

Residual Protein Check in MIC-Instruments





Project-Team

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State Hospital Klagenfurt

28	Departments
1.500	Beds
35.000	Operations per year
450.000	Ambulant treatments p.a.
78.000	Stationary patients p.a.
4.300	Employees



Central Sterilization Supply Dept. (CSSD) State Hospital Klagenfurt

25 Employees

- 6 nurses
- 19 sterilization-assistants



**Conditioning of in total 100.000 sterilization units p.a.
thereof 1.200 instrument tabs for
Minimal Invasive Surgery (MIC/MIS)**



Aim of study

To find a method to detect residual protein amounts after conditioning, cleaning and (chemo thermal) disinfections of minimal invasive surgical instruments, which can be used routinely in high-throughput sterilization plants.

Initial consideration

Despite of optimized

- conditioning
- cleaning and
- disinfection

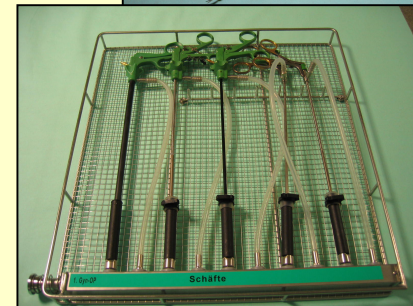
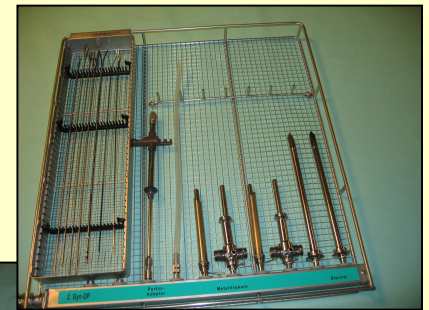


not any possibility of residual protein
amounts within MIC instruments can be
eliminated

Critical factors

Composition of instruments

- Many single components
- Narrow lumen
- Partly steep angles/strongly bent
- Diverse materials
- Complex conditioning and cleaning process



Projekt Set – up (1)

Selection of Operation tabs and respective MIC Instruments

Gynecology, Urology,
Common medical
Surgery

Conditioning / Pre-cleaning of instruments



Decision of evaluation pre or post thermo-disinfection in the Miele washing machine

Projekt Set-up (2)

Evaluation of the following test methods

Pro-**test**® M

Sep. 06 to Nov. 06



BCA TM Protein Assay Kit

Dez. 06 to Jan. 07



Miele Test Kit

Feb. 07 to Mar. 07



after thermo disinfection and drying

Pro-**test**® M



Method:

Semi-quantitative
Wipe test

Pro:

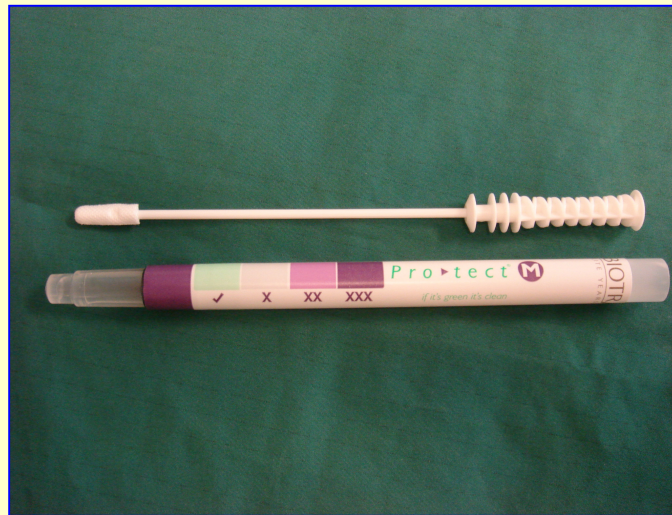
Easy to use

Con:

Not able to reach all surfaces of the instrument due to geometry of the detection system (thick and short)

