1. Title

Report, IS4000 8mm Basic Instruments, Automated Cleaning Validation, Franke Medical Oy Deko D32.

2. Originator

James Clarke, Head of Science and Innovation, 20/30Labs

3. Abstract

Test article and purpose of test: Intuitive IS4000 8mm Basic Instruments were used to demonstrate the automated cleaning efficacy in the Deko D32 washer-disinfector employing the Deko D32 da Vinci wash rack module.

Test methods: The automated cleaning validation was performed according to Intuitive Surgical protocol 1006406-01P, Rev A using a sample size of 18. Visual inspection and residual protein measurements were conducted to evaluate the cleaning efficacy.

Results and conclusions: The IS4000 8mm Basic Instruments met all acceptance criteria. No issues of safety or effectiveness and no new risks were identified. Therefore, the IS4000 8mm Basic Instruments met the cleaning requirements per Intuitive Surgical protocol 1006406-01P, Rev A.

4. Purpose

The purpose of this study was to demonstrate the efficacy of the automated cleaning process with the Franke Medical Oy Deko D32 washer-disinfector, employing the Deko D32 da Vinci wash rack module, for the Intuitive Surgical IS4000 8mm Basic Instruments.

Requirement(s) or Specification(s) being Verified or Validated by this Protocol	823033-40 Rev T:Architectural Requirements, IS4000 Instruments
Test Article Part Number(s) and Name(s)	IS4000 8mm Maryland Bipolar Forceps 470172-16T (8mm Maryland Bipolar Forceps, IS4000) IS4000 8mm Monopolar Curved Scissors 470179-19T (8mm Monopolar Curved Scissors, IS4000)
Test Equipment (System)	For cleaning validation, no test system is required.

Sample Size = 18 (6 test instruments x 3 cleaning cycles)	Per DOP 854021-H Addendum 5 §J, cleaning validation is Type Code J2, so the minimum sample size is specified by the test agency and/or external standard: AAMI TIR12: 2010 §4.2.1 "At least three replicates and one concurrent control should be used in the validation testing." For each of the 2 test samples identified, there will be 4 new instruments: 3 test instruments and 1 negative control

5. Scope

This study evaluated the efficacy of the automated cleaning process in the Franke Medical Oy Deko D32 washer-disinfector for the IS4000 8mm Basic Instruments. The testing was conducted at 20/30 Laboratories in Northampton, England. This automated cleaning validation utilised the Maryland Bipolar Forceps (MBF) and the Monopolar Curved Scissors (MCS) as the Master Products to demonstrate cleaning efficacy. As determined by Intuitive Surgical, the results apply to all of the following devices in their IS4000 8mm suite of instruments:

Part No.	Instrument Name
470001	Potts Scissors
470003	Small Clip Applier
470006	Large Needle Driver
470007	Round Tip Scissors
470033	Black Diamond Micro Forceps
470036	DeBakey Forceps
470048	Long Tip Forceps
470049	Cadiere Froceps
470093	ProGrasp™ Forceps
470157	Snap-fit™ Instrument
470171	Micro Bipolar Forceps
470172	Maryland Bipolar Forceps
470179	Monopolar Curved Scissors
470181	Resano Forceps

Part No.	Instrument Name
470184	Permanent Cautery Spatula
470190	Cobra Grasper
470194	Mega Needle Driver
470205	Fenestrated Bipolar Forceps
470207	Tenaculum Forceps
470215	Cardiac Probe Grasper
470230	Large Hem-o-lok® Clip Applier
470246	Atrial Retractor Short Right
470249	Dual Blade Retractor
470296	Large SutureCut Needle Driver
470309	Mega SutureCut™ Needle Driver
470318	Small Graptor™ (Grasping Retractor)
470327	Medium Hem-o-lok® Clip Applier
470344	Curved Bipolar Dissector
470347	Tip-Up Fenestrated Gasper
470400	Long Bipolar Grasper
470401	Small Clip Applier, Horizon

6. References

823033-40 Rev T	Architectural Requirements, IS4000 Instruments
861445-02T Rev E	Top Level Plan for IS4000 8mm Basic Instruments
1005073 Rev A	Work Instruction, Modified OPA Protein Assay
853184	DOP, Product Verification and Validation
854021	DOP, Statistical Techniques
AAMI TIR 12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR 30: 2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
BS EN ISO 15883-1:2009	Washer-Disinfectors- Part 1: General requirements, terms and definitions and test
ISO 15883-5:2005	Washer-disinfectors- Part 5: Test soils and methods for demonstrating cleaning efficacy

7. Definitions

8.1 Chemical: Formulation of compounds intended for use in reprocessing.

8.2 Cleaning: Removal of contamination from an item to the extent necessary for further processing or for intended use.

8.3 Distal Seal: A seal in the instrument located where the drive cables enter the instrument shaft. See diagram 1 below.

