Quality Assurance (QA)
&
Quality Control (QC)

In the laboratory

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City West Water

Laboratory water testing: QA & QC

City West Water

Water Supply &
Sewerage Authority

Pop. >800,000
Area 580 km^2

Laboratory water testing: QA & QC

Demonstrable, systematic **QA** and **QC** laboratory practices are critical to:

- obtaining accurate & precise analytical test results

- providing management, customers, regulators and the community with confidence about test results

- obtaining independent laboratory accreditation

accuracy = how close to the real result you are
precision = how reproducible your results are

Laboratory water testing: QA & QC

Quality Assurance (QA): a broad plan for maintaining quality in all aspects of operations. It describes how the laboratory functions in terms of:

- laboratory purpose,
- documentation of all procedures,
- staff training,
- data management and reporting, and
- specific quality control measures.

Quality Control (QC): consists of the steps taken to verify the validity of analytical procedures.

Laboratory water testing: QA & QC

The best way to address QA & QC is by preparing a

LABORATORY QUALITY MANUAL (LQM)

in line with AS ISO/IEC 17025 – 2005:

General requirements for the competence of testing and calibration laboratories

- outlines (all) QA & QC issues that a competent laboratory should address

Laboratory water testing: QA & QC

Note:

Every single point and process that is mentioned in the LQM **MUST be addressed** by laboratory management and operations.

Laboratory water testing: QA & QC

QA issues addressed in LQM

- Documented commitment & policy re. laboratory from most senior management.
- Define laboratory purpose.
- Staff structure that shows the responsibilities & roles of laboratory personnel to meet purpose.
- Identify someone with responsibility for QA / QC.
- Must be free of internal/external pressures that could influence testing / reporting.

QA issues addressed in LQM

- Sub-contracting tests – define criteria for selecting sub-contractors. List of approved sub-contractors.
- Criteria for, and list of approved equipment suppliers.
- Process for addressing nonconforming testing – who, what, when?
- Control of records – consistent, secure, retrievable, visible alterations, retention.

QA issues addressed in LQM

Regular INTERNAL AUDITS

need to check if we are doing everything that we "say" we are doing.

(Must be documented and kept – evidence).

Year ……. **Month** **Activity to be audited** (annually)	J	F	M	A	M	J	J	A	S	O	N	D
PRO-0001												
PRO-0002												
PRO-0003												
PRO-0004												
PRO-0005												
PRO-0006												
PRO-0007												
PRO-0008												
PRO-0009												
PRO-0010												
PRO-0011												
Document approval & issue												
Review of requests, tenders,& contracts												
Subcontracting OF tests												
Purchasing services & supplies												
Customer complaints												
Control of nonconforming testing												
Corrective action												
Preventative action												
Control of records												
Internal audits												
Personnel												
Accommodation & environment												
Equipment register												
Measurement traceability												
Sampling												
External proficiency testing												
Intralab duplicate / split sample testing												
Management Review												

Internal Audit Schedule
(refer LQM section 4.14)

QA issues addressed in LQM

- **Personnel** - must SHOW that staff are competent (qualifications, experience, knowledge of the tests, able to operate equipment, do tests, etc) – evidence.

- **Staff training program** – with personalised records.

1. Purpose

This document outlines the Laboratory's system of maintaining staff records for establishing and improving appropriate staff competence and training related to undertaking laboratory operations (e.g. sampling, operating equipment, performing tests and/or calibrations, evaluating results).

2. Scope

This document applies to all staff working in the microbiology section of the EDA~RANU Water Testing Laboratory.

3. References

The Microbiology of Drinking Water (2010) – Part 3 – Practices and Procedures for laboratories. Methods for the Examination of Waters and Associated Materials. Environment Agency.

NATA, Australia (2009). ISO/IEC 17025 Field Application Document: *Biological Testing, Supplementary requirements for accreditation*. NATA August 2009.

4. Principle

Staff performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. When using staff who are undergoing training, appropriate supervision shall be provided.

Staff responsible for opinions and interpretation of results shall (in addition to qualifications, training, experience and knowledge of the testing), have relevant knowledge of the testing technology used, uncertainty, interferences and relevant standards, guidelines and legislation.

5. Policy

The Laboratory's policy on staff training/competency is a guide to the planning, decision making, implementation and evaluation of training at all levels within the Laboratory by:

Laboratory water testing: QA & QC

QA issues addressed in LQM

Documentation:

all major processes / procedures must be documented.

