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Innovative Decontamination Solutions

The story behind the development of new Process Challenge Devices for evaluation of cleaning efficacy

Part 1 - Rising from chaos

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Wider Environment

The recent changes in guidance (HTM 01-01) are shifting the gravity of importance in decontamination of surgical instruments towards physical removal of contamination or as we simply call it – cleaning. Moreover, there is a long-awaited change in approach to process verification emphasising the quantifiable result rather than the process itself (Pawel de Sternberg Stojalowski wrote about this unfulfilled need in "Process versus the result" in February-April 2014, Vol. 18, No.3 release of the Journal). All these changes, together with the guidelines for the statistical analysis of results over time, still leave a lot of ambiguity about the method itself and provide sterile services professionals with almost as many new questions as answers. That is mostly due to the fact of how aforementioned documents approach the methodology of protein detection because, as in many other cases, here also theory does not translate into practice very well.

At Aseptium, we develop and manufacture cleaning and disinfecting equipment for complex surgical instruments. All our new technologies are born out of the need for more effective and efficient reprocessing of complex instruments with the core principle at heart that every innovation must be grounded in science and verified by evidence. Today, technology allows us to do wonders with Computer Aided Engineering where components are designed as 3d models and can be virtually tested with Finite Element Methods on structural stress and fluid flow. These methods are essential when it comes to rapid evaluation and optimisation of processes. That is how all our new spray arms and internal cleaning system were optimised to deliver uniform coverage of the entire chamber volume, as well as flow and pressure of the flushing system for lumens – the theory box was ticked and we got to the point of testing it in practice. That is where we have come across the age old question: what do we classify as a success? Or how effectively does the new system actually clean and how uniform is it across the washing chamber? We were looking for a solution that would allow us to map cleaning performance in the chamber as well as internal cleaning of lumens of few standard sizes – 1mm, 2mm and 4mm (based on ISO 15883). In essence, we needed a quantifiable, accurate and fast testing method for our new washer.

Exploring the current guidance (HTM 01-01) the "old methods" of swabbing and testing the residues with Ninhydrin were replaced with – well that is where it gets a little bit more complicated – other methods currently developed. Interestingly, while there is evidence on swabbing being insufficient in desorbing contamination from the samples based on the studies of Nayuni et al. (2013, 2013) and Lipscomb et al. (2006) the HTM 01-01 also mentions elution as an ineffective method. However, the latter is not directly backed with evidence. Whether it is through swabbing or elution, an additional step is introduced through desorbing or diluting contamination from surfaces onto swabs or into a liquid that in turn are tested for residual protein. Because this additional step of swabbing or dilution will be performed with some unknown degree of effectiveness and will vary from one test to another, it makes the method questionable in terms of effectiveness and repeatability. When the modus operandi of detecting below 5ug of protein per side of the instrument is taken into the account the HTM 01-01 guides us towards photo-fluorescence methods championed by ProReveal from Synoptic Health. These seem to offer in-situ, accurate, quantifiable results measured directly on instruments so – on paper – they fit the bill perfectly.

Guidance mentions the need for development of new methods for residual protein detection and highlights the possibility of using process challenge devices to simulate contamination on surgical instruments to perform daily and weekly testing. That seemed like a reasonable idea – develop a range of process challenge devices. Here we will attempt to explain the reasoning as well as the experiments we have performed, and lessons we have learned during the process.

The concept

The initial idea was to create process challenge devices that we will be able to use for testing of the internal and external cleaning that will represent the realistic challenges in cleaning of complex surgical instruments as closely as possible.

We knew from the start that this undertaking will be divided into different experiments that combined will build a product. Our evaluation philosophy was (and is) catered to complement the product development process. At times this may seem "non-scientific enough" to the purists, meaning that we would not continue an experiment if we saw the results were inconsistent beyond our experience and expertise. So far, in each case after investigation we found a reason why things did not work as anticipated. Regardless of the fact that this is more of a story of process challenge device development rather than a scientific study, we believe many lessons can be learned from this endeavour.

The main challenges were divided into three main sections: design of the process challenge device, identification of test soil for inoculation and identification/development of evaluation methodology. We also had to build a dedicated washer disinfector that would allow us to perform all the necessary steps.