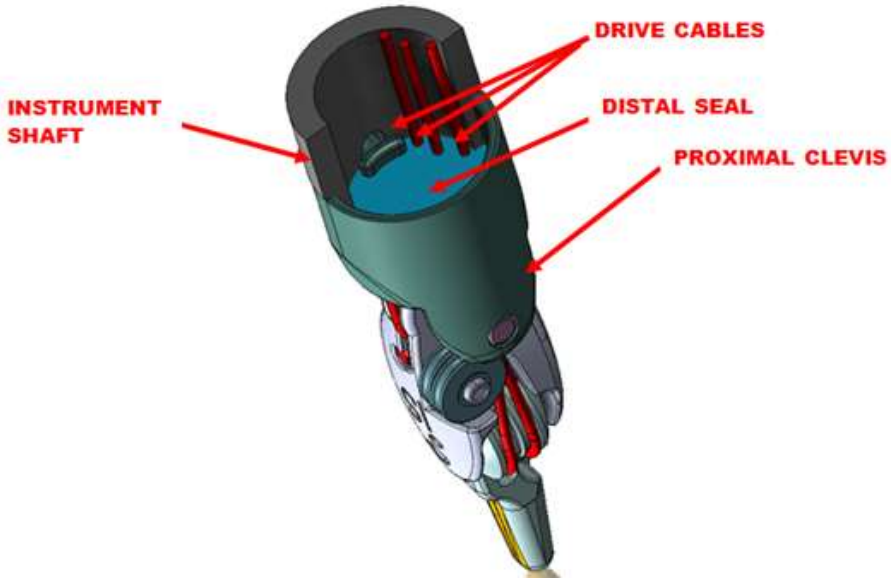


Diagram 1: IS4000 Interior Instrument Distal Assembly (Large Needle Driver shown) that is the same across IS4000 8mm Basic Instruments.

8.4 Extraction: Process to ensure adequate removals of residual soil from the critical area.

8.5 LOD: Limit of Detection

8.6 Preconditioning: Activity including cleaning, sterilization and simulated use on new devices to simulate the end-of-life of the device.

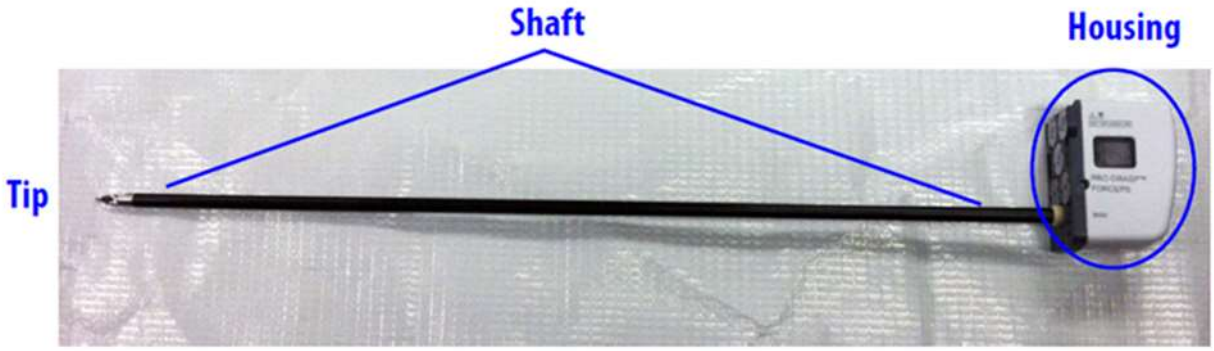
8.7 Processing: Activity including cleaning, sterilization, and necessary to prepare a new or used medical device for its intended use.

8.8 Reprocess: To make ready for reuse a device, instrument, or piece of equipment by any or a combination of the following processes: cleaning, decontamination/ disinfection, repackaging, and sterilization.

8.9 Reusable Medical Device: Device intended for repeated use on different patients, with appropriate decontamination and other processing between users.

8.10 SDS: Sodium Dodecyl Sulphate, an extraction fluid.

8.11 Shaft: Portion of instrument from the Distal Seal to the housing. Refer to the diagram below.



8.12 Sterilisation: Validated process used to render a product free from viable microorganisms.

8.13 Test Soil: Formulation designed as a substitute for soil or debris typically found on a medical instrument after clinical use and used as part of the procedure to validate a cleaning process.

8.14 Tip Cover: A sterile, single-use disposable, protective sleeve that is placed over the Monopolar Curved Scissors prior to use to present unwanted cauterisation from parts of the tip other than the distal tip of the cutting blades.

8.15 Validation: Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

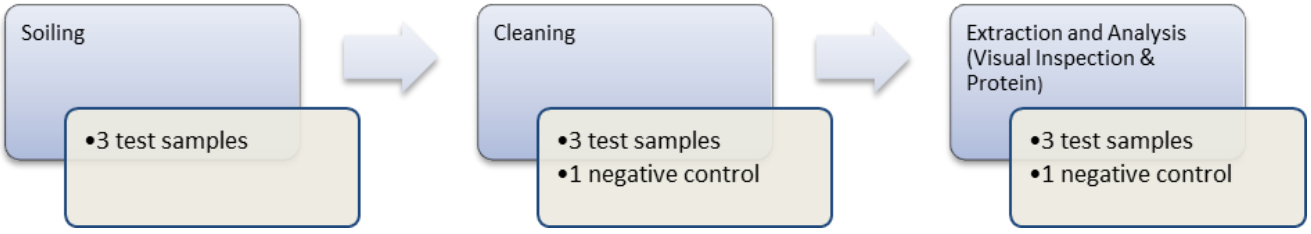
8.16 Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

8. Test Procedure

TEST OVERVIEW

IS4000 8mm Basic Instruments are reusable instruments and cleaned by the user according to instructions provided by Intuitive Surgical. This cleaning validation evaluated the efficacy of the cleaning process for the instruments. The cleaning efficacy was evaluated using visual inspection and protein analysis.