Document control:

only ONE version of ALL documents – no confusion, no mix-ups.

(Can't have conflicting processes).

Examples of documented procedures

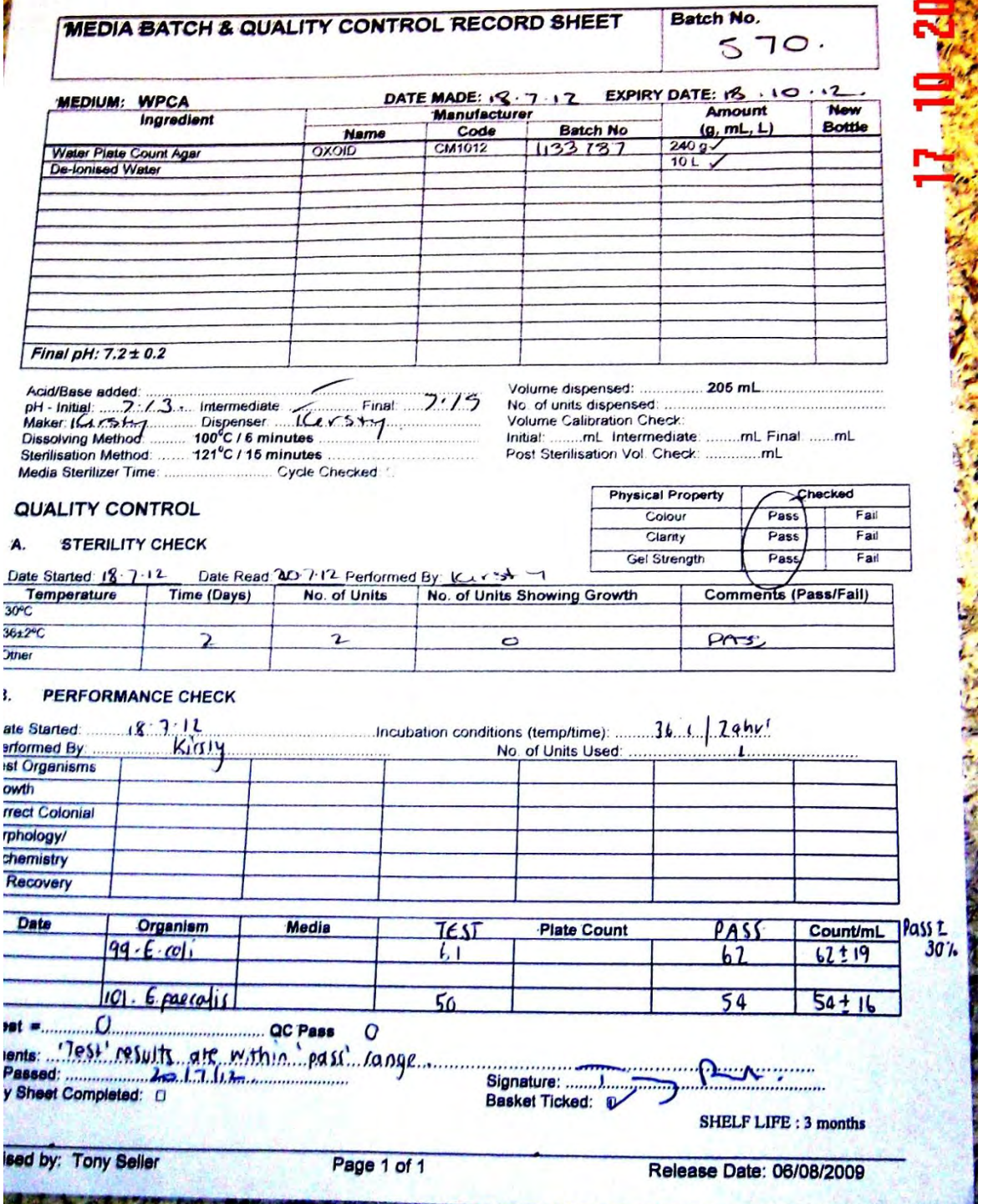
- sampling
- sample receipt
  (sample register)
- test methods
- quality control
- washing-up

More documentation - **FORMS** – to record:

- Receipt of samples - SAMPLE REGISTER
- Analytical observations – can be visual or instrumental
- QC observations – e.g. temperatures, records
- Preparation of reagents & media (what, how much?)
- Receipt of consumables
- Audits findings
- Calibration checks (e.g. balances, thermometers, pH)
- Staff training, etc, etc …….

