Microbiological Laboratory Quality Assurance

Laboratory quality assurance

A group of activities proceeded in order to ensure the validity of test results

Laboratory quality assurance according to ISO/IEC17025 clause 5.9

1. Internal quality control
2. External quality assessment

1. Internal quality control

Internal quality control consists of all the procedures undertaken by a laboratory for the continuous evaluation of its work in order to ensure the consistency of results day-to-day and their conformity with defined criteria

1. Internal quality control

1.1 Personel

- On the job training
- Competency test
- Job assignment

1.2 Environment

- Room temperature
- Air ventilation
- Air and work area cleanliness
- Humidity

1.3 Equipment

- Equipment profile
  - installation
  - Repair and maintenance
- Manual and instruction
- Preventive maintenance program
- Calibration
- Performance check

1.4 Reference culture

- Growth performance of culture media
- Method validation
- Quality control of test
- Competency test

1. Internal quality control

1.5 Culture media quality and water supplied

- Media assessment for new brand or new production lot
- Stock management and keeping of dehydrated media
- Production batch testing
  - pH
  - Sterility
  - Color and texture
  - Performance growth
  - Volume test

1.6 Culture media quality and water supplied

- Media storage and shelf life
- Reagent-grade water quality
  - pH
  - Conductivity
  - Total metal
  - Residual chlorine
  - Total bacteria

1.7 Glassware and laboratory apparatus

- Detergent and inhibitory residues
- Volume verification (Pipette, cylinder, micropipette, auto-dispenser)
- Sterility (For sterilized materials)

1.8 Sample handling

- Sample identification
- Sample receiving and registration
- Sample storage
- Sample retention
- Sample disposal

1.9 Quality control of test

- Positive and negative control
- Sterility control
- Replicate test

2. External quality assessment (Proficiency testing)

- Laboratory should regularly participate in proficiency testing to conduct performance evaluation studies among all participant laboratories.

- Results of such studies indicate the quality of analysis of each laboratory as compared to group performance

Quality assurance of temperature controled equipments

The main temperature controled equipments in microbiological laboratories

- Incubator
- Water bath
- Autoclave

Three requirements for equipment handling

Three requirements for equipment handling

1. Equipment maintenance

- Preventive maintenance plan by the rate of use
- Avoidance of cross-contamination
  - Clean and disinfect internal surfaces

Three requirements for equipment handling

2. Equipment calibration

- Calibration plan
- Uncertainty of measurement
- Temperature stability
- Temperature uniformity

Three requirements for equipment handling

3. Performance verification

- Maximum permissible error criteria (MPE)
- Time required to achieve equilibrium condition
- Monitor of the operating temperature with thermocouple or thermo data logger
  - Daily check
  - Each use check
  - Intermediate check

Three requirements for equipment handling

3. Performance verification

- Corrective action for non-conformity performance
- Validation after significant repair or modification

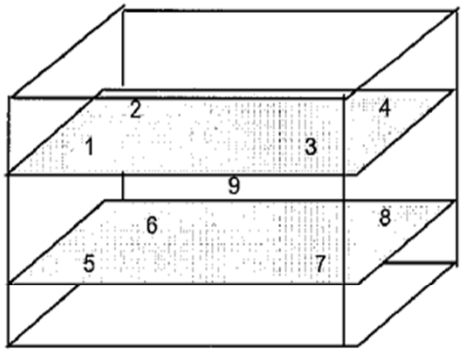
Case study of temperature controled equipment validation

Incubator

Installed place : Bacteria lab
Code No. : B-IN-09
Objective : For pathogenic bacteria growth
Temperature requirement : 37◦c

MPE :
Temperature uncertainty : ±1◦c
Temperature uniformity : ±0.5◦c
Temperature stability : ±0.5◦c

Result of calibration
Incubator



Result of Calibration :- (*) Without Adjustment

Function of UUC* : Temperature Source

Calibration Point	UUC* Setting	UUC* Reading	Average* Standard Reading (°C)								
			Position								
(°C)	(°C)	(°C)	1	2	3	4	5	6	7	8	9 (ref.)
37.0	37.0	37.0	37.051	37.020	36.888	36.882	37.012	37.008	36.855	36.916	37.037