Testing, visual inspection and residual tip protein analysis were performed according to the Intuitive Surgical protocol, 1006406-01P Rev A. For each of the two instrument types, there were 4 new instruments (1 negative control and 3 test samples). The set of instruments underwent 3 cleaning validation cycles. Each cycle consisted of soiling, cleaning and extraction per instructions for validation in Attachment 2, 3 and 4, and visual inspection under 4x magnifying glass and protein analysis, in that order. Refer to the diagram below.



The negative control was cleaned but not soiled. See Intuitive Surgical document 1006406-01P Rev A for test method.

Soiling:

The test sample instruments were soiled with coagulating sheep's blood per protocol, as per Intuitive Surgical protocol 1006406-01P Rev A, Attachment 2. The shafts of the instruments were soiled with 600µL of coagulating sheep's blood and the tips of the instruments were soiled by immersing the instrument tips into approximately 5mL of test soil.

Cleaning:

The instruments (test samples and negative controls) were cleaned according to Intuitive Surgical protocol, 1006406-01P Rev A, Attachment 3. A pre-soak step was performed using 2% neodisher MediClean forte at a maximum temperature of 40 °C. The cleaning cycle in the Deko D32 used a dosing schema of 215ml neodisher MediClean forte in 27 litres. The DAVINCI cleaning cycle is a cycle used for cleaning validations only and follows the same pre-wash, wash, and rinse cycles of the DAVINCI PLUS 90 program that is used in the field. The DAVINCI differs from the DAVINCI PLUS 90 program in that the DAVINCI program modifies the thermal disinfection and drying steps that take place at the end of the DAVINCI PLUS 90 program. The Thermal disinfection stage is limited to a maximum temperature of 50°C and the drying phase is omitted. These cycle modification prevent the fixation or modification of proteins in the instrument which occurs at elevated temperature, allowing extraction and quantification of any potential residual protein.

Extraction:

All instruments (test samples and negative controls) were extracted with 1% SDS for residual protein per Intuitive Surgical Work Instruction, 1005073 Rev A (Modified OPA Protein Assay). The extracted residual protein values were corrected for turbidity.

TESTER(S)

Testing was performed by James Clarke (JC) at 20/30 Laboratories in Northampton, England.

TEST LOCATION AND DATE

Testing was performed at 20/30 Laboratories, Osyth Close, Brackmills Industrial Estate, Northampton UK NN47DY on the 10th September, 2020 to the 6th of October, 2020.

9. Results

- Attachment 1: Datasheets Cycle 1-3.
- Appendix 1: Datasheets from Spectrophotometer cycle 1-3
- Appendix 2: Validation data cycle 1-3

The test results in Attachment 1 and Appendix 1 showed that all test samples met all acceptance criteria listed for every test case.

Table 1: IS4000 8mm Basic Instruments – PN, Version & Lot #

Instrument Type			PN w/ Version #	Lot Number	Serial Number
Maryland Bipolar Forceps	MBF New	Test Sample 1	470172-16T	N10200622	0099
		Test Sample 2	470172-16T	N10200622	0089
		Test Sample 3	470172-16T	N10200622	0100
		Negative Control	470172-16T	N10200622	0102
Monopolar Curved Scissors	MCS New	Test Sample 5	470179-19T	N10190205	0017
		Test Sample 6	470179-19T	N10200127	0059
		Test Sample 7	470179-19T	N10200127	0088
		Negative Control	470179-19T	N10200713	0087

Table 2: IS4000 8mm Basic Instruments, Results of Visual Inspection – Cycle # 1 to 3.

Instrument Type			**VISUAL INSPECTION PASS/FAIL** (per 1006406-01P Rev A, Section 8)		
			Cycle # 1	**Cycle # 2**	**Cycle # 3**
Maryland Bipolar Forceps	MBF New	Test Sample 1	PASS	PASS	PASS
		Test Sample 2	PASS	PASS	PASS
		Test Sample 3	PASS	PASS	PASS
		Negative Control	PASS	PASS	PASS
Monopolar Curved Scissors	MCS New	Test Sample 5	PASS	PASS	PASS
		Test Sample 6	PASS	PASS	PASS
		Test Sample 7	PASS	PASS	PASS
		Negative Control	PASS	PASS	PASS

Table 3: Total Residual Protein for IS4000 8mm Basic Instruments – Cycle1 to 3.

