

Do cleaning procedures always guarantee cleaner instruments?

- Optimizing the reprocessing workflow

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31 OKTOBER



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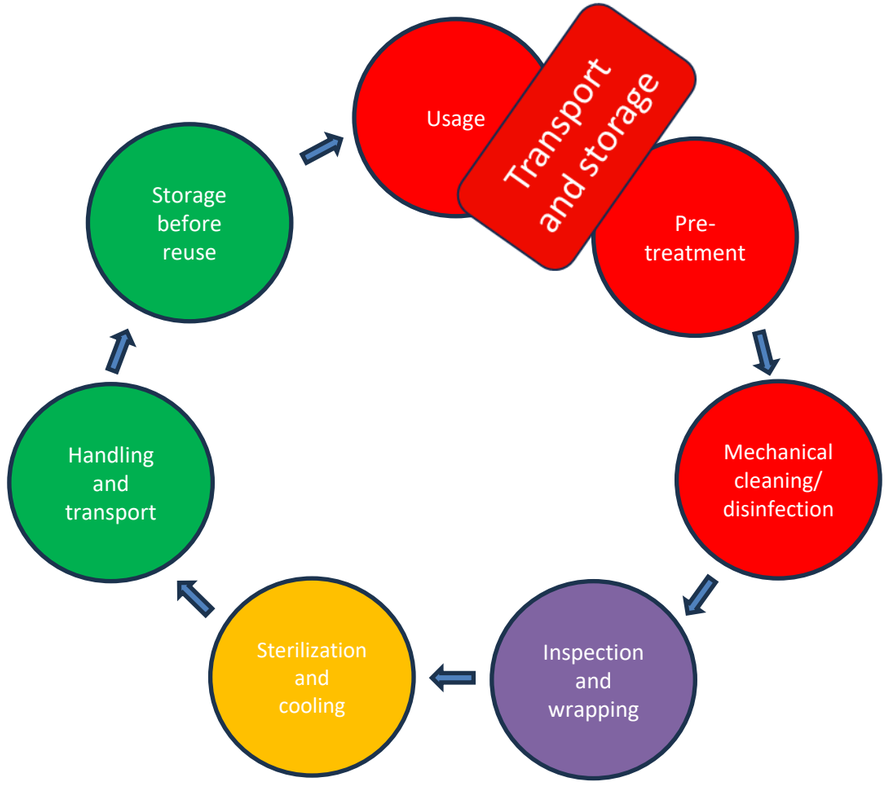
Why did they invite me ??



Dirty → Clean → Sterile

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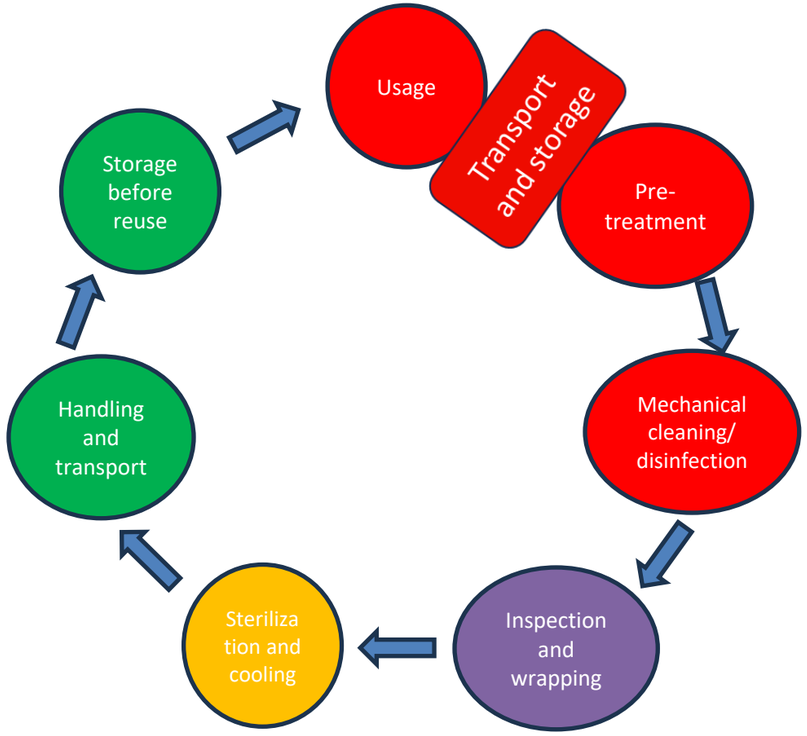
Did the research have an impact



Challenges in guidelines/recommendations:

6-hour rule

- Instruments must be cleaned within 6 hours after use

Transportation environment:

- Recommends a moist transportation environment

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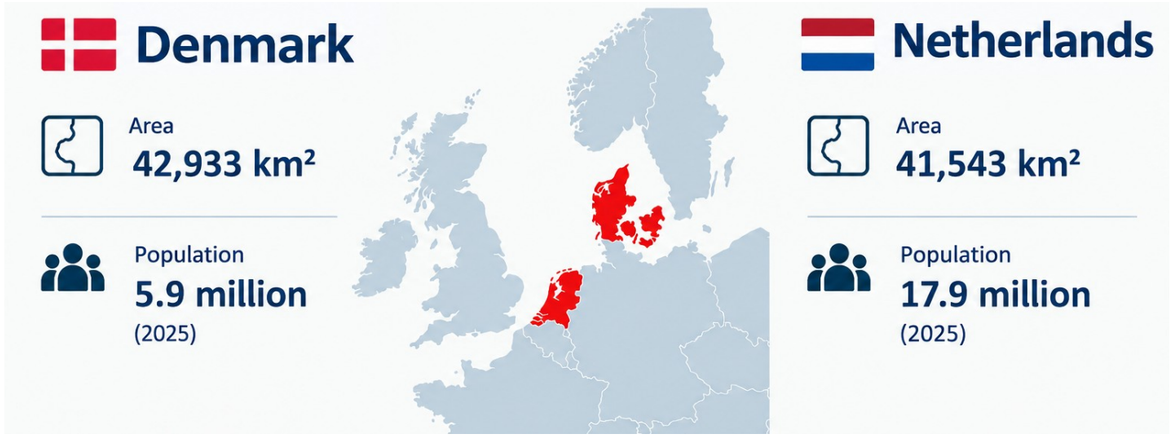
Differences between Denmark and The Netherlands



