Consultancy Report

Tamper evidence assessment

Prepared for Versapak International Limited

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Commercial in confidence

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1 Background

Versapak have produced a new doping control kit which is designed to accommodate the test sample within a standard 'Vacutainer'. The canister is designed for single use and includes tamper evident features to indicate unauthorised access and substitution of the test sample.

2 Objective

To assess the level of tamper evidence provided by the doping control canister.

3 Samples supplied

A total of approximately 30 canister components (body and closure) were supplied for testing.

Figure 1 – Test sample components and a 5.0ml Vacutainer

4 Programme of work

The security of the doping control kit canister was evaluated using a range of physical and thermal techniques. These were limited to a window of opportunity of 1 hour and the use of non-specialist equipment.

4.1 Tamper assessment

The resistance of the canister to tampering was assessed by attempting to violate the Vacutainer contained within the canister. The tamper resistance was referenced to the time taken, product knowledge and sophistication of tooling required, together with the ease of detecting the violation.

4.2 Opening assessment

The robustness of the tamper evidence features were evaluated by investigating the opening performance of the canisters at freezer
(-20°C), ambient (23°C) and elevated temperature (80°C*).

** Just below temperature which caused material distortion*

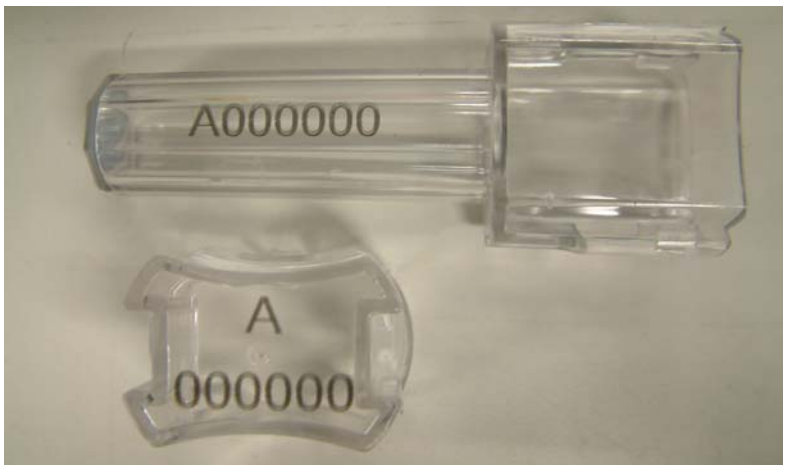
5 Canister review

The Versapak doping control canister is a single use canister designed to house a single Vacutainer. The canister is comprised of three parts; a canister body and lid, which are joined together by latching features and a grey cap insert. Inside the canister lid, the grey cap provides an additional layer between the Vacutainer and the canister lid. After the canister has been closed, access to the sample Vacutainer is gained by removing the lid of the canister, which causes the latches to break, preventing reclosure. The key tamper evidence features of the canister are listed below.

5.1 Serial numbered canister components

The body and lid of each kit are labelled with corresponding identification numbers as shown in Figure 2 below. The serial numbers prevent substitution with parts from other kits and ensure traceability of the samples.

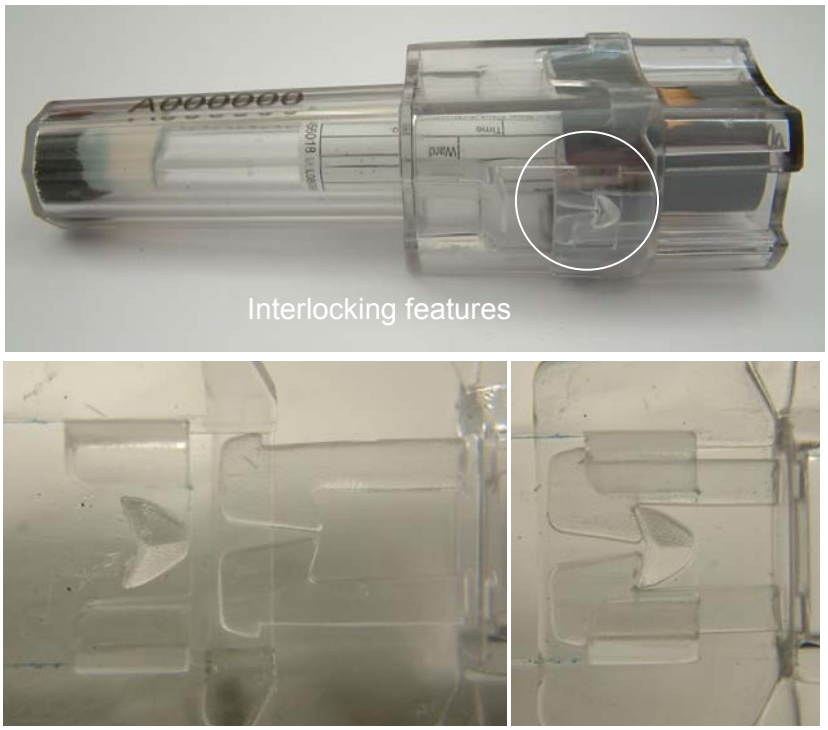
Figure 2 – Serial numbers present on canister components