Process Challenge Devices (PCDs)

The idea was to create a range of Process Challenge Devices (PCDs) to test for different cleaning conditions, like vertical and horizontal surface cleaning, which can be adopted for chamber mapping, shadowing effect, narrow gap cleaning like in the case of box joints and lumen cleaning. Ideally, we wanted to have common shape samples that could be used in conjunction with accessories to create conditions mentioned above.

The overarching concept was to create samples or "tags", as we call them, which would be inoculated with a known quantity of test soil. These would be used to simulate real surgical instruments and evaluated using methods allowing for quantification of test result. Edinburgh Test soil was to be used as a reference test soil used to benchmark different methods and cleaning conditions and also other test soils. Quantification of result was a critical condition that beyond giving the simple pass or fail answer would allow us to spot trends and analyse data in a much more comprehensive way.

When it came to the tags themselves, we took several factors into account: the size and overall shape, materials used and surface finish. These tags were intended to be multifunctional, therefore we had to take different possible uses under consideration and also reflect on the ways these will be evaluated for the residual contamination. Material choice and surface finish have

proven to be a much bigger challenge than initially anticipated. The obvious, go-to material was 316L stainless steel but beyond that we wanted to also use one of the plastics commonly used in construction of surgical instruments. After allowing for material mechanical properties and manufacturing costs we have settled with Acetal C.

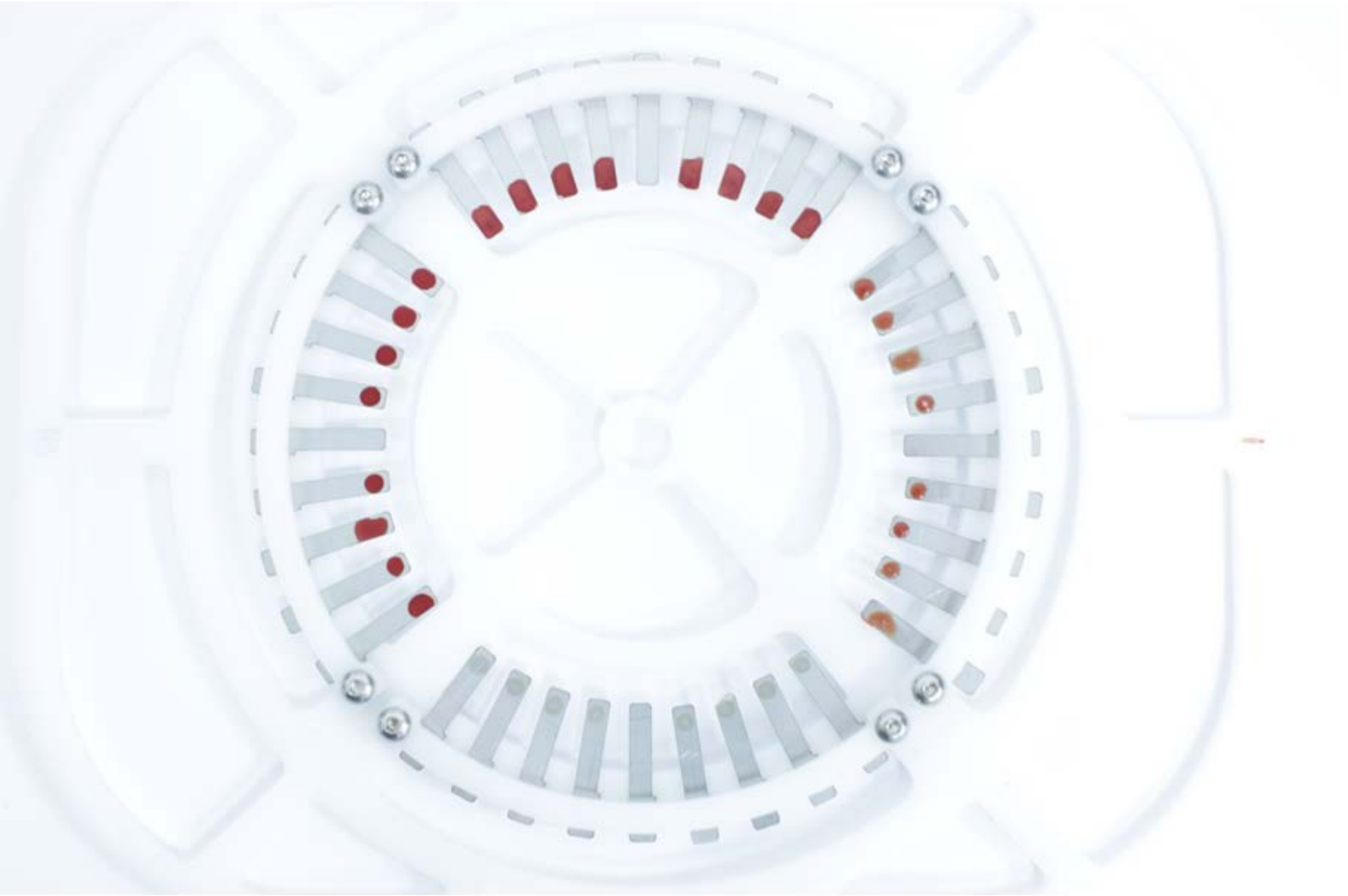
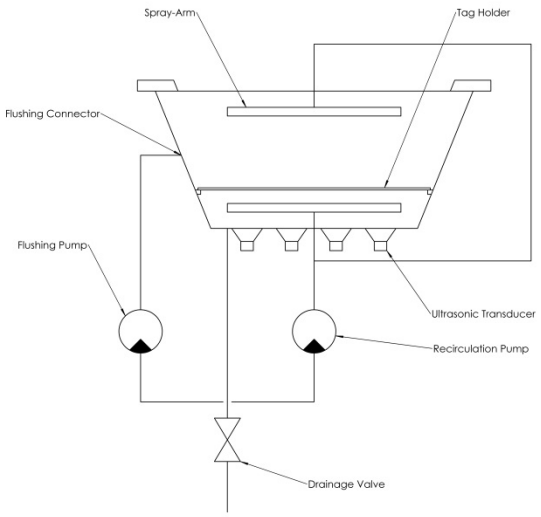