Can be ELECTRONIC - but how to personalise?

Reagent / Medium Preparation Record Sheet



MEDIA BATCH & QUALITY CONTROL RECORD SHEET — Batch No. 570.

MEDIUM: WPCA — DATE MADE: 18.7.12 — EXPIRY DATE: 18.10.12.

Ingredient	Manufacturer: Name	Manufacturer: Code	Manufacturer: Batch No	Amount (g, mL, L)	New Bottle
Water Plate Count Agar	OXOID	CM1012	1133737	240 g ✓	
De-Ionised Water				10 L ✓	
Final pH: 7.2 ± 0.2					

Acid/Base added: ✓
pH - Initial: 7.13 Intermediate: ✓ Final: 7.13
Maker: Kirsty Dispenser: Kirsty
Dissolving Method: 100°C / 6 minutes
Sterilisation Method: 121°C / 15 minutes
Media Sterilizer Time: Cycle Checked: ✓

Volume dispensed: 205 mL
No. of units dispensed:
Volume Calibration Check:
Initial: mL Intermediate: mL Final: mL
Post Sterilisation Vol. Check: mL

QUALITY CONTROL

Physical Property	Checked	
Colour	Pass	Fail
Clarity	Pass	Fail
Gel Strength	Pass	Fail

A. STERILITY CHECK

Date Started: 18.7.12 Date Read: 20.7.12 Performed By: Kirsty

Temperature	Time (Days)	No. of Units	No. of Units Showing Growth	Comments (Pass/Fail)
30°C				
36±2°C	2	2	0	PASS
Other				

B. PERFORMANCE CHECK

Date Started: 18.7.12 Incubation conditions (temp/time): 36.1 | 24hr
Performed By: Kirsty No. of Units Used: 1

Test Organisms						
Growth						
Correct Colonial						
Morphology/						
Biochemistry						
% Recovery						

Date	Organism	Media	TEST	Plate Count	PASS	Count/mL
	99 - E. coli		61		62	62 ± 19
	101 - E. faecalis		50		54	54 ± 16

Pass Σ 30%

Test = 0 QC Pass 0
Comments: 'Test' results are within 'pass' range
Passed: 20.7.12
Sheet Completed: ☐
Signature: ✓
Basket Ticked: ✓

SHELF LIFE : 3 months

Issued by: Tony Seller Page 1 of 1 Release Date: 06/08/2009

Laboratory water testing: QA & QC

QA issues addressed in LQM

Need to demonstrate Proficiency testing

- **INTRAlab - between staff**
- **INTERlab – between laboratories**

All outcomes must be recorded / documented.

QA issues addressed in LQM

- **Laboratory environment** must be suitable for its operations (e.g. temperature, humidity, tidiness)

- equipment operations
- storage of chemicals reagents
- incubation temperatures

- separate officework area
- no food / drinks

QA issues addressed in LQM

Regular MANAGEMENT REVIEWS – of laboratory operations & records (e.g. audits, complaints, training).

- Continuing relevance of policies & procedures.
- Outcomes of audits.
- Customer feedback.
- Staff training and resources.
- Results of interlab comparisons and proficiency tests.

(Must be documented and retained).

Laboratory water testing: QA & **QC**

The most important issue that **QUALITY CONTROL** addresses is:

HOW DO YOU KNOW?

e.g. that the reported result is correct **and that you can verify this.**

Laboratory water testing: QA & **QC**

Balances

How do you know the weight /mass is true?

- Weekly checks using standard weights

- Repeatability checks

- Six monthly calibrations

- Record all observations / adjustments / dates on a specific Form.

Laboratory water testing: QA & **QC**

Temperatures – laboratory, ovens, incubators, fridges

How do you know the temperature is true?