Calibration Point (°C)	Temperature stability (± °C)	Temperature uniformity (°C)	Overall Variation (°C)	Uncertainty of measurement (± °C)	Coverage Factor k
37.0	0.031	0.20	0.26	0.31	2

Verification of incubator performance

Instrument Name: Incubator

Model: KB240

Serial No.: 08-40420 -

ID No.: B-IN-09

Manufacturer: Binder

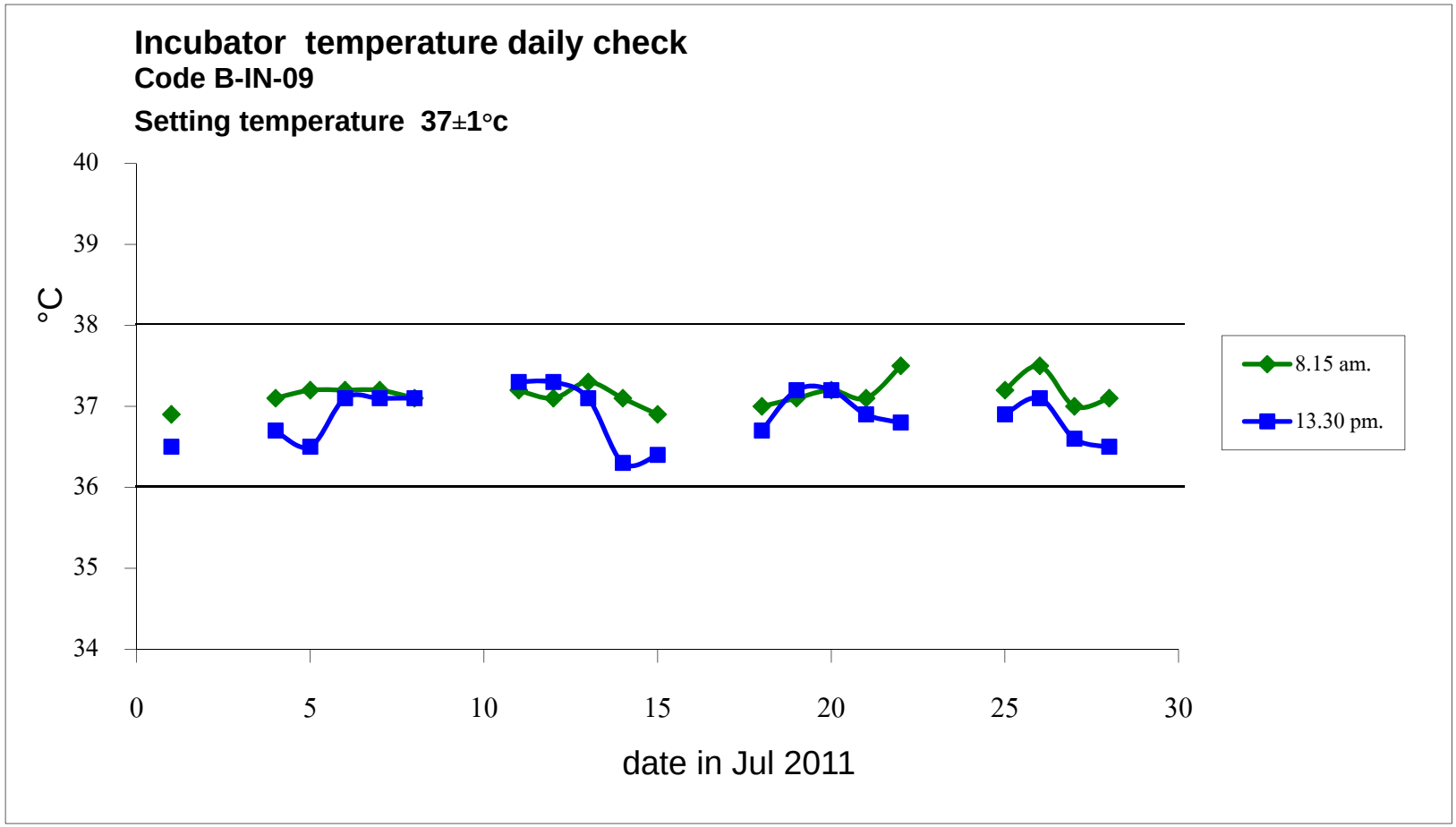
Calibration Date: May 3, 2011

Calibration by: Technology Promotion Association (Thailand-Japan)

