

CERTIFICATE OF CALIBRATION

ISSUED BY Priorclave Ltd

DATE OF ISSUE CERTIFICATE NUMBER



Priorclave Ltd.
 129-131 Nathan Way
 West Thamesmead Business Park
 London
 SE28 0AB
 Tel 020 8316 6620 Fax 020 8855 0616

Page 1 of 9 pages

Approved Signatory
 Terry Ashenden

Customer :

Site :

Customers order No:

Priorclave reference:

Equipment calibrated: Laboratory autoclave

Manufacturer: Priorclave Ltd.

Model:

Serial No:

Date of calibration:

Environmental conditions

Laboratory temperature 24 - 35°C (Measured at air inlet to electrical compartment of autoclave.)

Autoclave description

Temperature controller : Priorclave Tactrol, resolution 0.1°C, range 0-150°C

Process dwell timer : Priorclave Tactrol, resolution 1 minute, range 0-999 minutes

Calibration

Procedure

In accordance with Priorclave procedure number P1, Autoclave Calibration.

Before calibration commenced the measuring equipment was allowed to equilibrate with the laboratory temperature and where possible the temperature controller resolution was set to a display resolution of 0.1°C.

Measurements were conducted with the calibrated thermocouple connected to channel 1 of the Data Logger identified below. The thermocouple tip was located as close as possible to the tip of the autoclave control probe as permitted by the restrictions in P1.

The mean temperature during the process dwell time is derived from the mean of 180 readings taken over a 3 minutes period starting 1 minute after the start of the plateau and a further 180 readings taken immediately prior to the end of the measurement period. The drift over holding time is the difference between the means of the two sets of readings.

The remaining figures are the maxima and minima observed over the period between the two sets of readings.

This certificate is issued in accordance with the laboratory accreditation requirements of the United Kingdom Accreditation Service. It provides traceability of measurement to recognised national standards, and to units of measurement realised at the National Physical Laboratory or other recognised national standards laboratories. This certificate may not be reproduced other than in full, except with the prior written approval of the issuing laboratory.

©Priorclave 2007

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 2 of 9

The autoclave was set to run through a standard sterilizing stage with the temperature controller and process dwell timer set as below. The readings below were taken from the digital display associated with channel 1 of the data logger listed under test equipment.

The start and finish times of the process dwell timer were compared to the elapsed time of a time keeping device calibrated in accordance with procedure P11 calibration of timekeeping devices, and the following results were obtained with the process dwell timer elapsed time set as indicated

Autoclave set temp. (°C)	Mean temp. during dwell. (°C)	Drift during dwell. (°C)	Set time (min:sec)	Elapsed time. (min:sec)	Equipment temperature reading. (°C)		Pressure gauge reading. (Bar)	
					Max	Min	Max	Min
134	133.87	0.08	15:00	15:02	134.2	133.5	2.04	2.00
121	121.42	0.09	15:00	15:02	121.2	120.7	1.06	1.01
115	115.75	-0.02	15:00	15:02	115.3	114.6	0.71	0.69

The autoclave mean temperature and drift were taken from averaged readings. The uncertainty of the individual temperature readings was +/- 0.68°C

Uncertainty of elapsed time measurement +/- 2 seconds

Performance studies

On completion of calibration performance studies were conducted on 3 load types. The following Priorclave standard procedures were used for the performance of the studies.

P2 Autoclave Performance Qualification Procedure

P5 Media Preparation

P8 Make Safe of Laboratory Waste

Loads:

Each load type was analysed by evenly distributing thermocouples throughout the load.

The thermocouples were connected to the multi channel data logger listed under measuring equipment. The results of the measurements were recorded and a printout from the original logged data is attached as annex A of this certificate.

The records from the permanently attached printer or chart recorder are attached as annex B.

Following is a description of the loading conditions for each study and a summary of the results.