Cost:

Expensive



BCA TM Protein Assay Kit

Method:

Semi-quantitative

Wipe test

Pro:

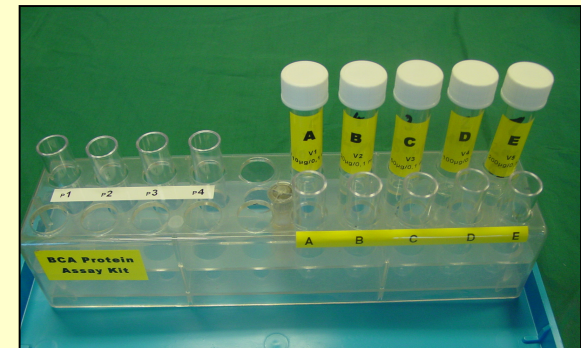
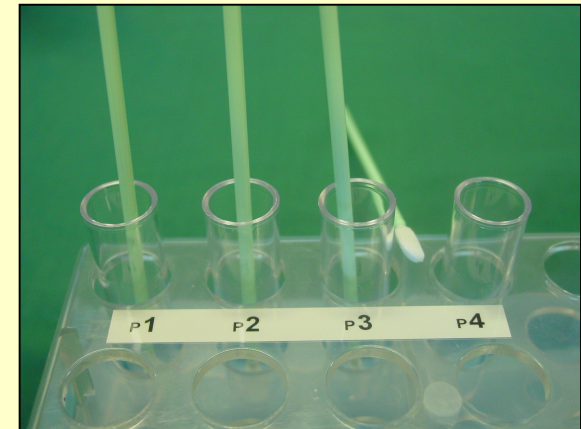
Easy to use

Con:

Not able to reach all
surfaces of the instrument

Cost:

Cheap



Miele Test Kit

Method:

Semi-quantitative and quantitative
Wash-test with optional
subsequent photometric detection

Pro:

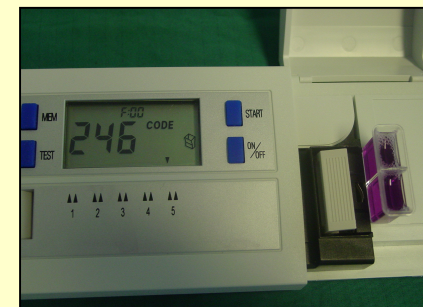
Semi-quantitative and exact
quantitative detection possible

Con:

Very time-consuming

Cost:

Expensive



Result (1)

	#	K
Pro-TECT M	436	0,71
BCA Test	368	0,91
<u>Miele Test Kit</u>	<u>364</u>	<u>0,50</u>
	1.168	

Each Instrument was checked with each of the three methods in min. 21 time and in max. 44 times. These differences are statistically not relevant ($\chi^2=21,6$; $df=22$, $p=0,485$)

#.....Amount of single tests performed (excl. double testing)