Temp Aecept: 37±1°C (36-38)

Verification parameter	Position1	Position2	Position3	Position4	Position5	Position6	Position7	Position8	Position9
UUC reading temp.	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0
Reference reading temp.	37.05	37.02	36.89	36.88	37.01	37.01	36.86	36.92	37.04
Error	-0.05	-0.02	0.11	0.12	-0.01	-0.01	0.14	0.08	-0.04
Uncertainty ±	0.31	0.31	0.31	0.31	0.31	0.31	0.31	0.31	0.31
UUC reading - Error - Unc.	36.74	36.71	36.58	36.57	36.70	36.70	36.55	36.61	36.73
UUC reading - Error + Unc.	37.36	37.33	37.20	37.19	37.32	37.32	37.17	37.23	37.35
Maximum permissible error 37±1°c	36 - 38°c								
Result of verification	passed	passed	passed	passed	passed	passed	passed	passed	passed

Monitor of operating temperature
(Daily check)

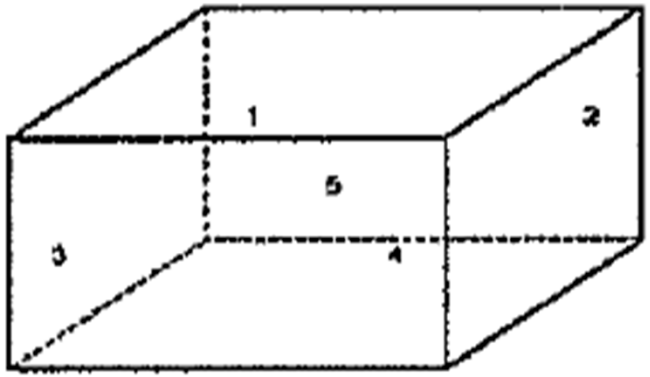


Water bath

Installed place : Bacteria lab
Code No. : B-WB-04
Objective : For selective growth of *E.coli* at 44.5◦c
and *Clostridium perfringens* at 46◦c
Temperature requirement : 44.5◦c and 46◦c

MPE :
Temperature uncertainty at 44.5◦c: ±0.2◦c
Temperature uncertainty at 46◦c: ±0.5◦c
Temperature uniformity : ±0.5◦c
Temperature stability : ±0.5◦c

Result of calibration
Water bath



Equipment	:	Water Bath
Manufacturer	:	Lauda
Model	:	E125
Serial No.	:	LCB0697-06-0309
ID No./Tag No.	:	B-WB-04
Date Receipt	:	09-Jan-11
Date Calibrated	:	09-Jan-11
Ambient Temperature	:	Start record 26 °C , Stop record 24 °C
Relative Humidity	:	Start record 44 %RH , Stop record 42 %RH
Calibrated by	:	Mr. Chaiya Engchoun

Result of calibration
Water bath

Table 1

Calibration Temperature (°C)	Setting Temperature (°C)	Indicating Temperature (°C)	Measured Stability (°C)	Measured Uniformity (°C)	Overall Variation (°C)
44.5	44.5	44.5	0.00	0.03	0.031