Topic	Denmark	Netherlands
Funding	Public, tax-funded	Mandatory private basic health insurance
Patient payment	Free hospital care	Premiums + EUR 385 deductible (adults)
Hospital ownership	Public; run by five regions	Mostly private nonprofit organisations
Hospital structure	Centralised; 21 acute hospitals	Decentralised; 69 organisations, 113 locations

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Differences between Denmark and The Netherlands

CSSD – Denmark vs. Netherlands

Organisation | Structure | Key figures







Topic	Denmark	Netherlands
CSSD model	Centralised regional/hospital CSSDs	CSSD/CSA at hospital organisations/locations
Number	>30 nationwide	No national total; approximately one per hospital
Scale	Fewer, larger units	More, smaller units
Trend	Strong centralisation	More decentralisation
Effect	Fewer, larger, more automated units	More local, smaller units

New CSSD



Where to start the validation process





What they do	What they bring
Quality Control Specialist	Hands-on experience
Process Engineer	Process flow overview
Researchers	Knowledge of evidens

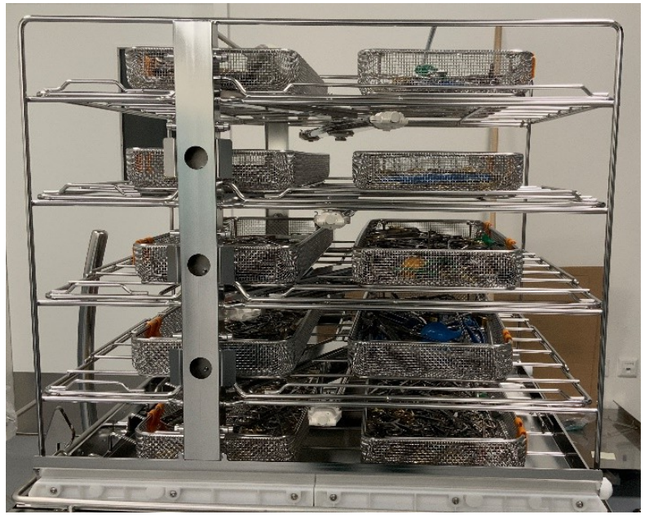
The old process

OR

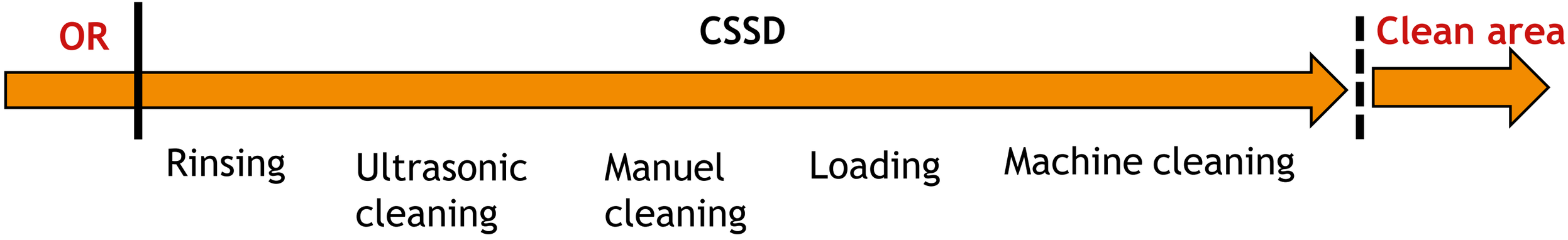
CSSD

Clean area





What to test before the validation process ?



What to test before the validation process ?

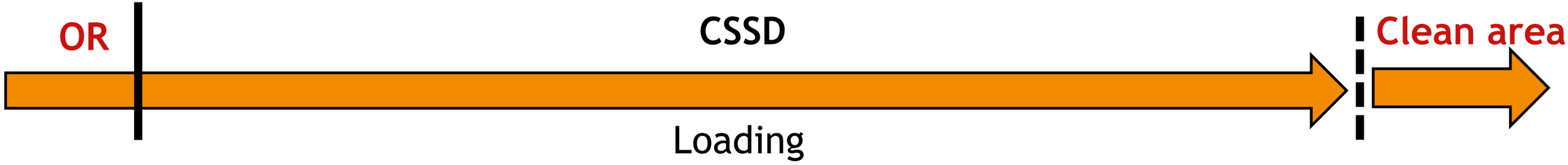


Rinsing + ultrasonic cleaning





What to test before the validation process ?

