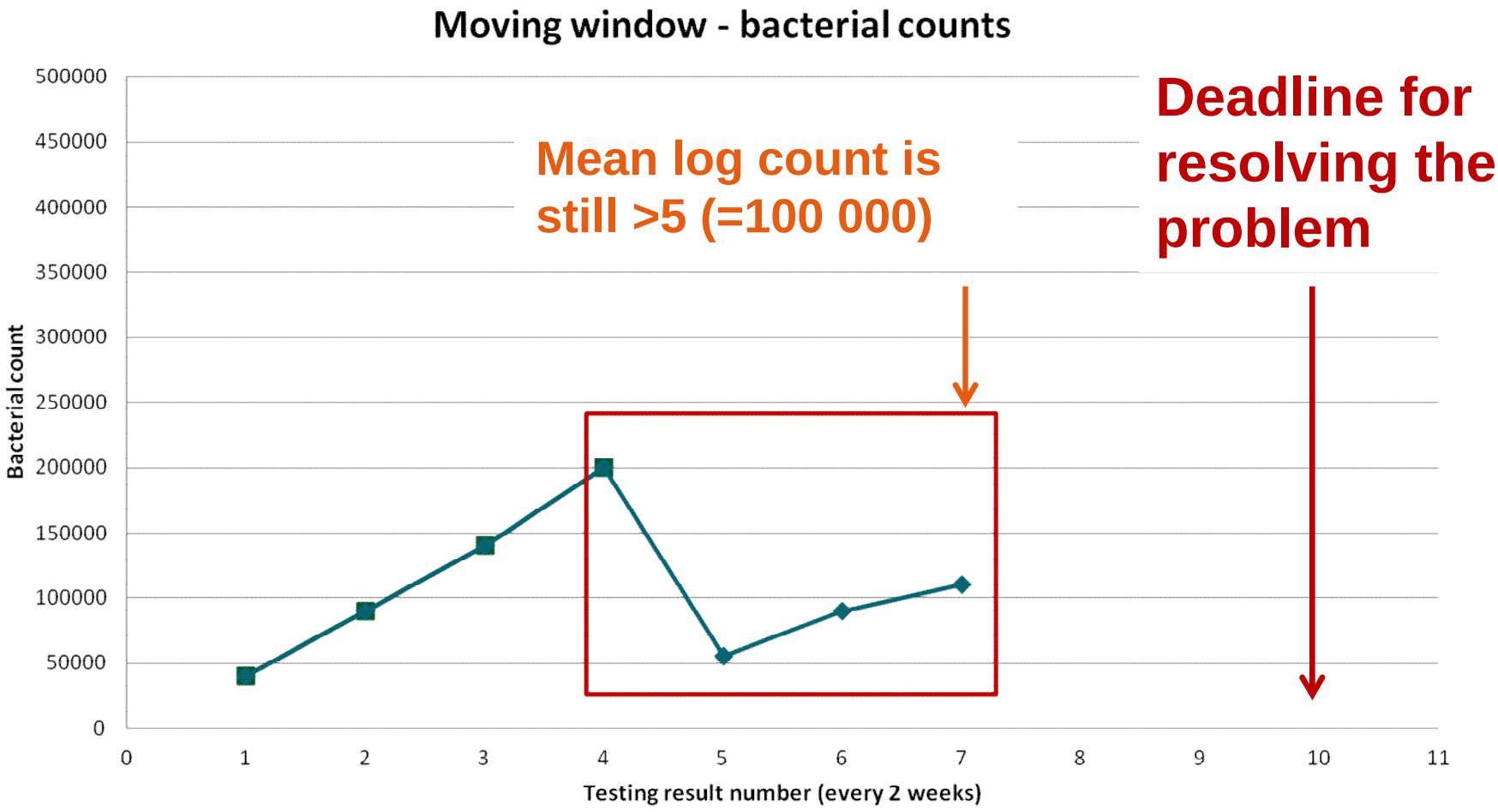
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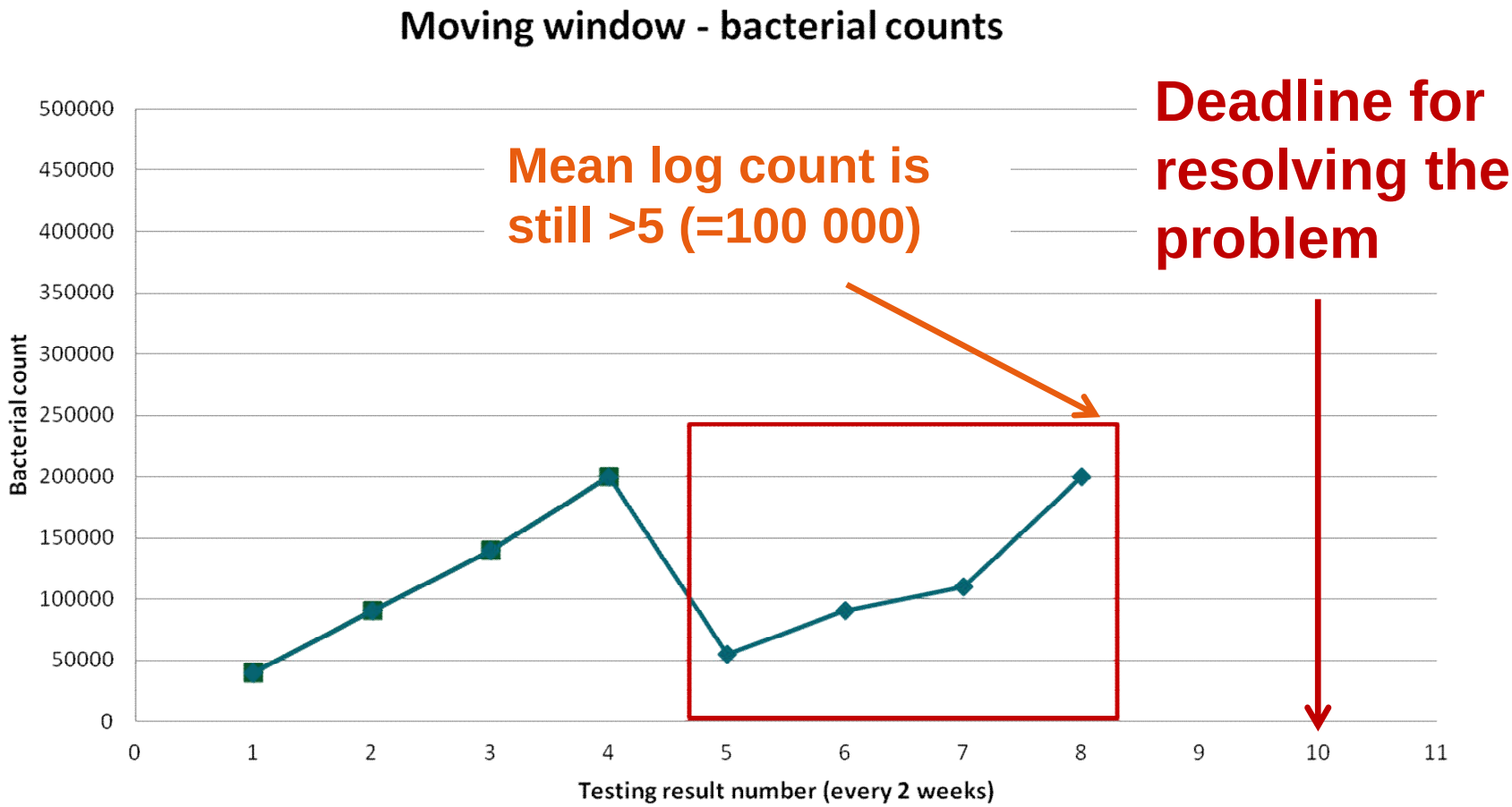