Table 2

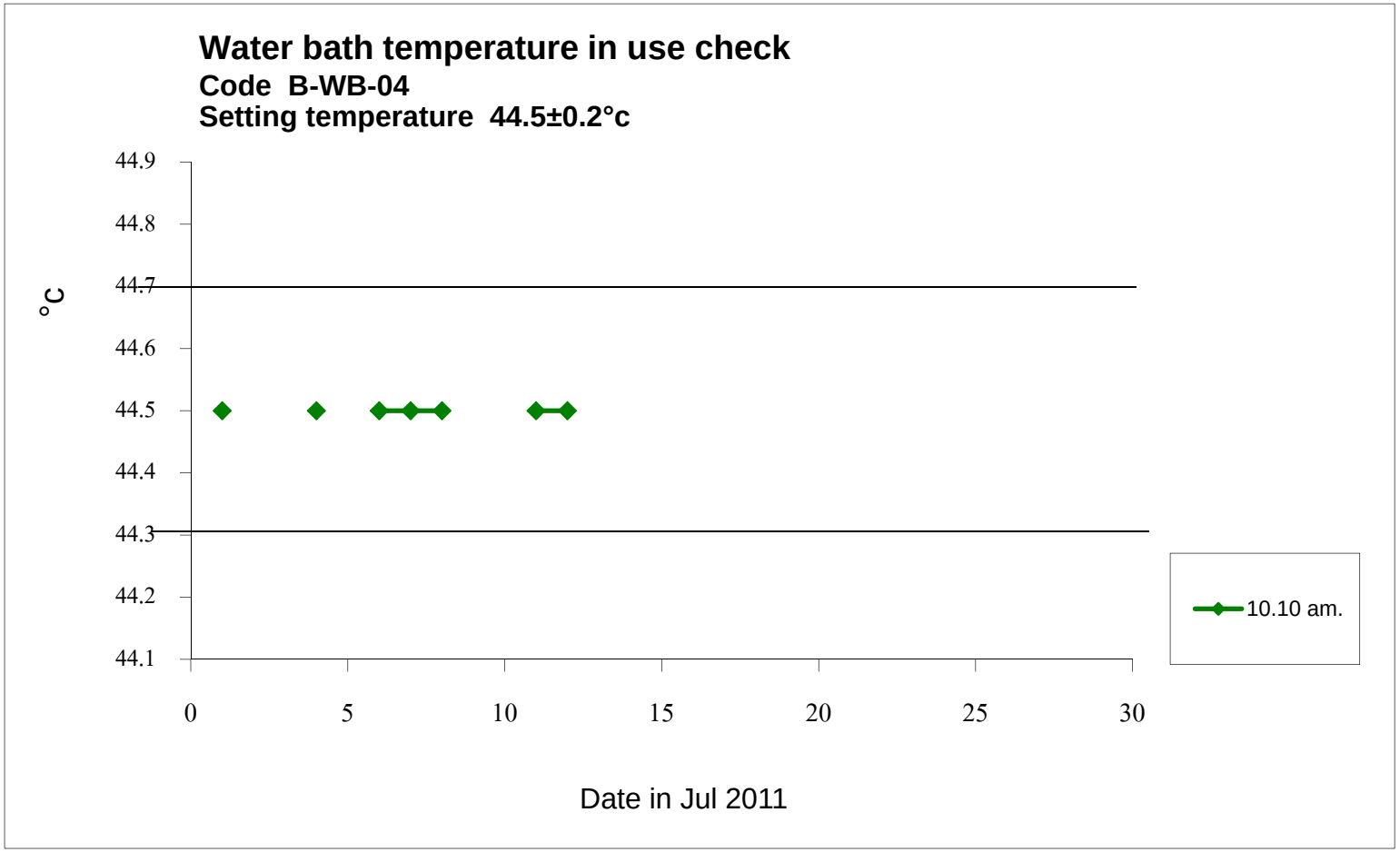
Calibration Temperature (°C)	Standard Reading (°C), Probe No. 5 is Reference Probe					Uncertainty (±°C)
	No. 1	No. 2	No. 3	No. 4	No. 5	
44.5	44.48	44.50	44.49	44.48	44.50	0.14

Verification of water bath performance

Instrument Name: Waterbath
Model: E125
Serial No.: LCB0697-06-0309
ID No.: B-WB-04
Manufacturer: Luada
Calibration Date: January 9, 2011
Calibration by: MIT
Temp Aecept: 44.5±0.2°C (44.3-44.7)

Verification parameter	Position1	Position2	Position3	Position4	Position5
UUC reading temp.	44.5	44.5	44.5	44.5	44.5
Reference reading temp.	44.48	44.50	44.49	44.48	44.50
Error	0.02	0.00	0.01	0.02	0.00
Uncertainty ±	0.14	0.14	0.14	0.14	0.14
UUC reading - Error - Unc.	44.34	44.36	44.35	44.34	44.36
UUC reading - Error + Unc.	44.62	44.64	44.63	44.62	44.64
Maximum permissible error 44.5±0.2°c	44.3 - 44.7°c				
Result of verification	passed	passed	passed	passed	passed

Monitor of operating temperature
(In use check)