Load types analysed:

1. Media Load, 1 litre bottles.
2. Media Load, mixed bottles.
3. Mixed Waste load.

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of $k=2$, providing a level of confidence of approximately 95%. The uncertainty evaluation has been carried out in accordance with UKAS requirements.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 3 of 9

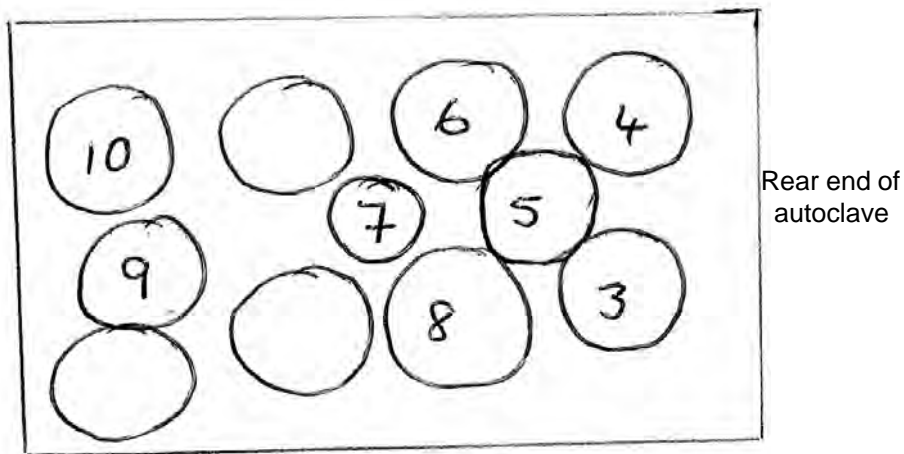
1. Media Sterilization Program number 1

Nature of load: Ten 1 litre bottles with 400ml agar gel with 500ml loadsense bottle.

Thermocouple locations:

- | No. | Location |
|-----|--|
| 1 | Attached to autoclave control probe. |
| 2 | Attached to autoclave control probe. |
| 3 | In 1 litre bottle as shown in sketch below. |
| 4 | In 1 litre bottle as shown in sketch below. |
| 5 | In 1 litre bottle as shown in sketch below. |
| 6 | In 1 litre bottle as shown in sketch below. |
| 7 | In 500ml bottle with loadsense probe as shown in sketch below. |
| 8 | In 1 litre bottle as shown in sketch below. There are indications that this probe was above the surface of the liquid in the bottle. |
| 9 | In 1 litre bottle as shown in sketch below. |
| 10 | In 1 litre bottle as shown in sketch below. |
| 11 | Air purge outlet. |
| 12 | Chamber free space. |
| 13 | Load simulator. |
| 14 | Laboratory temperature. |
| 15 | Reference Temperature sensor |
| 16 | Chamber pressure. |

SKETCH OF LOADING CONDITION



A sterilisation temperature of 121°C was selected. The autoclave was set to run a cycle at 123°C for 25 minutes. 5 minutes freesteaming, Loadsensed process timing and accelerated cooling were selected.

The equilibration time for the slowest item to achieve 121°C was thermocouple number 4, 11 minutes 28 seconds. A holding time of 22 minutes 30 seconds was recorded for this cycle.

The total cycle time was 156 minutes 19 seconds. The cycle aborted after a short time in cooling and the operation of the cooling lock could not be checked.

The minimum set time to ensure that all points within the load have achieved a temperature in excess of 121°C for 15 minutes is 18 minutes. Routine microbiological testing should be used to show the product to be acceptable.

Opinions shown in italic type are not within the scope of our UKAS accreditation, and are offered as guidance only; no responsibility can be accepted for the accuracy of opinions offered.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 4 of 9

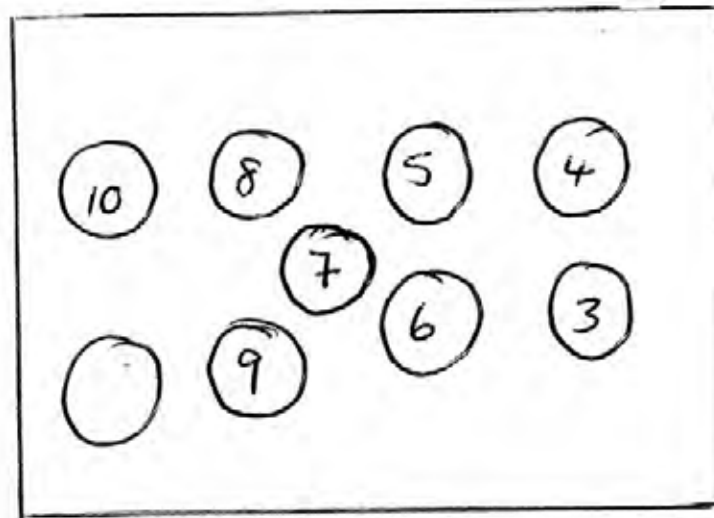
2. Media Sterilization Program number 2.