Cycle #	**Instrument Type**		**Total Protein (Adjusted for Turbidity)** (µg)	**PASS/FAIL** (per 1006406-01P Rev A) < 200 µg
1	MBF New	Test Sample 1	13.16	PASS
		Test Sample 2	6.56	PASS
		Test Sample 3	26.32	PASS
		Negative Control	0	PASS
	MCS New	Test Sample 5	29.58	PASS
		Test Sample 6	14.82	PASS
		Test Sample 7	4.92	PASS
		Negative Control	21.38	PASS
2	MBF New	Test Sample 1	87.36	PASS
		Test Sample 2	21.5	PASS
		Test Sample 3	9.18	PASS
		Negative Control	42.9	PASS
	MCS New	Test Sample 5	0	PASS
		Test Sample 6	22.98	PASS
		Test Sample 7	0	PASS
		Negative Control	0	PASS
3	MBF New	Test Sample 1	12.48	PASS
		Test Sample 2	12.48	PASS
		Test Sample 3	4.14	PASS
		Negative Control	8.28	PASS
	MCS New	Test Sample 5	4.14	PASS
		Test Sample 6	4.14	PASS
		Test Sample 7	0	PASS
		Negative Control	0	PASS

Below is a summary of the acceptance criteria. The datasheets in Attachment 1 to 4 showed that all test articles met all of the Intuitive Surgical specified acceptance criteria for every test case.

Acceptance Criteria per 1006406-01P Rev A	Summary of Results	Reference	Acceptance Criteria met?
The test instruments and negative control instruments shall have no visible test soil observed during visual inspection using 4X magnification.	No soil was observed after cleaning on the negative control and the test samples using 4X magnification.	§12.4.1	Yes
The test instruments and negative control instruments shall have a total residual protein (combined results of the tip and shaft extracts) of < 200µg.	All of the test samples and negative controls had <200µg of total residual protein	§12.4.2	Yes

10. Discrepancies

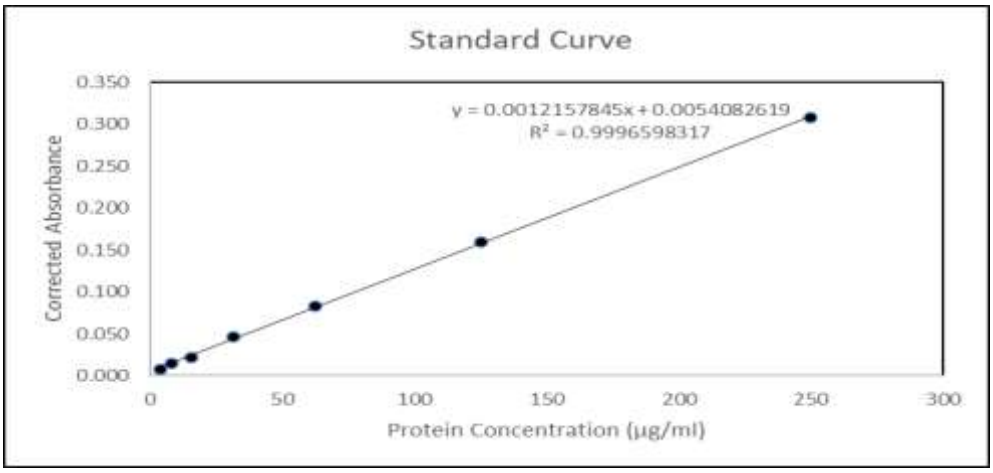
	Test Case(s) Affected	Description	Justification / Resolution
ANOMALIES			
Item 1	N/A	N/A	N/A
TEST ARTICLE / TEST EQUIPMENT DEVIATIONS			
Item 2	N/A	N/A	N/A
OTHER DEVIATIONS			
Item 3	N/A	N/A	N/A
Item 4	N/A	N/A	N/A
ADMINISTRATIVE DISCREPANCIES			
Item 4	N/A	N/A	N/A

11. Conclusions

The IS4000 8mm Basic Instruments were tested and successfully passed all requirements as described in Intuitive Surgical protocol, 1006406-01P Rev A. These results demonstrate that IS4000 8mm Basic Instruments can be cleaned using the automated cleaning process with the Franke Medical Oy Deko D32 washer-disinfector with neodisher MediClean forte used in the soaking step (detergent prepared according to the detergent manufacturer's instructions) and with neodisher MediClean forte in the automated washer cleaning step where the daVinci wash rack module is employed. Refer to Intuitive Surgical 1006406-01P Rev A, Attachment 3 for detailed cleaning instructions. Furthermore, the testing identified no new issues of safety or effectiveness and no new risks.