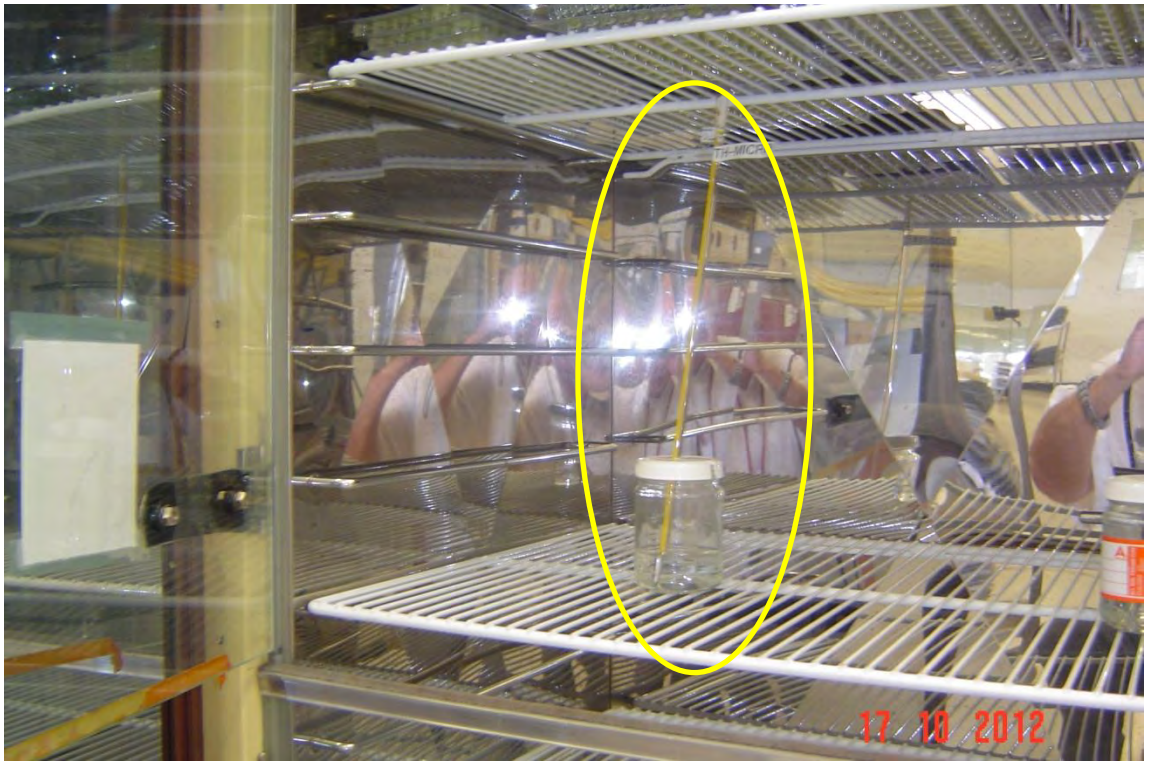
- In built thermostat / controller ??

Laboratory water testing: QA & **QC**

Temperatures – laboratory, ovens, incubators, fridges

How do you know the temperature is true?

- In built thermostat / controller ??
- Internal thermometer ?