Nature of load: Various sizes of bottles of Agar gel.

Thermocouple locations:

No.	Location	Holding Time (mm:ss)
1	Attached to autoclave control probe.	
2	Attached to autoclave control probe.	
3	In 500ml bottle with 275ml of agar as shown in sketch below.	17:36
4	In 500ml bottle with 275ml of agar as shown in sketch below.	27:45
5	In 500ml bottle with 275ml of agar as shown in sketch below.	16:18
6	In 500ml bottle with 275ml of agar as shown in sketch below.	15:36
7	In bottle of water with loadsense probe as shown in sketch below.	20:32
8	In 500ml bottle with 275ml of agar as shown in sketch below.	16:25
9	In 500ml bottle with 275ml of agar as shown in sketch below.	16:59
10	In 250ml bottle with 200ml of agar as shown in sketch below.	21:33
11	Air purge outlet.	
12	Chamber free space.	
13	Load simulator.	
14	Laboratory temperature.	
15	Reference Temperature sensor	
16	Chamber pressure.	

SKETCH OF LOADING CONDITION



A sterilisation temperature of 121°C was selected. The autoclave was set to run a cycle at 123°C for 20 minutes. 5 minutes pulsed freesteam, Loadsensed process timing and accelerated cooling were selected.

The equilibration time for the slowest item to achieve 121°C was thermocouple number 6, 13 minutes 8 seconds. A holding time of 15 minutes 36 seconds was recorded for this cycle.

The total cycle time was 121 minutes 3 seconds. All points within the load had cooled to below 80°C before the thermal cooling lock released.

The minimum set time to ensure that all points within the load have achieved a temperature in excess of 121°C for 15 minutes is 20 minutes. Routine microbiological testing should be used to show the product to be acceptable.

Opinions shown in italic type are not within the scope of our UKAS accreditation, and are offered as guidance only; no responsibility can be accepted for the accuracy of opinions offered.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

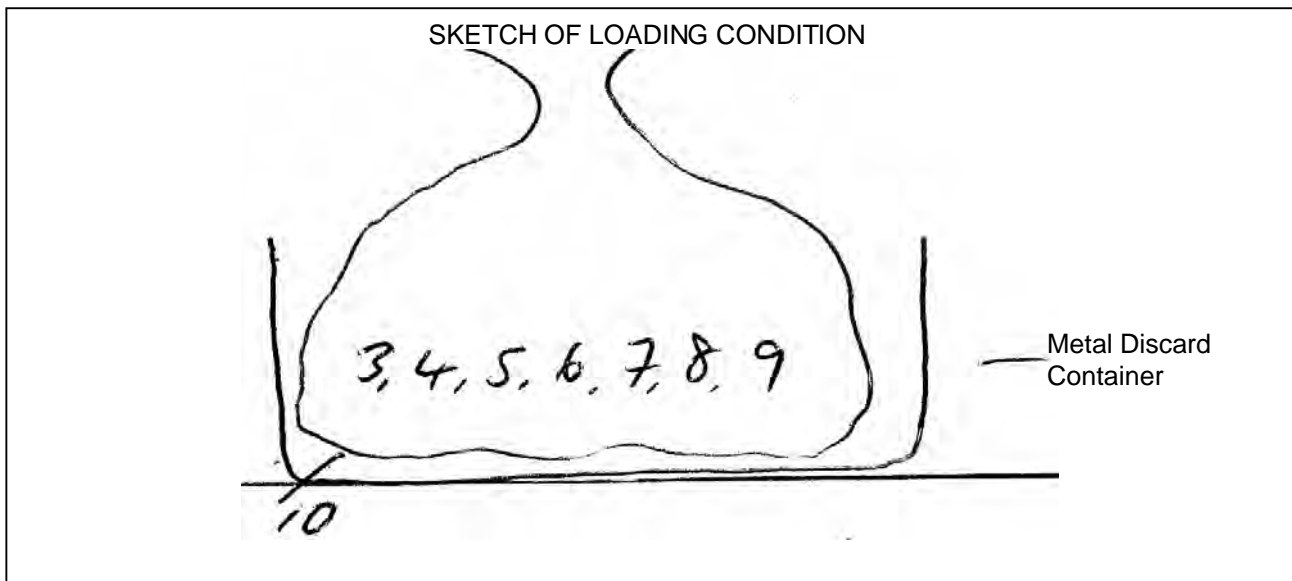
Page 5 of 9

3. Plastic Waste Discard Program number 3

Nature of load: 1 bag of petri dishes, pipettes, gloves, etc in a metal discard container. Water was added to both the bag and the container prior to the test.