Autoclave

Installed place : Sterilizing room

Code No. : B-AU-05

Objective : For culture media sterilization

Temperature requirement : 121◦c

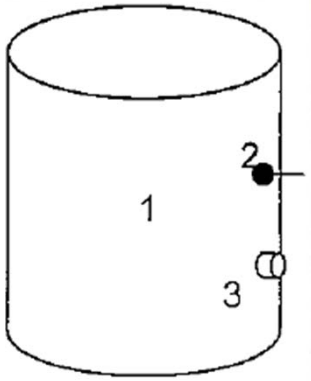
MPE :

Temperature uncertainty : ±3◦c

Result of calibration
Autoclave

Equipment : Autoclave
Model : HV-85
Serial No. : 30406120400
ID No. : B-AU-05
Manufacturer : Hirayama
Received Order : 11 January 2011
Condition As-Received : Used Item
Calibrated Date : 13 January 2011
Reference : 101-304-1 OC
Result of Calibration :- (*) Without Adjustment

Cert. No.: 11TM194



Operating parameter Set : Temperature = 121 °C
Sterilization period = 15 minutes

UUC* Setting (°C)	UUC* Reading (°C)	Position	Average* Standard Reading (°C)	Stability (± °C)	Pressure Reading MPa	Uncertainty of measurement (± °C)	Coverage Factor k
121	121	1	121.229	0.13	0.12	0.86	2
		2	121.070				
		3	121.151				

Verification of sterilization

Result of calibration

UUC* Setting (°C)	UUC* Reading (°C)	Average* Standard Reading (°C) Position			Stability (+/- °C)	Pressure Reading Mpa	Measurement Uncertainty (+/-°C)
		1	2	3			
121	121	121.229	121.070	121.151	0.13	0.12	0.86

Verification parameter	Position1	Position2	Position3
UUC reading temp.	121.0	121.0	121.0
Reference reading temp.	121.229	121.070	121.151
Error	-0.229	-0.070	-0.151
Uncertainty ±	0.86	0.86	0.86
UUC reading - Error - Unc.	-121.631	-121.79	-121.709
UUC reading - Error + Unc.	122.089	121.930	122.011
Maximum permissible error 121±3°c	118 - 124°c		
Result of verification	passed	passed	passed

Monitor of sterilizing performance (In use check)

- Physical check
  - Maximum thermometer
  - Thermo data logger
- Chemical check
  - Chemical indicator strip
- Biological check
  - Bio-indicator
    (*Bacillus stearothermophilus*)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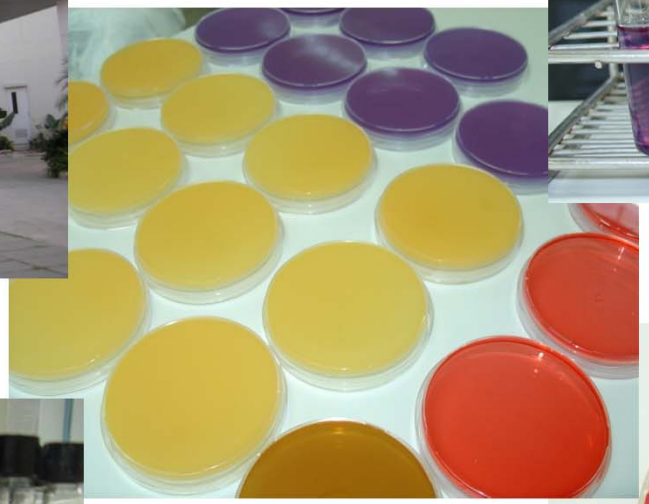

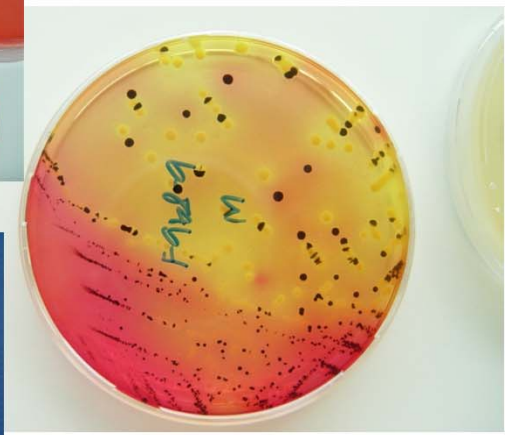

Thank You