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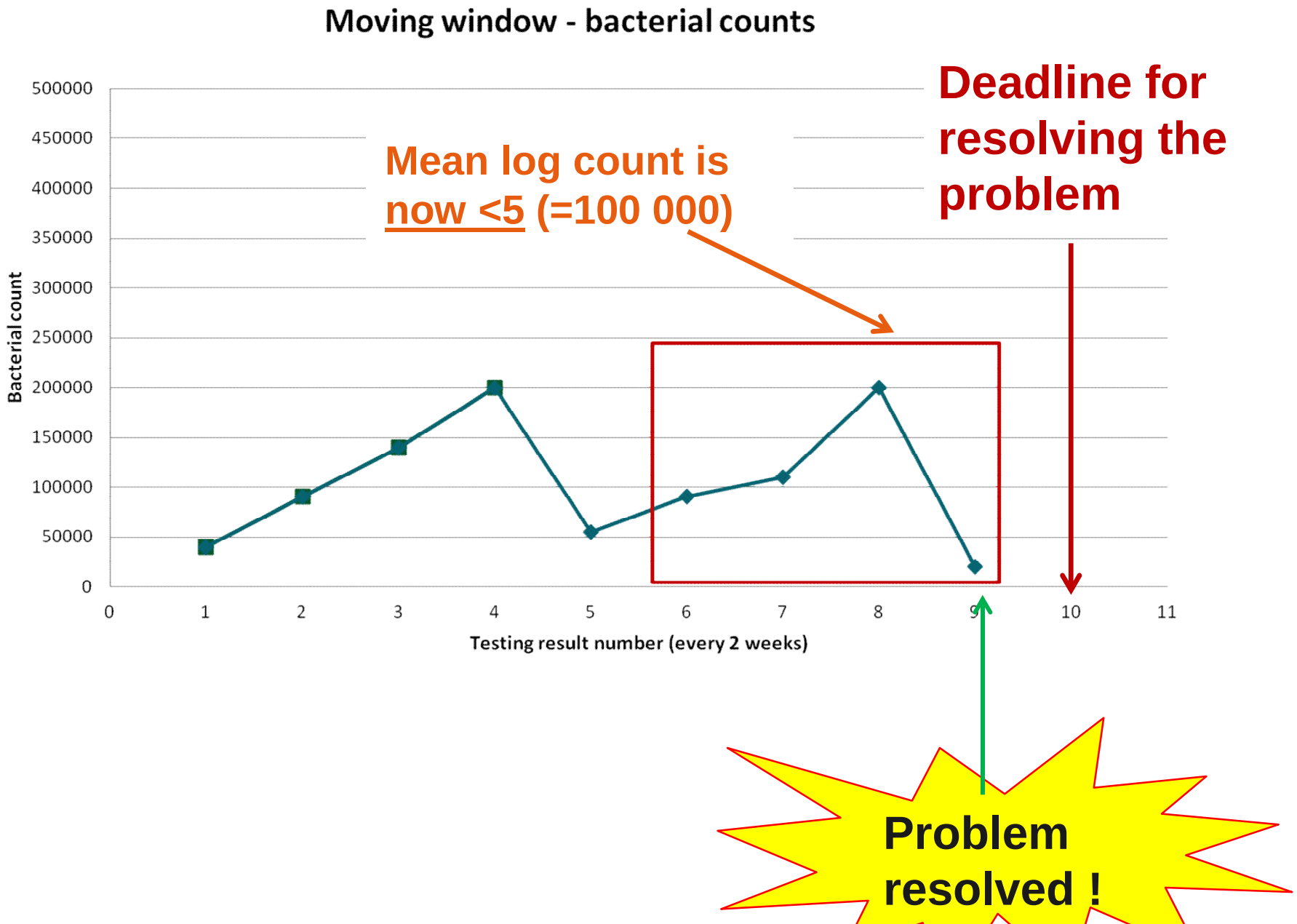
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Testing result number (every 2 weeks)
Mean log count is now <5 (=100 000)
Deadline for resolving the problem
Problem resolved !

Thank you!