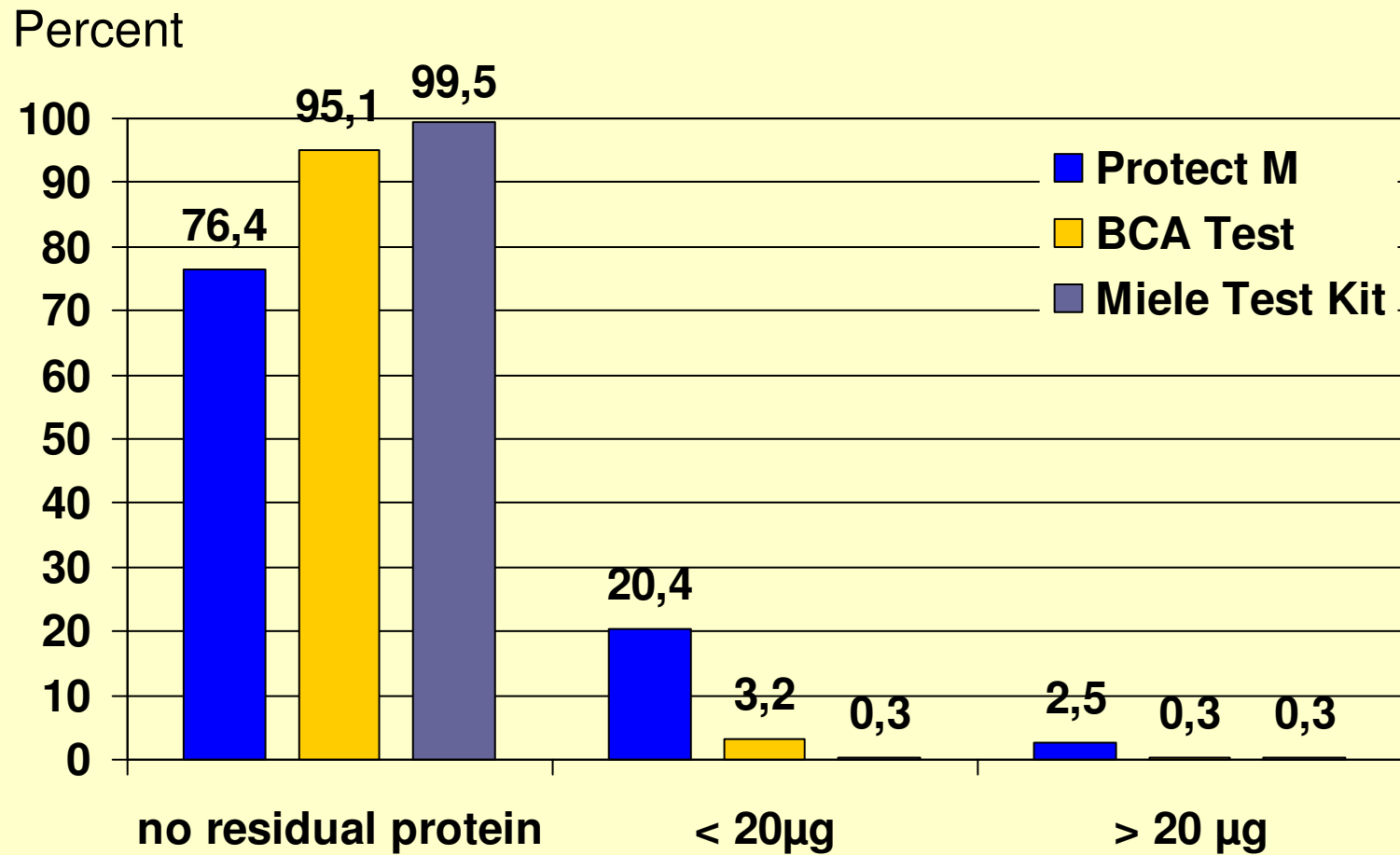
KJudgment Compliance / Inter-Rater-Reliability