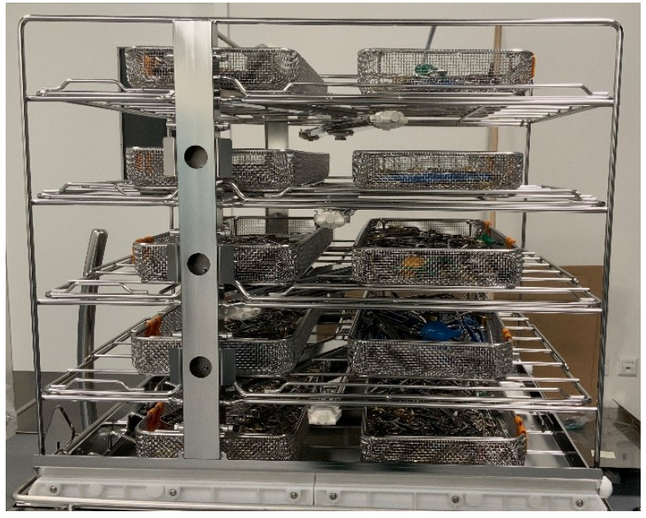




Wagner

Aicon

Aesculap
(JG222R)



VS



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What to test before the validation process ?

OR

CSSD

Clean area

Machine cleaning

MediClean
- Advanced



Pre-rinse → Washing → Int-rinse

Prozyme
Alka-X



Pre-rinse → Washing → Int-rinse 1 → Int-rinse 2

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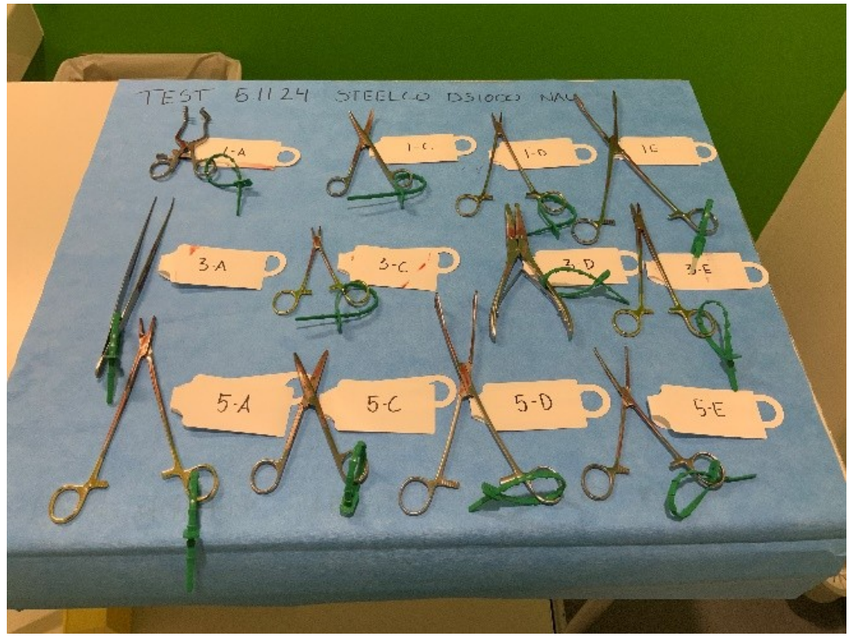
Standardization - Choosing instruments

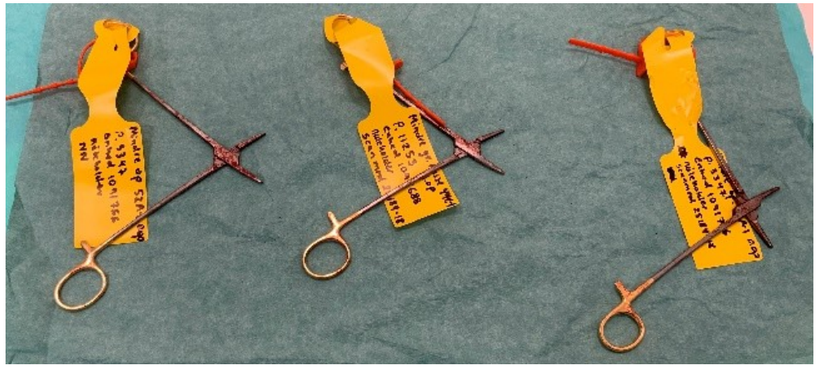
Discarded instruments from basic trays



For example:

- Scissors
- Tweezer
- Forceps
- Needleholders

Real-life instruments used at OR



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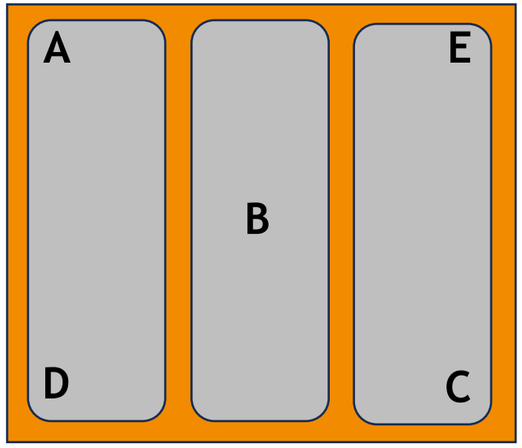
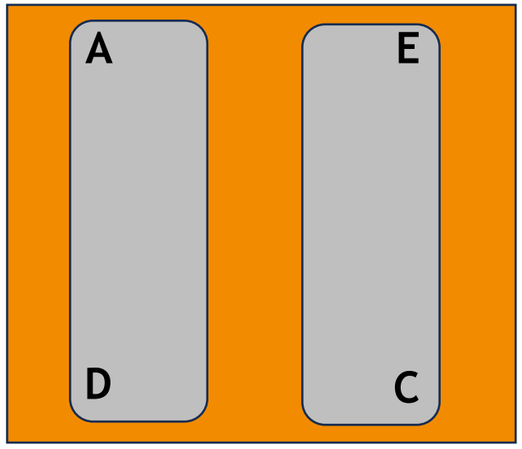
Standardization – Placing the instruments