Appendix 1: Photometric Report 1

Dekomed Cycle 14 10-09-2020

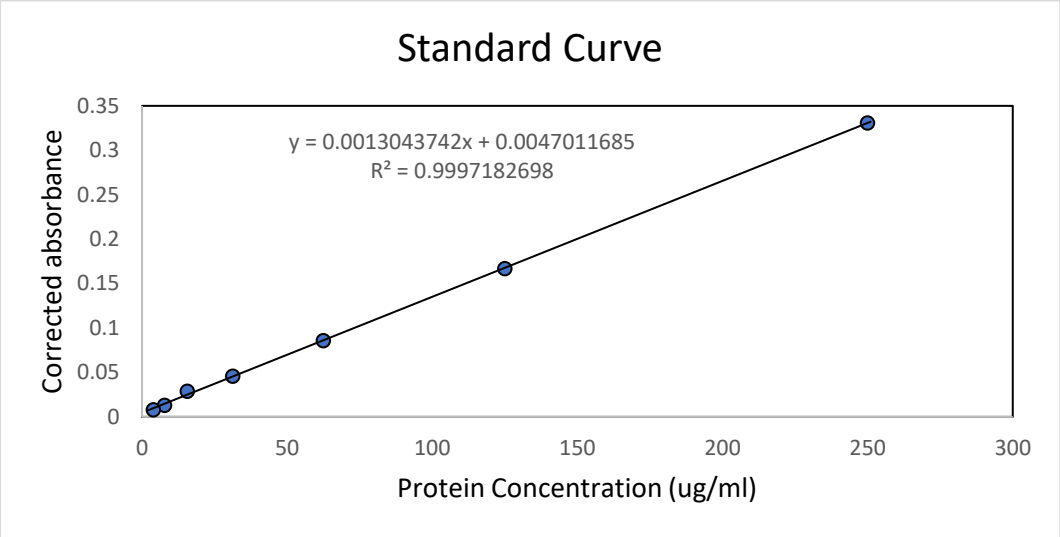


Wavelength:	340.00 nm
Instrument:	GeneQuest CE 2301
Measuring mode:	Absorbance
Correlation coefficient r2 :	0.999659819
Date/Time:	10/09/2020 19:12:34 PM
X =:	0.005408064
Y =:	0.001215786

Instrument	Location	Turbidity (absorbance at 340nm)	Test (absorbance at 340nm)	Extraction volume (ml)	Dilution factor	Sample turbidity, as protein (ug)	Uncorrected Instrument protein result (ug)	Corrected Test protein result (ug)	Corrected total instrument protein result (ug)	Result
MBF_1	Tip	0.003	0.010	4	1	1.96	15.12	13.16	13.16	PASS
	Shaft	0.006	0.006	6	1	2.94	2.94	0		
MBF_2	Tip	0.002	0.008	4	1	1.96	8.52	6.56	6.56	PASS
	Shaft	0.001	0.003	6	1	2.94	2.94	0		
MBF_3	Tip	0.007	0.015	4	1	5.24	31.56	26.32	26.32	PASS
	Shaft	0.003	0.003	6	1	2.94	2.94	0		
MBF_NEG	Tip	0.001	0.002	4	1	1.96	1.96	0	0	PASS
	Shaft	0.001	0.005	6	1	2.94	2.94	0		
MCS_1	Tip	0.003	0.006	4	1	1.96	1.96	0	29.58	PASS
	Shaft	0.006	0.012	6	1	2.94	32.52	29.58		
MCS_2	Tip	0.001	0.005	4	1	1.96	1.96	0	14.82	PASS
	Shaft	0.011	0.014	6	1	27.6	42.42	14.82		
MCS_3	Tip	0.001	0.003	4	1	1.96	1.96	0	4.92	PASS
	Shaft	0.003	0.007	6	1	2.94	7.86	4.92		
MCS_NEG	Tip	0.002	0.008	4	1	1.96	8.52	6.56	21.38	PASS
	Shaft	0.008	0.011	6	1	12.78	27.6	14.82		

Appendix 1: Photometric Report 2

Dekomed D32 Cycle 19 15-09-2020

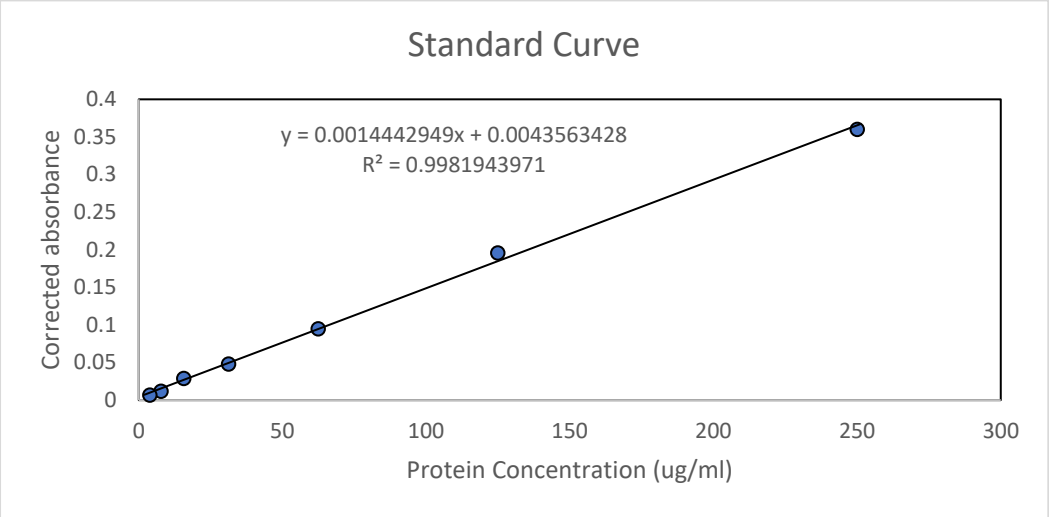


Wavelength:	340.00 nm
Instrument:	GeneQuest CE 2301
Measuring mode:	Absorbance
Correlation coefficient r2 :	0.9997182698
Date/Time:	15/09/2020 16:42:12 PM
X =:	0.0047011685
Y =:	0.0013043742