Thermocouple locations:

- | No. | Location |
|-----|--------------------------------------|
| 1 | Attached to autoclave control probe. |
| 2 | Attached to autoclave control probe. |
| 3 | As shown in sketch below. |
| 4 | As shown in sketch below. |
| 5 | As shown in sketch below. |
| 6 | As shown in sketch below. |
| 7 | As shown in sketch below. |
| 8 | As shown in sketch below. |
| 9 | As shown in sketch below. |
| 10 | As shown in sketch below. |
| 11 | Air purge outlet. |
| 12 | Chamber free space. |
| 13 | Load simulator. |
| 14 | Laboratory temperature. |
| 15 | Reference Temperature sensor |
| 16 | Chamber pressure. |



A sterilisation temperature of 134°C was selected. The autoclave was set to run a cycle at 136°C for 60 minutes. 20 minutes pulsed freesteam and accelerated cooling were selected.

The equilibration time for the slowest item to achieve 134°C was thermocouple number 10, 22 seconds. A holding time of 61 minutes 28 seconds was recorded for this cycle.

The total cycle time was 147 minutes 19 seconds. All points within the load had cooled to below 90°C before the thermal cooling lock released. Following the run the complete temperature was reduced by 12°C.

Steam penetration of the load appears adequate. The minimum set time to ensure that all points within the load have achieved a temperature in excess of 134°C for 10 minutes is 9 minutes however due to the inherent variability of this class of load it is not recommended to reduce the time setting quite that far.

Opinions shown in italic type are not within the scope of our UKAS accreditation, and are offered as guidance only; no responsibility can be accepted for the accuracy of opinions offered.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 6 of 9

Measuring equipment

Data Logger

Manufacturer: Anville Electronics Model: 425 Serial no: 4250183

Reference RTD

Channel 15 Serial No: PCL0342

Last calibrated: 8th March 2007.

Reference resistors

Channel 15 Serial Nos: PCL0129 and PCL0130

Thermocouple(s)

Channel 1 Serial No: PCL0512

Channel 2 Serial No: PCL0513

Last calibrated: 8th March 2007.

The above equipment is certified calibrated traceable to national standards through a UKAS accredited laboratory.

Pressure transducer

Channel 16 Jumo DTRANS, Model P30, Serial No: PCL0336

Engineer S Tillman.

-end-

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of $k=2$, providing a level of confidence of approximately 95%. The uncertainty evaluation has been carried out in accordance with UKAS requirements.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 7 of 9

Annex A

Data logger records (7 Pages)

The printouts following are marked as indicated below:

Printout Heading	Test
Media @ 121, cycle number: 003	Media cycle, 1 litre bottles
As above.	Sterilisation stage of above cycle.
Media @ 121, cycle number: 004	Media cycle, mixed bottles
As above.	Sterilisation stage of above cycle.
Plastic Waste @ 136, cycle number: 006	Waste Cycle
As above.	Air removal stage of above cycle.
As above.	Sterilisation stage of above cycle.

Note: The legend on the graphs may be inaccurate in respect to probe locations and autoclave settings. Refer to text of report and sketch for these details.

Note: The date and time on the printout are the date the data was saved – which may be the day after the run was started and the time the run was started.

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 8 of 9

Annex B Printer records

Calibration

Media load

DATE 10/04/07
TIME 12:05:17

EVENT	PROBE TEMP deg C	TIME
Cycle St	44.5	12:05:17
Load Sens	48.7	12:05:17
Free St	103.9	12:13:45
Load Sens	102.2	12:13:45
Free End	99.6	12:18:46
Load Sens	99.9	12:18:46
Chamber	133.9	12:27:37
Load Sens	132.7	12:27:37
Ster St	133.9	12:27:37
Load Sens	132.7	12:27:37
Chamber	134.0	12:30:38
Load Sens	133.6	12:30:38
Chamber	133.6	12:33:39
Load Sens	133.7	12:33:39
Chamber	133.7	12:36:40
Load Sens	133.7	12:36:40
Chamber	134.1	12:39:41
Load Sens	133.8	12:39:41
Chamber	133.6	12:42:42
Load Sens	133.8	12:42:42
Ster End	133.6	12:42:42
Load Sens	133.8	12:42:42