Photo 1: Bespoke tag holder with inoculated tags.

It soon became obvious that we would have to build a bespoke washer disinfector in order to be able to run experiments quickly and efficiently, since testing of such small tags in a full size machine would consume a tremendous amount of water and chemicals. We have, therefore built an experimental washer disinfector with the chamber capacity of 12 litres. The machine is equipped with two spray arms – one on the top of the chamber and one on the bottom, recirculation pump, flushing pump for internal cleaning with two connection ports in the chamber, heater and a bank of 6 ultrasonic transducers delivering 300W of power to the chamber. The washer disinfector was designed in such a way that we could simulate different modes of cleaning



Schematic 1: Experimental washer-disinfector.

separately, which means that the machine could run spray arms, flushing and ultrasonics independently. This particular arrangement allows testing of different cleaning mechanisms in the same piece of equipment. Water consumption is 1 litre of water per stage during spray arm cleaning and 10 litres during ultrasonication. The machine is filled and drained manually and chemicals are also added manually with a syringe.

We have also designed a dedicated holder for the tags, which sits directly underneath the top spray arm. Design was such that 36 tags are positioned in a circular pattern with centre axis being collinear with the spray arm axis. This way spray arm jets were equally covering every tag allowing us to test 36 tags simultaneously.

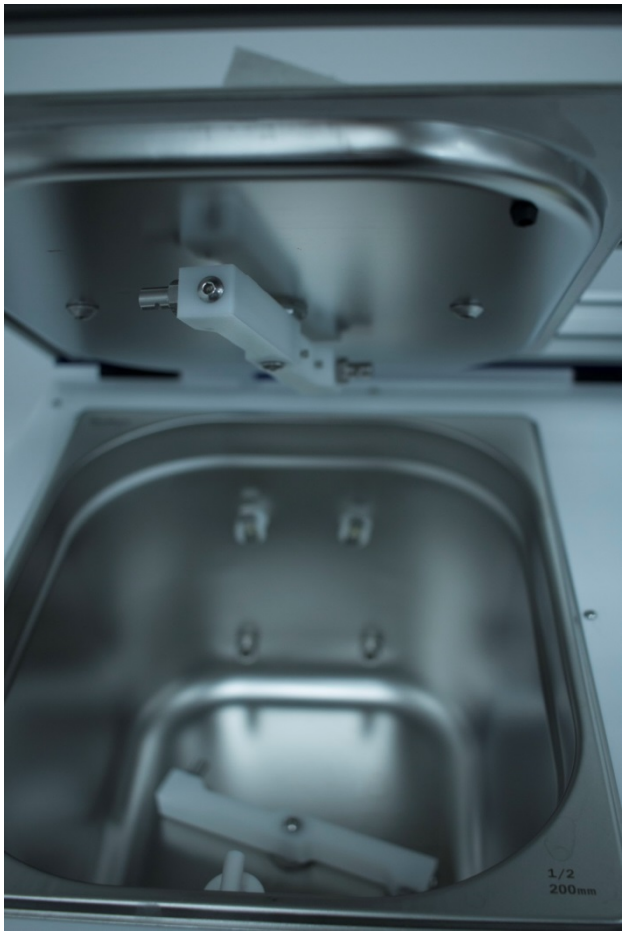


Photo 2: Experimental washer-disinfector.

Evaluation methods

Following the UK guidelines we have chosen fluorescence methods and managed to borrow a ProReveal (Photo 3) from Synoptic Health, as this is the only technology currently available that offers almost immediate answers, quantifies and visualises results with very high accuracy. Most importantly, the results are measured directly on samples, which allows us to compare results with ease. This in conjunction with a small fast washer and careful planning means that we are able to perform several tests per hour.

Photo 3: ProReveal.

Initial process development

The design of the process aimed at identifying process variables that would result in around 5ug (Figure 1) of contamination remaining on the tags – a borderline pass/fail condition on the ProReveal – this way it would be possible to easily visualise any differences resulting from surface finish of the tags, soils, soil drying times, etc.