Instrument	Location	Turbidity (absorbance at 340nm)	Test (absorbance at 340nm)	Extraction volume (ml)	Dilution factor	Sample turbidity, as protein (ug)	Uncorrected Instrument protein result (ug)	Corrected Test protein result (ug)	Corrected total instrument protein result (ug)	Result
MBF_1	Tip	0.000	0.000	4	1	0.92	0.92	0	87.36	PASS
	Shaft	0.027	0.046	6	1	102.6	189.96	87.36		
MBF_2	Tip	0.000	0.006	4	1	0.92	4	3.08	21.5	PASS
	Shaft	0.002	0.009	6	1	1.38	19.8	18.42		
MBF_3	Tip	0.000	0.005	4	1	0.92	0.92	0	9.18	PASS
	Shaft	0.001	0.007	6	1	1.38	10.56	9.18		
MBF_NEG	Tip	0.000	0.007	4	1	0.92	7.04	6.12	42.9	PASS
	Shaft	0.005	0.013	6	1	1.38	38.16	36.78		
MCS_1	Tip	0.000	0.001	4	1	0.92	0.92	0	0	PASS
	Shaft	0.000	0.004	6	1	1.38	1.38	0		
MCS_2	Tip	0.000	0.000	4	1	0.92	0.92	0	22.98	PASS
	Shaft	0.001	0.010	6	1	1.38	24.36	22.98		
MCS_3	Tip	0.000	0.005	4	1	0.92	0.92	0	0	PASS
	Shaft	0.000	0.002	6	1	1.38	1.38	0		
MCS_NEG	Tip	0.000	0.001	4	1	0.92	0.92	0	0	PASS
	Shaft	0.000	0.004	6	1	1.38	1.38	0		

Appendix 1: Photometric Report 3

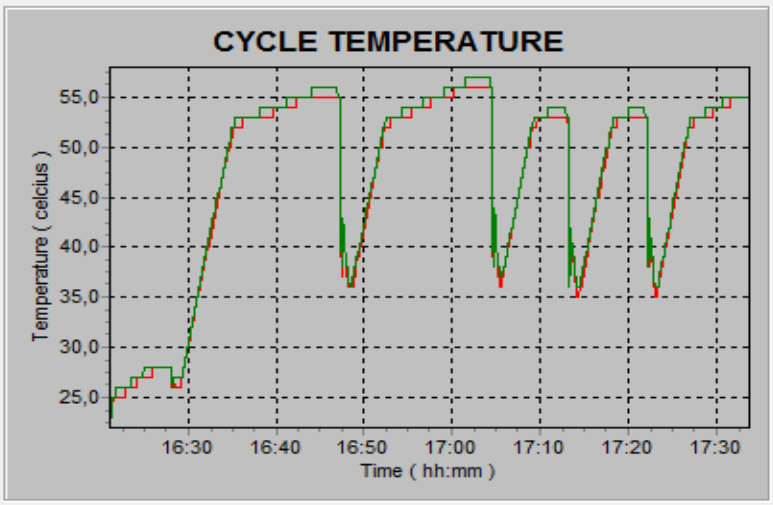
Dekomed D32 Cycle 24 6-10-2020

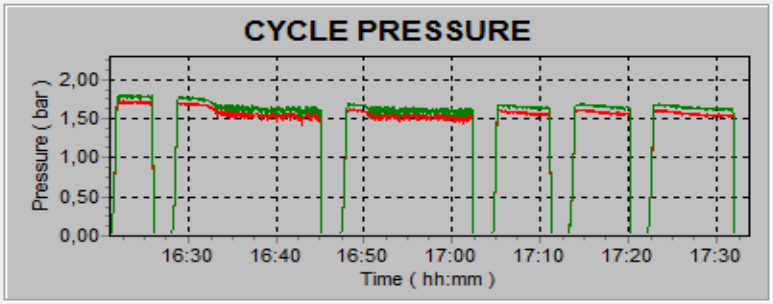


Wavelength:	340.00 nm
Instrument:	GeneQuest CE 2301
Measuring mode:	Absorbance
Correlation coefficient r2 :	0.9981943971
Date/Time:	06/10/2020 18:04:10 PM
X =:	0.0043563428
Y =:	0.0014442949