10/04/07 12:43:55
CYCLE ABORT

Calibration
T. Mills

DATE 10/04/07
TIME 13:57:10

EVENT	PROBE TEMP deg C	TIME
Cycle St	25.5	13:57:10
Load Sens	20.5	13:57:10
Free St	103.9	14:18:08
Load Sens	70.9	14:18:08
Free End	99.7	14:23:10
Load Sens	99.4	14:23:10
Load Sens	113.4	14:36:01
Ster St	122.8	14:42:33
Load Sens	120.5	14:42:33
Chamber	123.1	14:45:34
Load Sens	121.6	14:45:34
Chamber	123.1	14:48:35
Load Sens	122.2	14:48:35
Chamber	122.7	14:51:36
Load Sens	122.6	14:51:36
Chamber	122.6	14:54:37
Load Sens	122.7	14:54:37
Chamber	122.9	14:57:38
Load Sens	122.9	14:57:38
Chamber	122.9	15:00:39
Load Sens	122.8	15:00:39
Chamber	123.0	15:03:40
Load Sens	122.8	15:03:40
Chamber	123.1	15:06:41
Load Sens	122.8	15:06:41
Ster End	122.6	15:07:41
Load Sens	122.8	15:07:41

10/04/07 15:33:36
CYCLE ABORT

T. Mills
media 1st load

CERTIFICATE OF CALIBRATION

ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602

Certificate number
N3737

Page 9 of 9

Annex B

Printer records (Continued.)

Media load

Plastic waste load

Media mixed bottles
DATE 10/04/07
TIME 16:58:40

PROGRAM NUMBER 3
Discard
DATE 11/04/07
TIME 12:53:22

EVENT	PROBE TEMP deg C	TIME
Cycle St	28.4	16:50:40
Load Sens	23.8	16:50:40
Free St	103.9	17:08:57
Load Sens	79.9	17:08:57
Free End	99.9	17:13:58
Load Sens	93.8	17:13:59
Chamber	122.8	17:22:45
Load Sens	111.8	17:22:45
Ster St	123.1	17:29:17
Load Sens	120.5	17:29:17
Chamber	123.0	17:32:18
Load Sens	121.7	17:32:18
Chamber	122.6	17:35:19
Load Sens	122.3	17:35:19
Chamber	123.1	17:38:20
Load Sens	122.6	17:38:20
Chamber	123.1	17:41:21
Load Sens	122.7	17:41:21
Chamber	123.0	17:44:22
Load Sens	122.7	17:44:22
Chamber	123.0	17:47:23
Load Sens	122.8	17:47:23
Ster End	122.8	17:49:24
Load Sens	122.8	17:49:24
Cycle Count	61	
Cycle End	49.9	19:18:09
Load Sens	71.6	19:18:09
CYCLE COMPLETE		
PASS		

OPERATOR SIGNATURE

Media Cycle

EVENT	PROBE TEMP deg C	TIME
Cycle St	27.4	12:53:22
Free St	111.8	13:12:25
Free End	109.4	13:32:31
Ster St	135.8	13:41:20
Chamber	136.0	13:44:21
Chamber	136.0	13:47:22
Chamber	135.8	13:50:23
Chamber	135.7	13:53:24
Chamber	136.0	13:56:25
Chamber	135.8	13:59:26
Chamber	136.0	14:02:27
Chamber	135.9	14:05:28
Chamber	135.9	14:08:29
Chamber	135.7	14:11:30
Chamber	135.6	14:14:31
Chamber	135.7	14:17:32
Chamber	135.8	14:20:33
Chamber	135.9	14:23:34
Chamber	136.1	14:26:35
Chamber	136.1	14:29:36
Chamber	135.8	14:32:37
Chamber	135.7	14:35:38
Chamber	135.7	14:38:39
Chamber	135.7	14:41:40
Ster End	135.8	14:41:40
Cycle Count	62	
Cycle End	59.8	15:14:23
CYCLE COMPLETE		
PASS		

OPERATOR SIGNATURE

Plastic Waste

CERTIFICATE OF CALIBRATION
ISSUED BY PRIORCLAVE LTD

UKAS Accredited Calibration Laboratory No 0602 SIII

Certificate number
N3737

Autoclave serial Number:



Table of program numbers

Program No.	Cycle Description
1	Media – 1 Litre Bottles
2	Media – Mixed Bottles
3	Plastic Waste
4	
5	