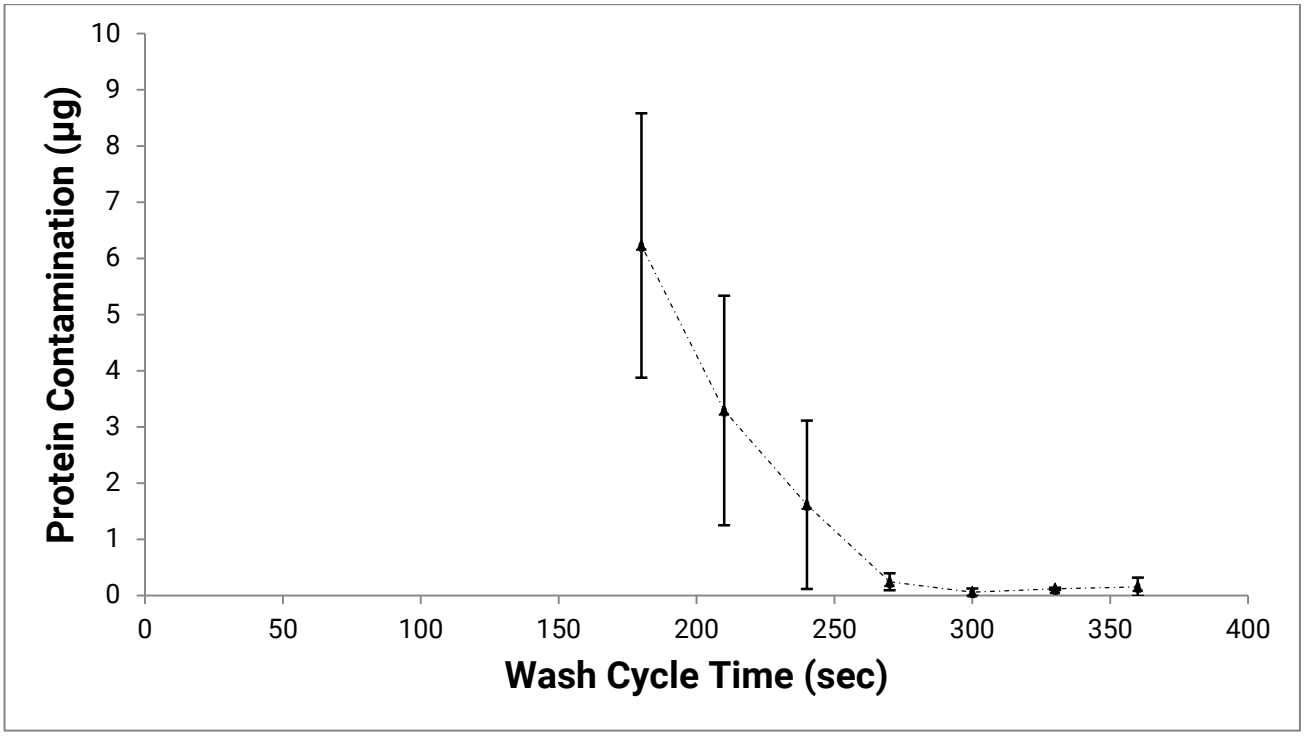


Figure 1: Process performance optimisation. Cleaning effectiveness with different wash cycle time. 7 different cycles were run: 180, 210,240, 270, 300, 330 and 360 seconds. Each point is the average contamination of one tag (run with 4 replicates and n = 4).

For all preliminary tests we have chosen Borer Chemie 23-Neutrazym X as our washing chemical. After running over 50 cycles we have identified a satisfactory cycle profile to include:

- Pre Wash - 1.5min, cold (cold mains water *)
- Main Wash - 4min at 45C^{o} with 10ml/l Borer Chemie 23-Neutrazym X
- Rinse - 2 x 0.5min, cold (cold mains water*) Rinse

*Cold water temperature was between 18C^{o} and 21C^{o}.

We have optimised the methodology, where we prepare the water at desired volume and temperature, to the point where we can run 2 to 3 tests per hour.

Surface finish of the tags

One of the first research questions was to look into whether surface finish on different materials affects adhesion of the soil to the tags and how it relates to the cleaning effectiveness. For this experiment we have prepared 12 tags (6 made out of 316L stainless steel and 6 made of natural Acetal C). Individual tags were wet sanded with 600, 800, 1200, 1500 and 2000 grit sand paper to

achieve different surface roughness. One tag was left unprocessed in the cold rolled 2B finish (same finish as the sheet it was cut from). Natural Acetal C is of a white colour and comes as a gloss finish. Respectively Acetal tags were wet sanded with the same grit sand papers.