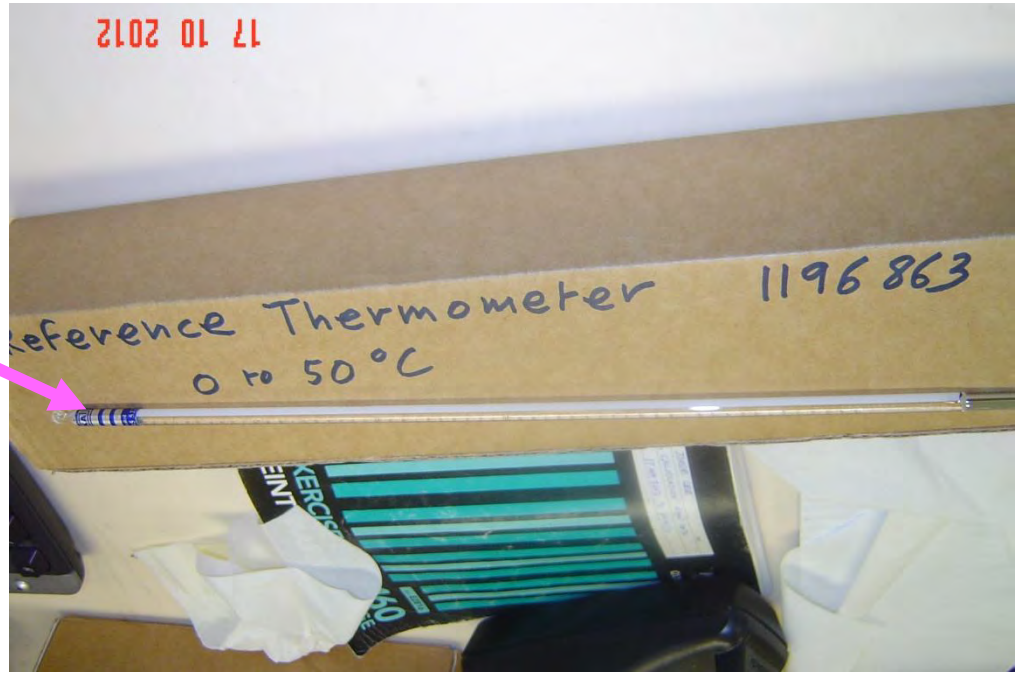
Laboratory water testing: QA & **QC**

Temperatures – laboratory, ovens, incubators, fridges

How do you know the temperature is true?

- In built thermostat / controller ??
- Internal thermometer ?
- Reference thermometer !

calibrate



Laboratory water testing: QA & **QC**

Temperatures – laboratory, ovens, incubators, fridges

How do you know the temperature is true?

RECORD temperatures
& adjustments daily

Temperatures – laboratory, ovens, incubators, fridges

Incubator I.D.: .... Month/ Year: ....

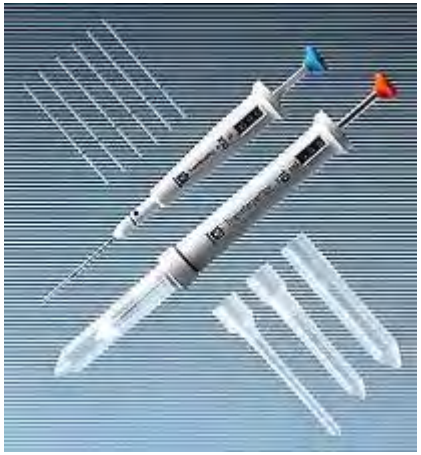
Date	Time	Upper shelf	Lower shelf	Max / Min	Initials	Date	Time	Upper shelf	Lower shelf	Max / Min	Initials	Comments / Adjustments (& date)

Laboratory water testing: QA & **QC**

Laboratory water testing: QA & **QC**

Volumes – pipettes

How do you know the volume is true?



- Weigh it using a calibrated balance

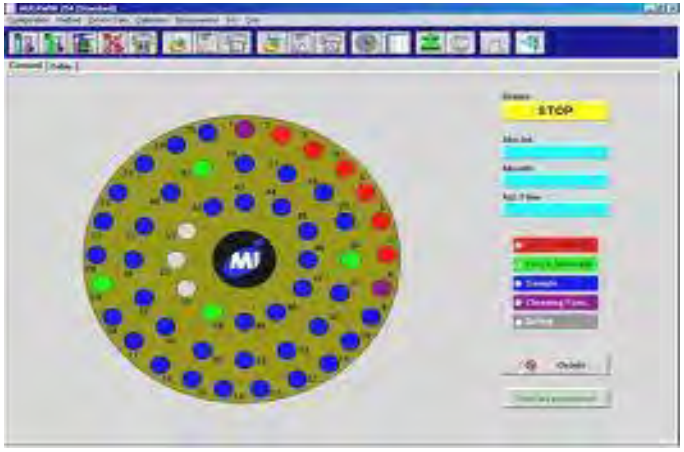
- Adjust pipettor if required

Laboratory water testing: QA & **QC**

Chemistry

How do you know the result is valid?