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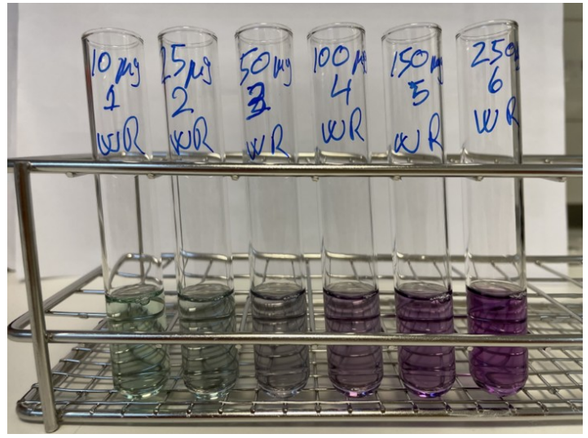
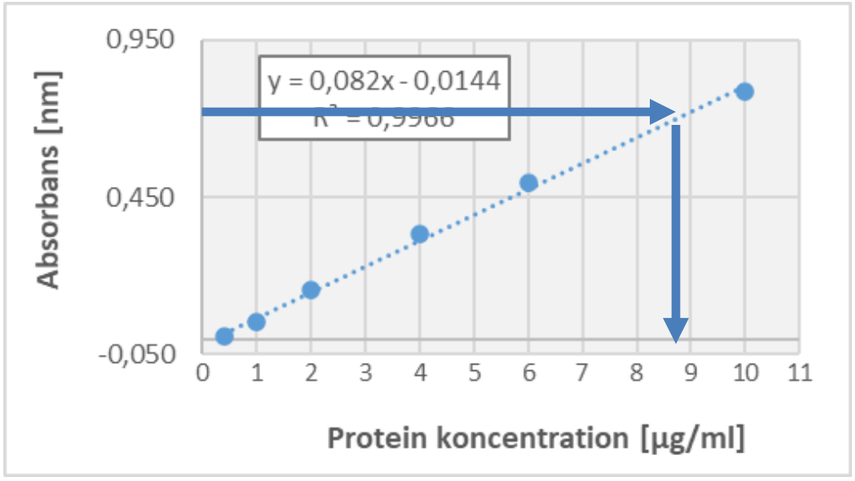
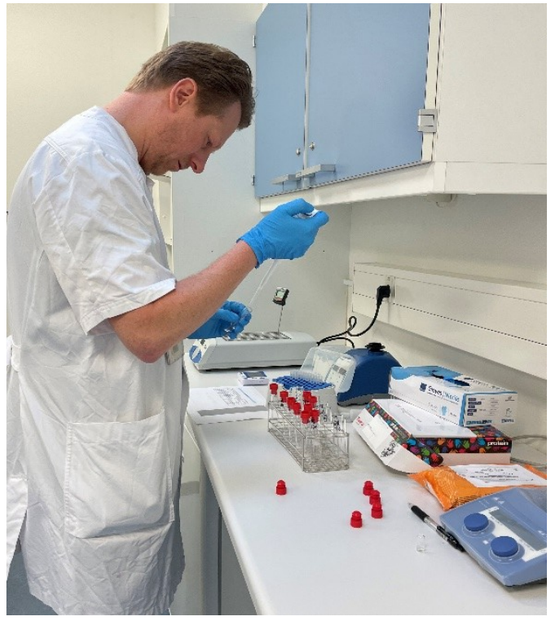
What to test and how ?







	Acceptable	Alert	Not acceptable
Quality limites [µg/Instrument]	< 100	100 - 200	> 200

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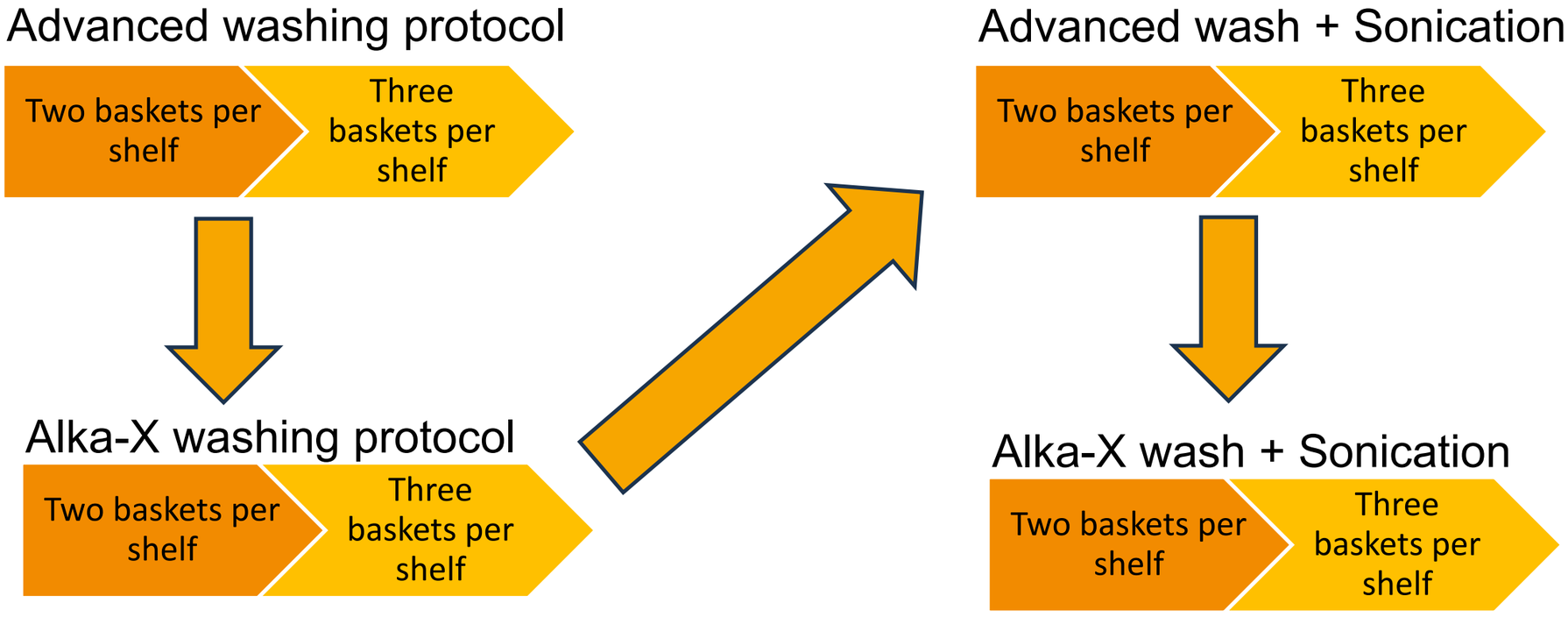
Test sequence