Once prepared, each tag was inoculated with 3x 5µL of Edinburgh Test Soil using a manual pipette.

Such prepared tags were processed in the washer-disinfector. Preliminary results from the test of the stainless steel tags approximated from the visual display on the ProReveal are presented in the table below.

Surface	**Contamination**[µg]
Not processed	15
600 grit wet sandpaper	6.3
800 grit wet sandpaper	9.4
1200 grit wet sandpaper	6.2
1500 grit wet sandpaper	15.3
2000 grit wet sandpaper	14.2

Table 1: Preliminary data Edinburg Test soil after washing process on different surface roughness.

There is a visible difference between the samples, although more testing is required to understand the results better. We will also need to test a more coarse as well as polished finishes to identify the worst case scenario but one thing is certain – all of those surface finishes are used on surgical instruments.

You are probably wondering what were the results of the same experiment on the natural Acetal. Unfortunately natural Acetal C is one of those materials that reflects ultraviolet light and is incompatible with epifluorescence protein detection methods (Photo 4). That only proves that so far there is no one method that we can use to directly measure contamination of the instruments – more research and development is needed in this field.

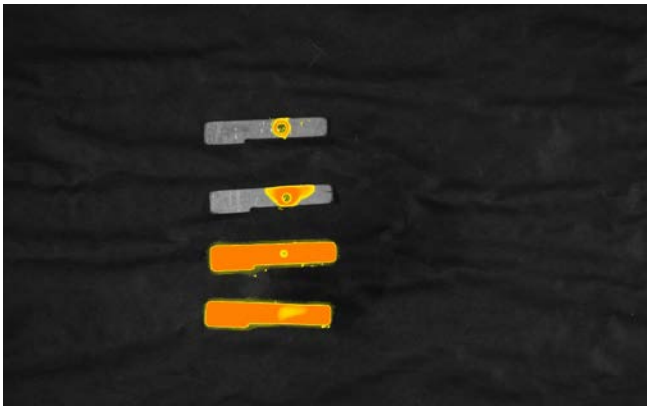


Photo 4: Stainless steel and natural Acetal C tags in ProReveal.