Spikes/recoveries, blanks, standards



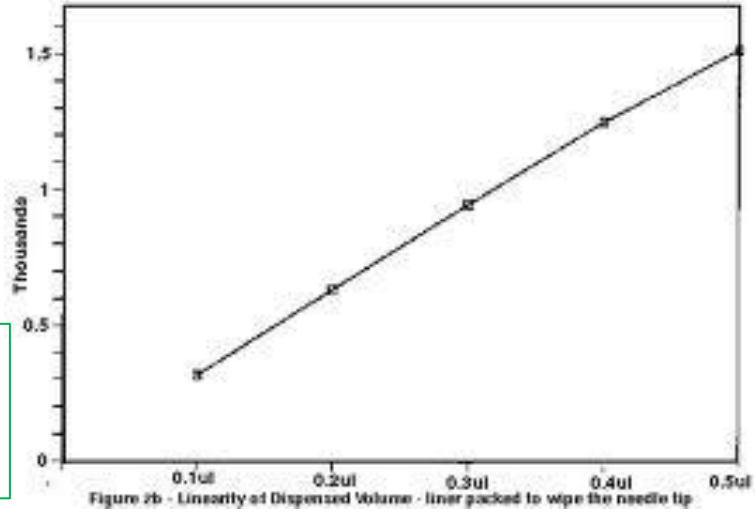


Figure 2b - Linearity of Dispensed Volume - liner packed to wipe the needle tip

Not so easy in **MICRO** –
viability, enumeration issues

Laboratory water testing: QA & **QC**

Microbiology

How do you know things are sterilised ?

use an AUTOCLAVE

but, how do you know?