Instrument	Location	Turbidity (absorbance at 340nm)	Test (absorbance at 340nm)	Extraction volume (ml)	Dilution factor	Sample turbidity, as protein (ug)	Uncorrected Instrument protein result (ug)	Corrected Test protein result (ug)	Corrected total instrument protein result (ug)	Result
MBF_1	Tip	0.002	0.002	4	1	1.8	1.8	0	12.48	PASS
	Shaft	0.012	0.015	6	1	31.74	44.22	12.48		
MBF_2	Tip	0.001	0.002	4	1	1.8	1.8	0	12.48	PASS
	Shaft	0.007	0.010	6	1	10.98	23.46	12.48		
MBF_3	Tip	0.002	0.003	4	1	1.8	1.8	0	4.14	PASS
	Shaft	0.005	0.006	6	1	2.7	6.84	4.14		
MBF_NEG	Tip	0.003	0.003	4	1	1.8	1.8	0	8.28	PASS
	Shaft	0.006	0.008	6	1	6.84	15.12	8.28		
MCS_1	Tip	0.001	0.003	4	1	1.8	1.8	0	4.14	PASS
	Shaft	0.002	0.006	6	1	2.7	6.84	4.14		
MCS_2	Tip	0.000	0.003	4	1	1.8	1.8	0	4.14	PASS
	Shaft	0.003	0.006	6	1	2.7	6.84	4.14		
MCS_3	Tip	0.001	0.005	4	1	1.8	1.8	0	0	PASS
	Shaft	0.003	0.005	6	1	2.7	2.7	0		
MCS_NEG	Tip	0.001	0.002	4	1	1.8	1.8	0	0	PASS
	Shaft	0.001	0.005	6	1	2.7	2.7	0		

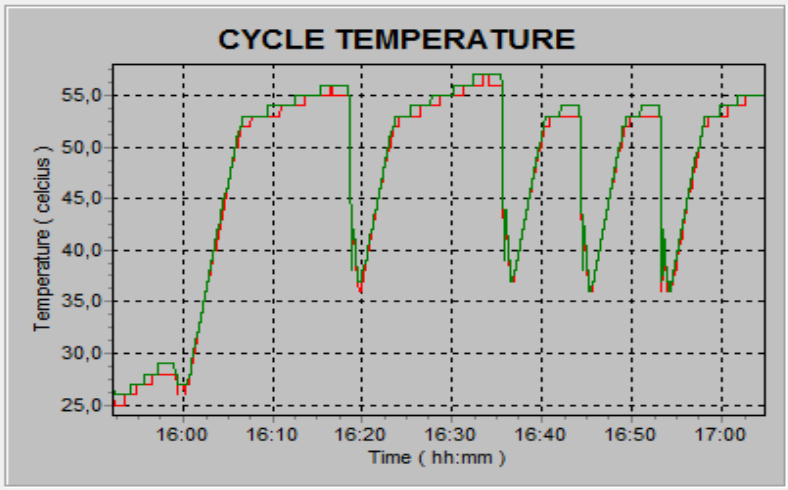
Appendix 2: Cycle Data

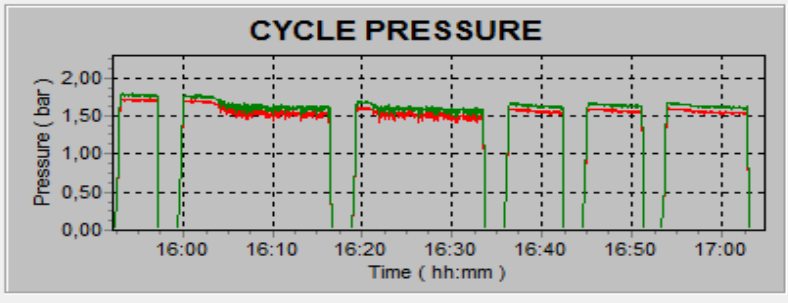




Cycle report
Owner:
Machine:
Machine serial#: 8N07
Instrument trays:
Cycle name: da Vinci
Cycle number: 14
Validated cycle: TRUE
User ID:
Cycle starting time: 10.9.2020 16:20:59
CW rinse start
16:26:00 CW rinse end
16:27:55 Wash 50 °C start
16:33:28 Chem1: meas 200 ml T: 45 °C p: 1,64 bar
16:35:07 Temperature reached T: 52 °C p: 1,66 bar
16:45:06 Wash end T: 55 °C p: 1,58 bar
16:47:07 Wash 50 °C start
16:50:46 Chem1: meas 200 ml T: 45 °C p: 1,65 bar
16:52:19 Temperature reached T: 52 °C p: 1,55 bar
17:02:18 Wash end T: 56 °C p: 1,61 bar
17:04:22 HW rinse T: 50 °C start
17:09:07 Temperature reached T: 52 °C p: 1,64 bar
17:11:07 HV rinse end T: 53 °C p: 1,63 bar
17:13:04 HW rinse T: 50 °C start
17:18:09 Temperature reached T: 52 °C p: 1,65 bar
17:20:10 HV rinse end T: 53 °C p: 1,63 bar
17:22:03 HW rinse T: 50 °C start
17:26:57 Temperature reached T: 52 °C p: 1,64 bar
17:31:57 HV rinse end T: 55 °C p: 1,59 bar
Cycle end time: 10.9.2020 17:33:51
Cycle completed: OK
Checksum in file: 9bc5
Checksum OK