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Test results

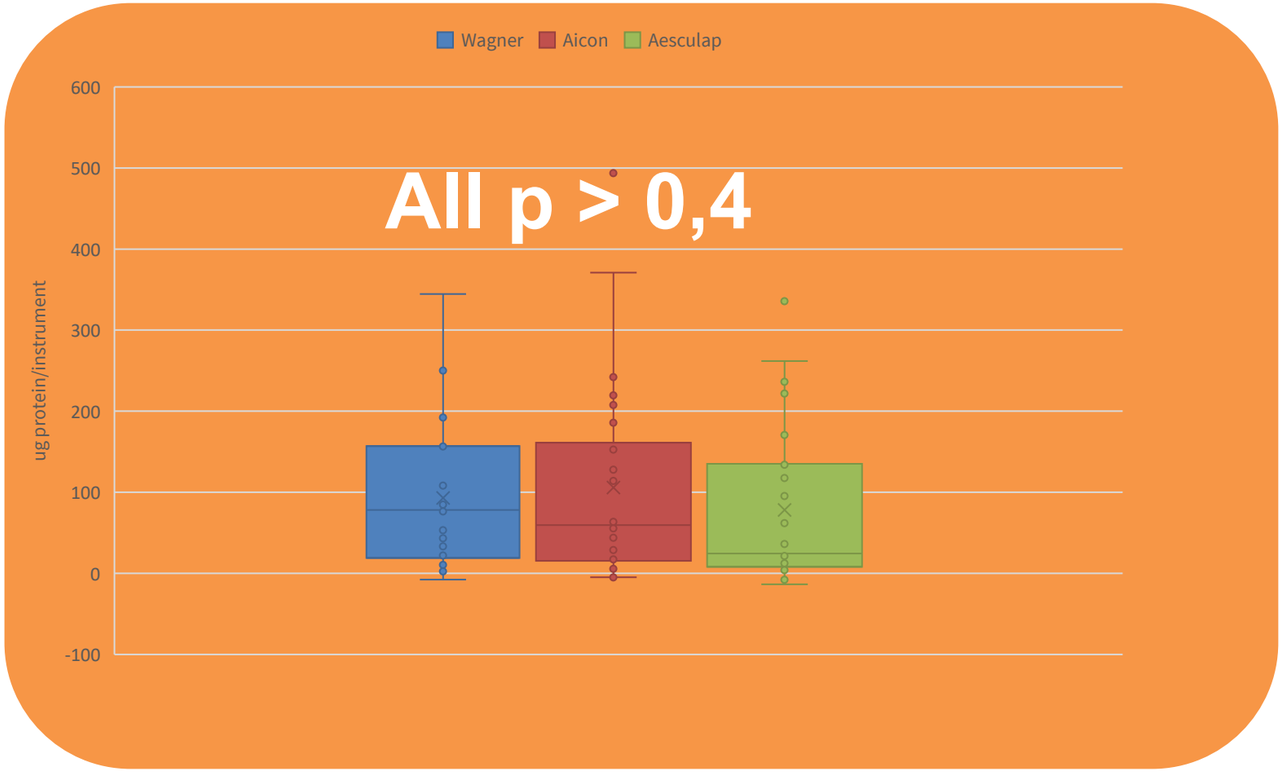
	Two baskets per shelf			Advanced Sonication
	Wagner	Aicon	Aesculap	Aesculap
Instrument 1-A				
Instrument 1-C				
Instrument 1-D				
Instrument 1-E				
Instrument 3-A				
Instrument 3-B				
Instrument 3-C				
Instrument 3-D				
Instrument 3-E				
Instrument 5-A				
Instrument 5-B				
Instrument 5-C				
Instrument 5-D				
Instrument 5-E				
OP 1				
OP 2				
OP 3				