740 Double tests performed

96,6% have given the same results

3,4% showed a variation of one single category

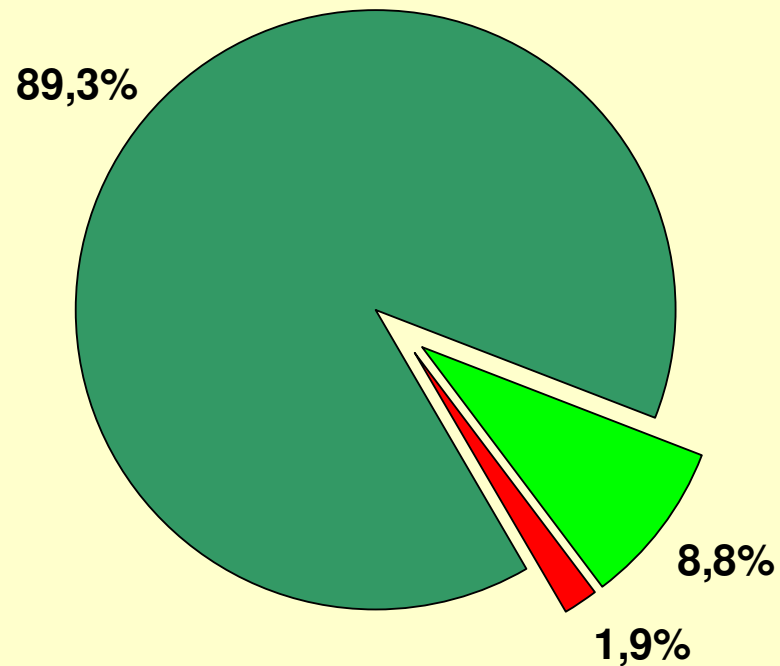
Result (2)



Result (3)

Total Residual Protein

- no residual protein
- < 20µg
- > 20µg



Result (4)

Instrument with the highest amount on residual protein

Portioadapter (Gynecology)

	no protein	< 20µg	>20µg
Protect M	35,1 %	37,8 %	18,9 %
BCA	62,8 %	25,6 %	11,6 %
Test Kit	95,2 %	2,4 %	2,4 %



Conclusion

Out of the three test methods performed

BCA TM Protein Assay Kit

has turned out to be the most appropriate method for routine testing

Reason:

- Set up of the method
- Cheap
- Best judgment compliance as far as the repeat determination is concerned

The other two test methods show drawbacks especially as far as the criteria “cost” and “easy to use” are concerned.



Summary (1)

Unique project

- Sound statistical evaluation of various semi-quantitative and quantitative test methods
- Testing performed during routine operation of a validated and ISO-certified high-throughput sterilization plant
- Implementation of a practical, reliable and economically reasonable lab test method
- Scientific support by
 - FH Technikum Kärnten, University of Applied Sciences
 - Alpen Adria University Klagenfurt



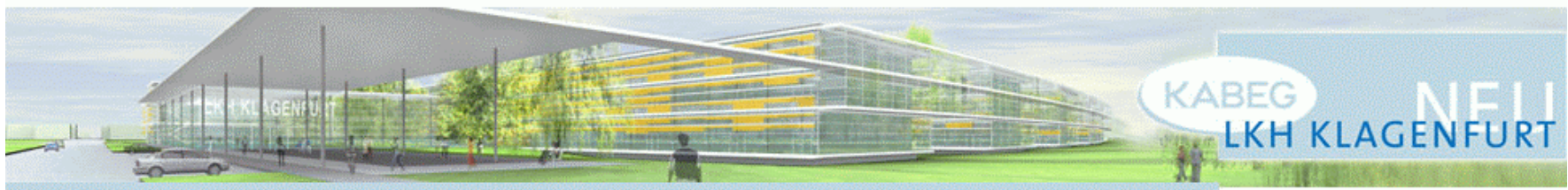
Summary (2)

The State Hospital Klagenfurt has laid the foundation for achieving an optimal result quality by implementing a Quality Management Systems and by getting validated and certified according to MPG.

Optimal Result Quality contributes considerably to the safety of patients and users.

Simplified – easy to use – residual protein test methods will be integrated in future **SPC (statistical process control)** steps and thus contribute essentially to the **optimization of overall processes**.

Many thanks for your attention



Backup slide

Proposed process:

- *Routine residual protein check* – once a week / min. each seconds week for each washing machine
- *Periodical conditioning and pre-washing* - each 3 - 6 months
- *Handling and maintenance of MIC instruments* - according to manufacturer instruction (EN 17664)
- Pre-washing / conditioning of critical MIC instruments with complex design.

Tips for Industry:

- Already prepared reference solutions
- Various model variations of the test system itself
- Complete test equipment (test kit plus test block for samples and instruments....).
- Handling information video ,