Validation cycle 14: 10-09-2020

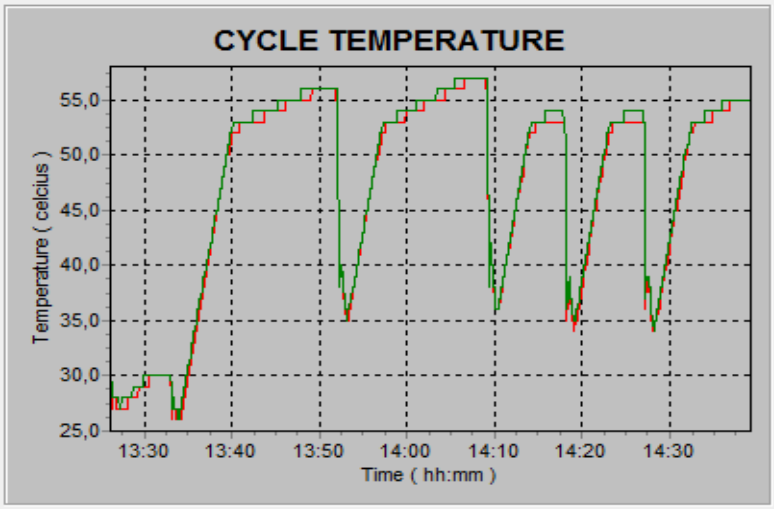


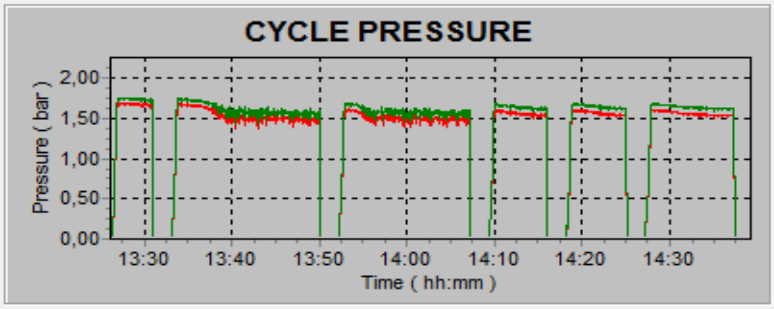


Cycle report
Owner:
Machine:
Machine serial#: 8N07
Instrument trays:
Cycle name: da Vinci
Cycle number: 19
Validated cycle: TRUE
User ID:
Cycle starting time: 15.9.2020 15:52:08
CW rinse start
15:57:12 CW rinse end
15:59:10 Wash 50 °C start
16:04:48 Chem1: meas 200 ml T: 45 °C p: 1,65 bar
16:06:24 Temperature reached T: 52 °C p: 1,63 bar
16:16:24 Wash end T: 55 °C p: 1,57 bar
16:18:30 Wash 50 °C start
16:21:51 Chem1: meas 200 ml T: 45 °C p: 1,62 bar
16:23:24 Temperature reached T: 52 °C p: 1,64 bar
16:33:25 Wash end T: 57 °C p: 1,58 bar
16:35:27 HW rinse T: 50 °C start
16:40:12 Temperature reached T: 52 °C p: 1,64 bar
16:42:12 HV rinse end T: 53 °C p: 1,63 bar
16:44:09 HW rinse T: 50 °C start
16:49:06 Temperature reached T: 52 °C p: 1,64 bar
16:51:06 HV rinse end T: 53 °C p: 1,64 bar
16:53:00 HW rinse T: 50 °C start
16:57:51 Temperature reached T: 52 °C p: 1,59 bar
17:02:51 HV rinse end T: 55 °C p: 1,62 bar
Cycle end time: 15.9.2020 17:04:48
Cycle completed: OK
Checksum in file: e901
Checksum OK

Validation cycle 19: 15-09-2020

Appendix 2: Cycle Data





Cycle report
Owner:
Machine:
Machine serial#: 8N07
Instrument trays:
Cycle name: da Vinci
Cycle number: 24
Validated cycle: TRUE
User ID:
Cycle starting time: 6.10.2020 13:25:56
CW rinse start
13:30:54 CW rinse end
13:32:48 Wash 50 °C start
13:38:22 Chem1: meas 200 ml T: 45 °C p: 1,58 bar
13:39:54 Temperature reached T: 52 °C p: 1,57 bar
13:49:54 Wash end T: 56 °C p: 1,61 bar
13:51:54 Wash 50 °C start
13:55:33 Chem1: meas 200 ml T: 45 °C p: 1,55 bar
13:57:06 Temperature reached T: 52 °C p: 1,60 bar
14:07:06 Wash end T: 57 °C p: 1,54 bar
14:09:06 HW rinse T: 50 °C start
14:14:00 Temperature reached T: 52 °C p: 1,63 bar
14:16:01 HV rinse end T: 53 °C p: 1,60 bar
14:17:57 HW rinse T: 50 °C start
14:23:06 Temperature reached T: 52 °C p: 1,63 bar
14:25:06 HV rinse end T: 53 °C p: 1,60 bar
14:27:00 HW rinse T: 50 °C start
14:32:24 Temperature reached T: 52 °C p: 1,65 bar
14:37:24 HV rinse end T: 55 °C p: 1,63 bar
Cycle end time: 6.10.2020 14:39:23
Cycle completed: OK
Checksum in file: 8dd1
Checksum OK

Validation cycle 24: 6-10-2020

Authorised by:

Authorised by:

James Clarke
Head of Innovation

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