Three baskets per shelf			Alka-X
Wagner	Aicon	Aesculap	Aesculap

Advanced Sonication	
Aicon	Aesculap

Alka-X Sonication
Aesculap

Hole size in the instrument trays





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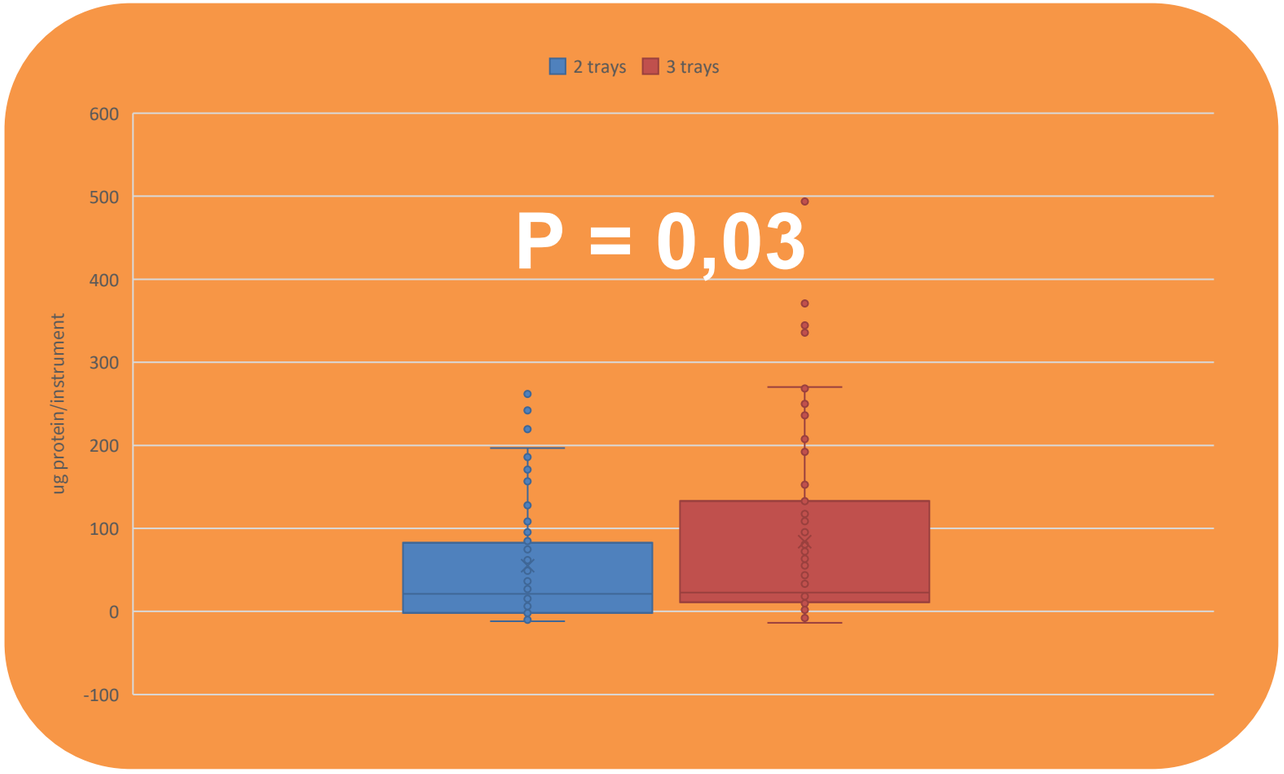
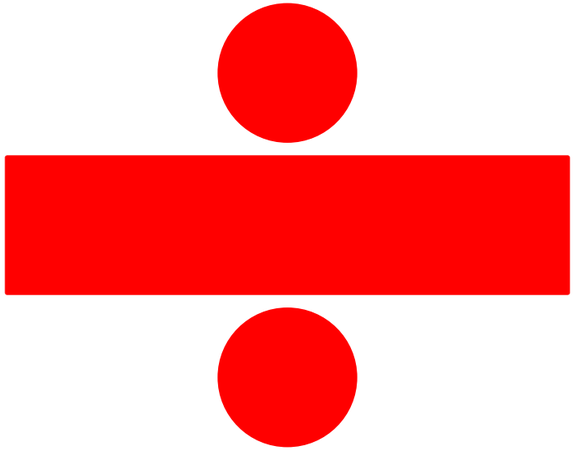
2 vs 3 trays





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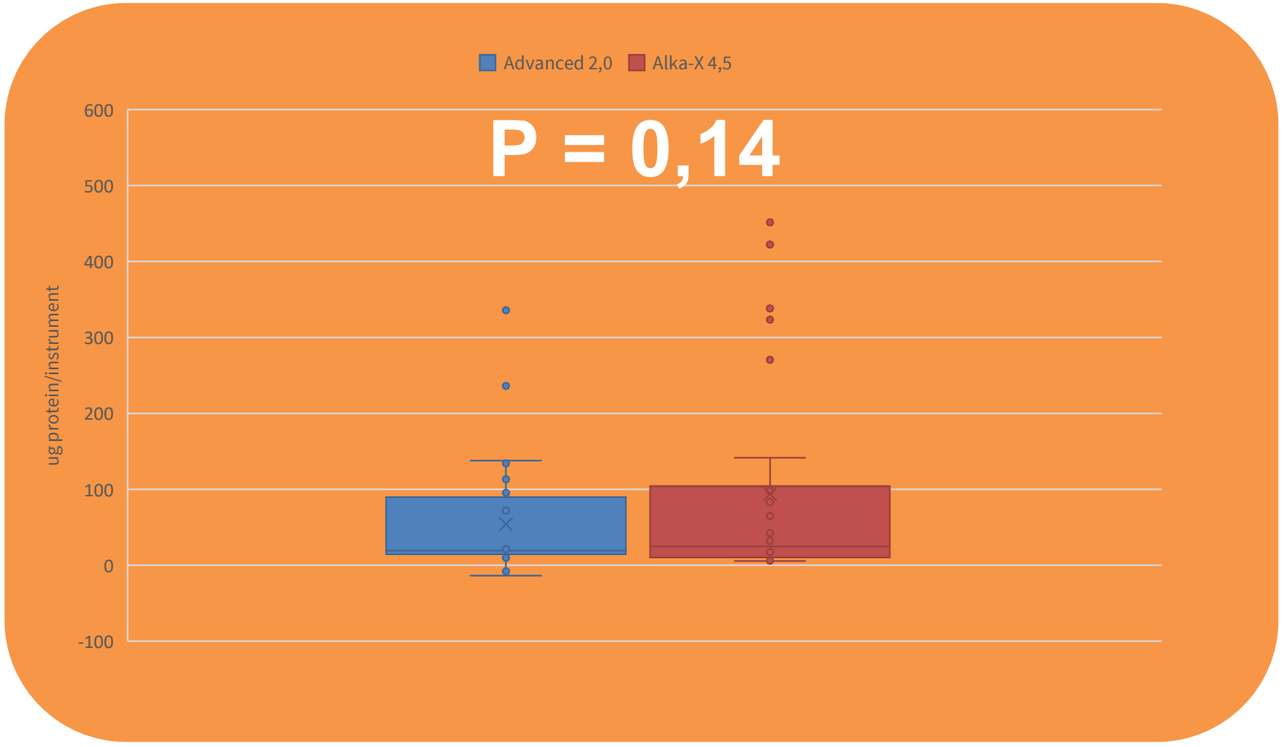
Changing detergent