Laboratory water testing: QA & **QC**

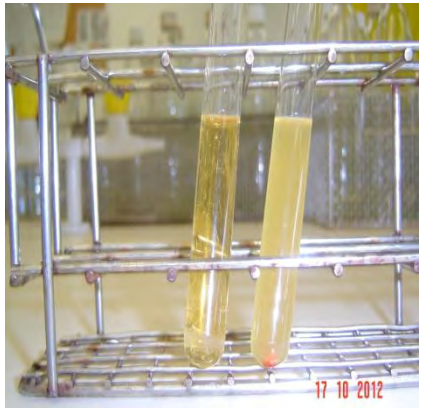
Microbiology

How do you know things are sterilised ? AUTOCLAVE

Cycle record

Indicator strips

Spore strips

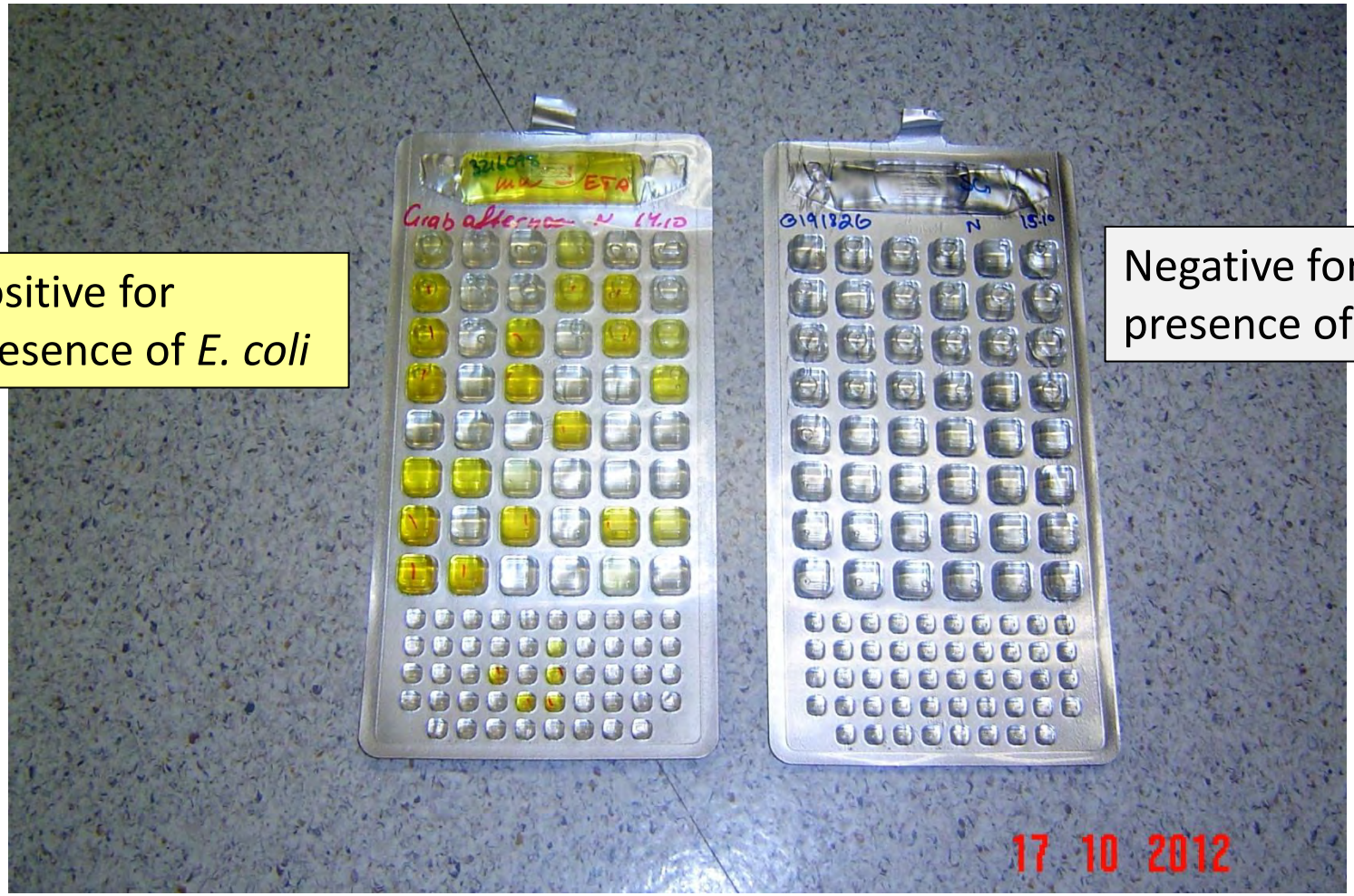


Check for GROWTH

Laboratory water testing: QA & **QC**

Microbiology

How do you know observations are valid?



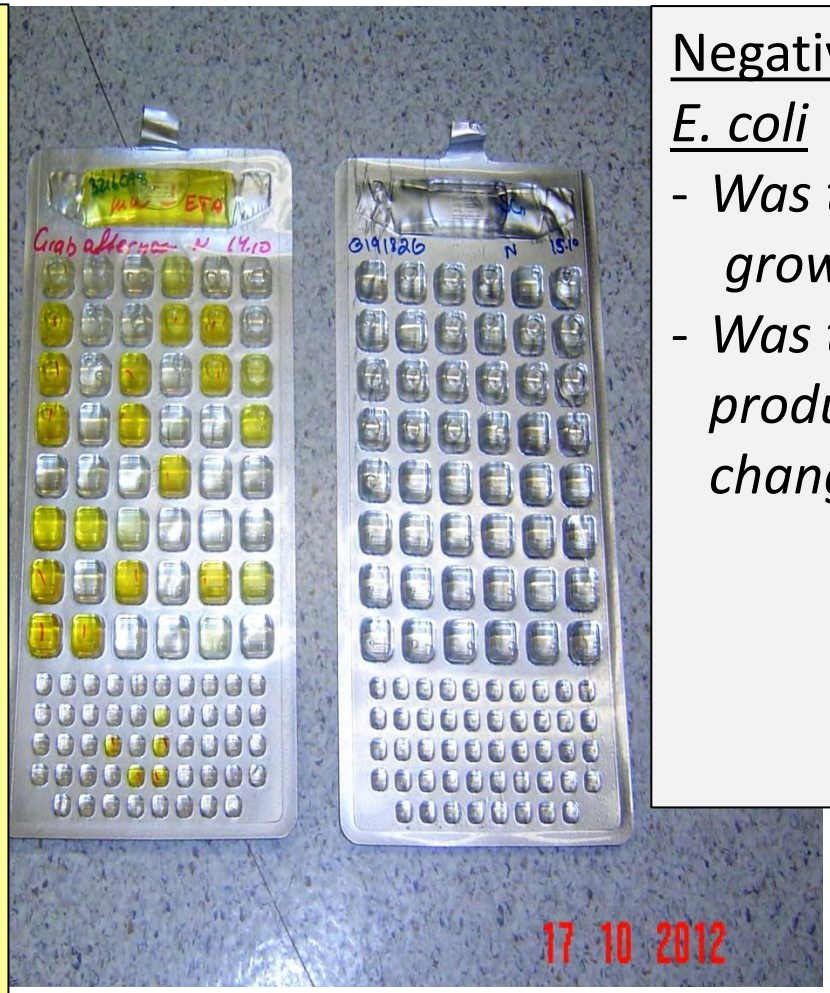
Laboratory water testing: QA & **QC**

Microbiology

How do you know observations are valid?