We have identified plastic materials that can be used with this method so this experiment will be repeated in the future to give a more complete answer.

By the time of writing, we have run over 100 cleaning cycles identifying different problems and cleaning conditions. A number of cycles were interrupted initially because of mechanical failures, like slowly spinning or non-spinning spray arms, blocked spray arm nozzles resulting from debris and contamination being recirculated in the system. Spray arm design was being optimised during initial stages of the project so that behaviour was expected. Once optimised, we were very impressed by the performance of this little experimental machine and the Chemistry from Borer Chemie AG. In conjunction with the quick results from the ProReveal we were able to respond to problems with agility and solve them immediately.

Interestingly, the failed cycles, especially in the case of non-rotating or intermittently stopping spray arms, when visualised on the ProReveal gave, immediate answer to the nature of the problem making it a very useful troubleshooting tool. The caveat is that one has to understand the design and processes well to be able to draw correct conclusions.

At the very early stage we identified that even at considerably longer cycles (15min main wash with 10ml/l 23-NeutrazymX detergent at 45degC) we were getting poor results (failing the 5ug limit per one side of the tag). It was especially prominent when a larger number of tags were reprocessed at a given time. We started placing clean tags together with the inoculated ones to eliminate the problem with the evaluation method, and that allowed us to identify the source of contamination. It was the diluted test soil that was circulating in the system that could be also found on the previously clean samples (Photo 5). The problem was resolved with addition of further rinsing stages. It does, however pose a question whether cross-contamination between tags, or instruments, which the tags represent, can be reduced by simply adding more rinsing stages; especially, if internal cleaning is performed with the same water.

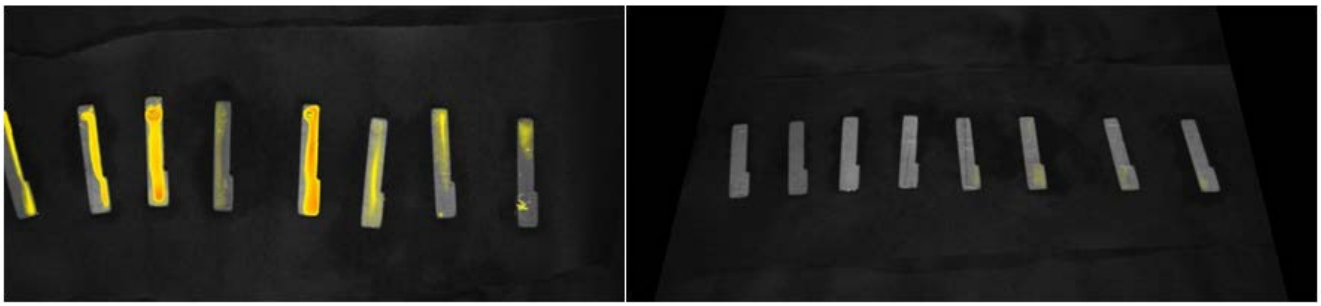


Photo 5: Cross contamination of samples during washing.

Conclusions so far

Overall, most of this early stage research still brings more questions than answers. However, it is certain that the family of process challenge devices we have created allows us to research different cleaning conditions and challenges looking for the worst case scenario.

We have known from the beginning that agility will be responsible for the success in this experiment and thanks to the experimental washer we have built paired with the ProReveal system

we were able to adapt to the changing conditions and gather substantial amount of data in a very short period of time.

In relation to the surface roughness of the tags it will be essential to compare a wider range of samples including mirror polished and electro-polished surfaces to have a more complete answer since both finishes are commonly used on instruments. Same methodology will be allied to the plastic samples.

We have already performed comparison studies of different test soils and different drying times. That part of the research will be presented in the next issue of the Journal.

One thing is without doubt – results clearly demonstrate how big and complex the problem of evaluation of instrument cleaning effectiveness really is. To be continued.

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