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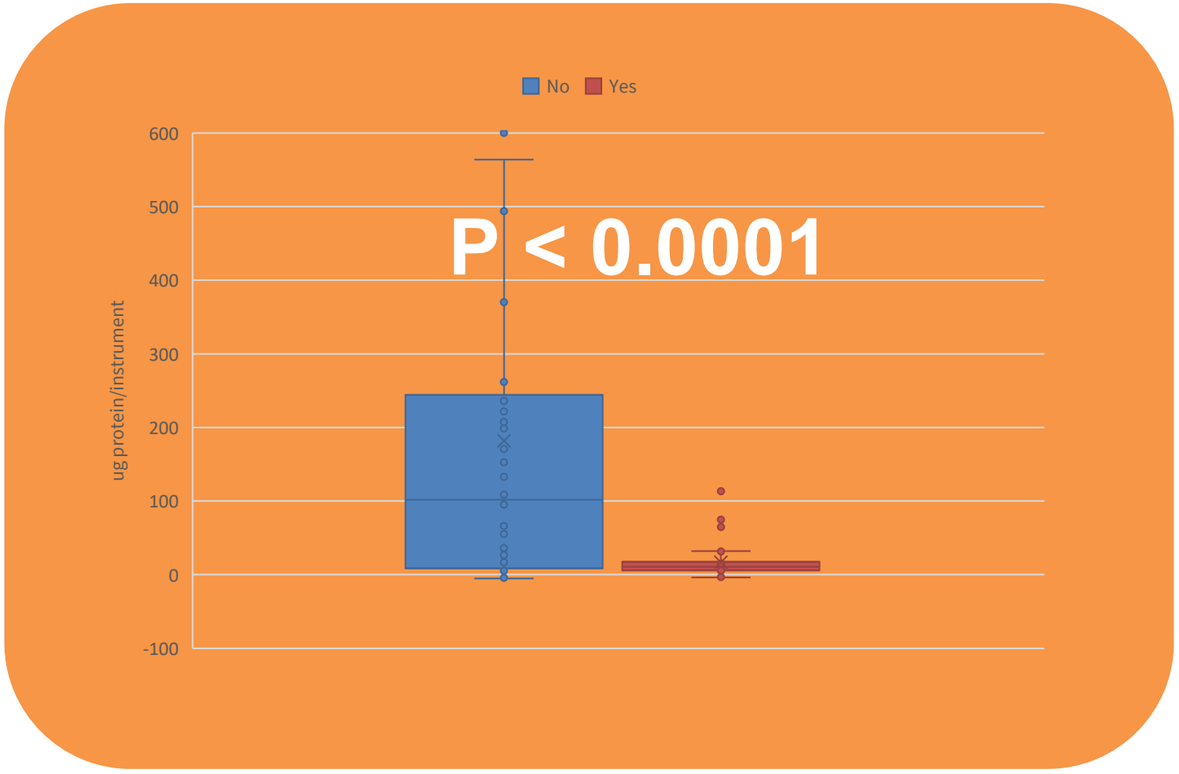
Ultrasonicating the instruments





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Setup of validation process

OR

CSSD

Clean area



30 sec



4 min



3 baskets per shelf



MediClean - Advanced

Setup of validation process

- Washer-disinfectors (WD): 6
- Washer-disinfectors rack: 4 types
- Validation runs per WD: 12 (3 runs for each rack type)









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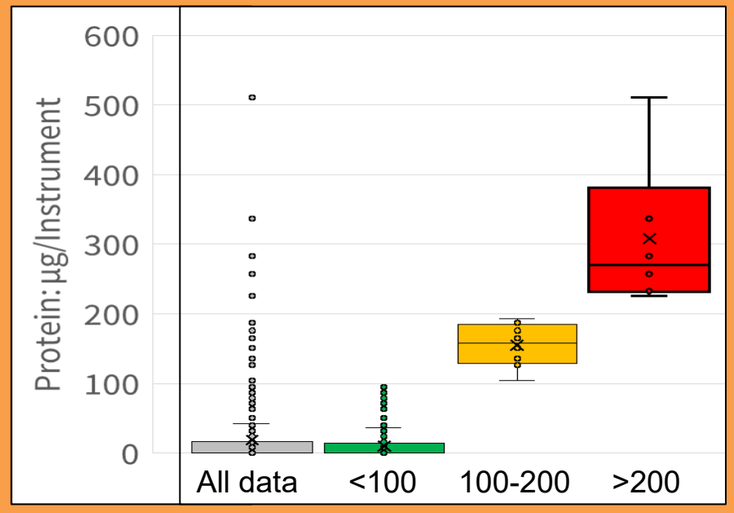
Setup of validation process

- Contamination: Real-life instruments used at OR
- Detergent: MediClean – Advanced
- Protein residue tests: Minmum of three instruments per run



Results from the validation process

	Total	Acceptable < 100	Alert 100 - 200	Not acceptable > 200
Instruments n, (%)	398 (100%)	380 (95%)	12 (3%)	6 (2%)
Protein: Median (Range) [µg/Instrument]	0 (0-511)	0 (0-97)	158 (104-193)	270 (226-511)