Positive for presence of *E. coli*

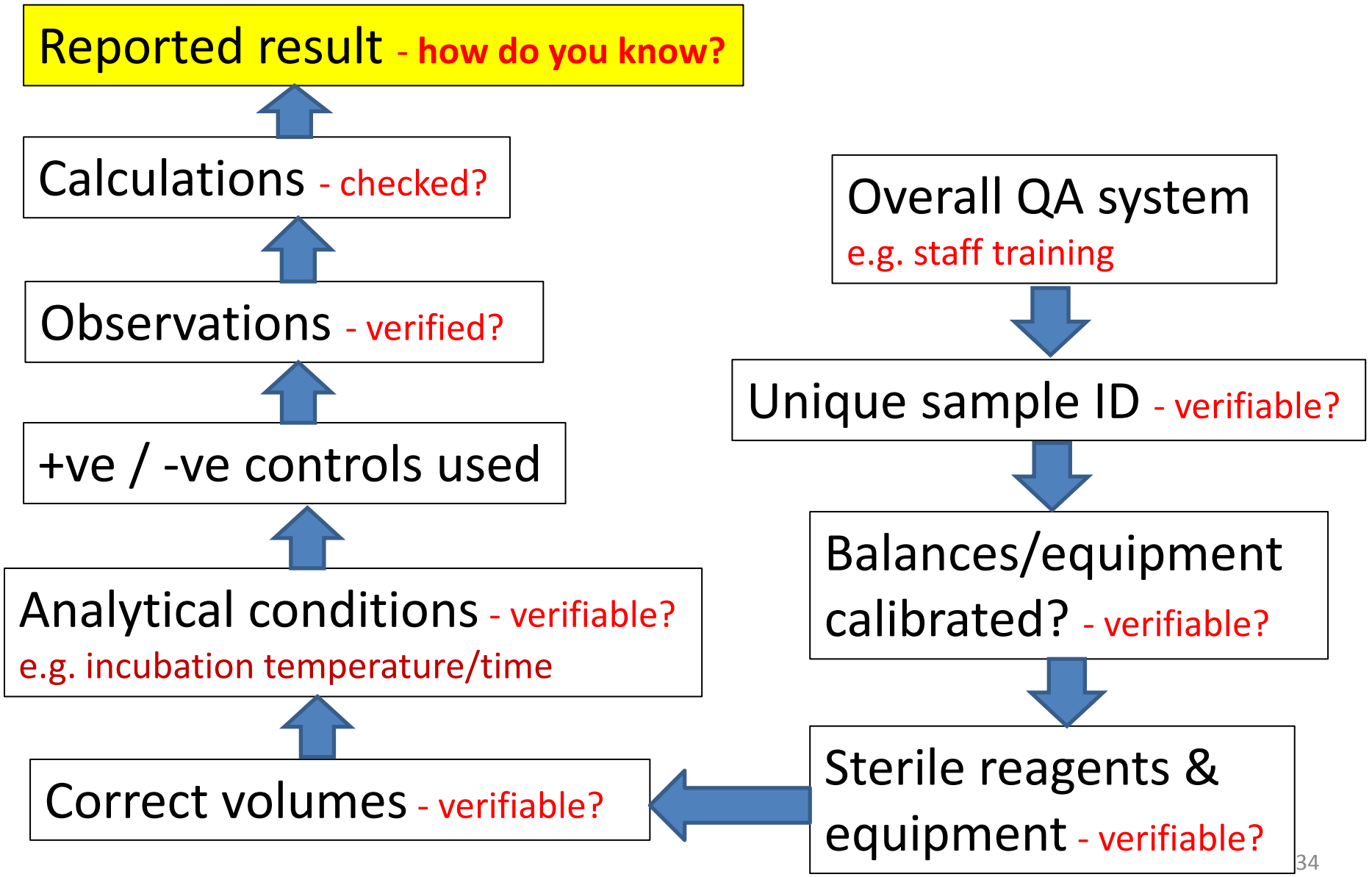
- *Is it indeed E. coli and not some other microbe?*
- *Was the medium contaminated with E. coli?*
- *Did the plastic pack contain E. coli?*
- *Would the colour have changed regardless of adding a real sample?*



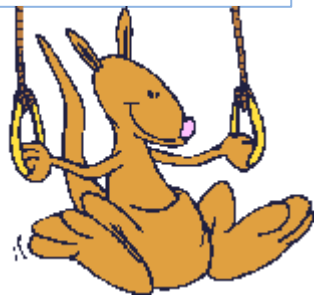
Negative for presence of *E. coli*

- *Was the kit capable of growing E. coli?*
- *Was the kit capable of producing a colour change?*

Laboratory water testing: QA & **QC**



Laboratory water testing: QA & **QC**



Thank You