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Influencing factor



Dato	Vaskemaskine nr.	Cyklus nr.	SDS fremstillet	Kørselsnummer (1-3)	Vaskeindsats	Test instrument nr.	Last nummer	Placering af instrumentnet	Placering af testinstrument	Placering af testinstrument i nettet	Antal instrumenter	T-DOC Produktnummer	Produktnavn	Serienummer	Enhedsnummer	Instrumenttype	Producentnavn	Producentnummer	Instrumentgruppe	Testresultat resprotein (µg/instrument)	Bemærkninger			
31-03-2025	4	151	10-10-2024	1	MIS	1	1		Ø 6,0mm nozzle, radial jets, closed								STRYKER DANMARK		4	511	Kørsel ikke godkendt, da der er et beskidt bor i Gammakassen. Ved udtag af frossen prøve ses bundfald i glasset			511
22-04-2025	6	335	1% solution pH 11	2	MIS	1	2		radial jets, closed			2894	DHS INSTRUMENTER	123A-1	1221505	T-Håndtag Quick-Kobling 120 mm DHS/DCS	Depuy Synthes	338.080	3	337	Kørsel ikke godkendt, da der sad noget skidt i en pincet. Denne var ikke et af testinstrumenterne.			337
31-03-2025	5	155	10-10-2024	1	DIN 3 (Høje)	1	2	3-AD	Eget	A	16	3792	GAMMA 3-SYSTEM 1	75B-1	1201846	Bor AO-Kobling Ø 4,2 x 300 mm Grøn Gamma	STRYKER DANMARK	1320-3042	4	283	Synlig forurenet da den lægges i SDS væske. Ved udtag af frossen prøve ses bundfald i glasset			283
26-03-2025	5	152	10-10-2024	1	DIN 5	1	1	5-AD	Eget	A	38	244	LAPAROSKOPI 2 A-OP	3A-2	1197950	Inderdel Tang Atraumatisk Fenestreret Laparoskopi Ø 5 x 330 mm	Richard Wolf	8393.181	4	257				257
29-04-2025	4	197	SDS væske 1% solution pH 11	1	MIS	3			Plug-in med silicone guards ø				TEM 14A-1	14A-1	1220132	Tang Fatte Monopolar Lige Højre Ø 4,6 x 405 mm	Richard Wolf	8840.623	4	233				233
30-04-2025	6	356	SDS væske 1% solution pH 11	3	MIS	1	1		Plug-in med silicone guards ø 5mm			3074	SYNTHES KABEL FØRERE	41A-1	1225378	Kabelfører Krum Stor 300 mm	Synthes	391.107	3	226				226
26-03-2025	4	150	10-10-2024	1	DIN 3 (Høje)	3	2	2-B	Test	B	43	2183	FØDEKASSE	6E-1	1182531	Nåleholder Lige MAYO-HEGAR TC 200 mm	Medicon	10.18.70	4	193			193	
19-06-2025	2	114	SDS væske 1% solution pH 11	1	MIS	1	1		Ø 2,5mm nozzle, radial jets, closed			2456	HALL 50 O-OP	27H-1	1274500	Wire Driver Kanyleret Ø 0,7-1,6 x 80 x 145 mm Hall PowerPro	NN	PRO6228	6	190	Omkørsel da kørslen før denne gav fejl. Der blev observeret en kortslutning/lysglimt over lågen før		190	

Factors that could influence the cleaning results:

- WD nr.
- Type of washing rack
- Instrument placement in washing basket
- Type of instrument

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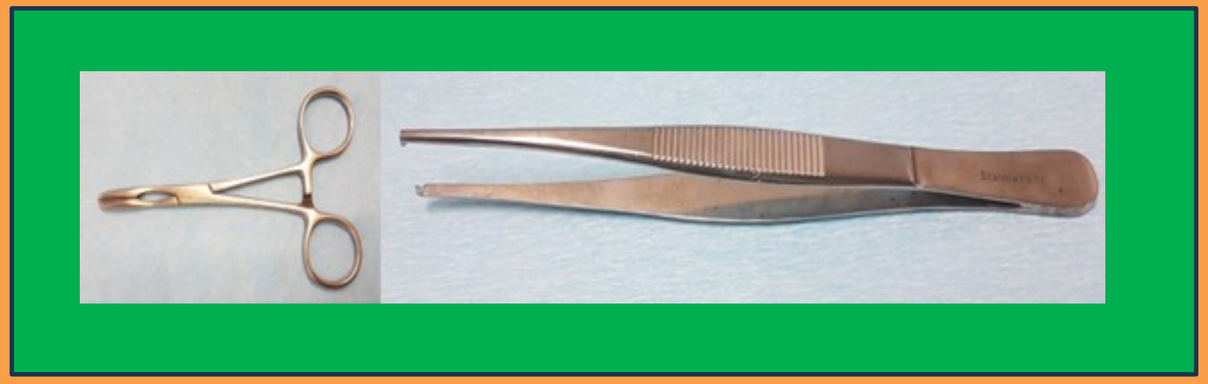
Results from the validation process







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Take home message

- Close collaboration between CSSD and research leads to:
  - Fast analysis of samples
  - Improved interpretation of results
  - Faster and more reliable validation process

- Examine only one parameter in the cleaning process at a time

- *“Real readiness for validation comes only after having completed one”*

Mette Hald Clausen



Acknowledgement

- Karin Mikkelsen
- Mette Hald Clausen and Diana Axelsen
- Mads Tanggaard Okholm and Thomas Rendal
- Hospital Administration on Aalborg University Hospital

Thank you for the attention

Questions are welcome