5.2 Double latching interlocking features

The canister components lock together using two pairs of double latching interlocks features – one pair located on each side of the lid. The latches align with corresponding features in the body of the canister and incorporate twisting interlocks at the centre of each pair and bending elements located on the outside. The location and appearance of the latches are shown in Figure 3 below.

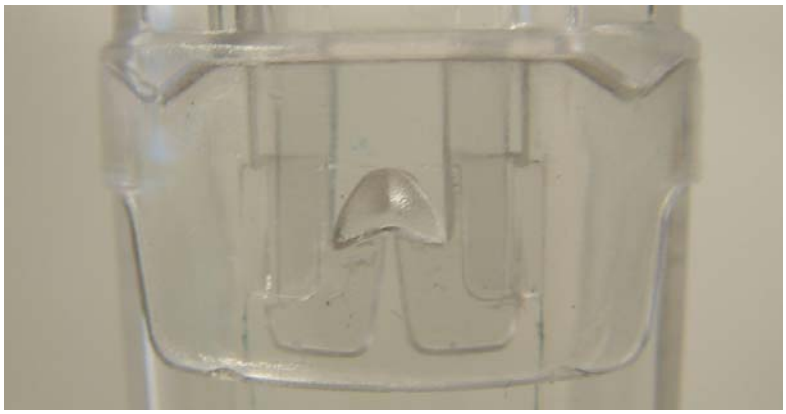
Figure 3 – Latching interlock features (top), before (bottom left) and after closing the canister (bottom right)



5.3 Shrouded interlocks

The canister lid incorporates a hood which extends as far as the interlocking features. When the lid is attached to the body of the canister, the interlocking sections of the lid and canister body are effectively shrouded by the lid's hood.

Figure 4 – Interlocking features covered by the lid



6 Test methods

The security of the Vacutainer inside the canister was evaluated using the following techniques.

6.1 Tamper assessment

Tampering resistance of the canister was assessed and reported as the ability to undetectably tamper with the contents of the canister. The level of sophistication or complexity of the technique together with the approximate time required to perform the violation are reported.

6.1.1 Code alteration

Attempts were made to alter the security code found on the lid and the side of canisters by removing the original code using emery paper. The surface was then polished and a new code substituted using permanent ink. This simulates the substitution of a sample into an alternate, re-numbered canister.

6.1.2 Open and repair

The canister was conventionally opened and then repaired by using solvents to reattach the broken latches. The canister components were then reassembled. This simulates the substitution of a test sample by opening and repairing the original canister.

6.1.3 Concealed violation

Attempts to covertly tamper with the contents of the sample Vacutainer were made using a drill and syringe. Damage to the canister was then repaired/disguised to hide the violation.

6.2 Opening assessment

The opening performance of the canister was investigated at cold, ambient and elevated temperatures to ensure that the interlocking features break consistently to prevent any subsequent reclosure of the canister.

Canisters were assembled at 23°C and conditioned for at least one hour at the following conditions:

- -20°C
- 23°C
- 80°C

The canister was then opened by pulling the lid from the body of the canister at 300mm/min using a universal tensile tester. The opening force and type of damage were reported. Tests were performed on three canisters at each temperature listed above.

7 Results

The results of each evaluation are shown with respect to the ease of detecting the tampering, the sophistication/difficulty and the time required to perform the tampering.

7.1 Summary of results

The results are summarised in tables 1 and 2 below.

Table 1 – Canister security assessment

Technique	Ease of tamper detection	Tool sophistication / difficulty	Tampering time (minutes)
Code alteration	Easy	Low	10
Open and repair	Easy - Moderate	Easy - Difficult	5 - 60
Concealed violation	Easy	Moderate	20

Table 2 – Canister opening characteristics

Temperature (°C)	Mean opening force (N)	Failure mode
-20	264	All latches broken
23	291	All latches broken
80	181	All latches broken

7.2 Discussion of results

The results of each evaluation are shown below.

7.2.1 Code alteration

The serial numbers on the body and lid of the canister could not be credibly altered using non specialist equipment because the code is present throughout the thickness of the canister. Figure 5 shows the serial number is still visible after abrading the surface of the canister with emery cloth. This means that code alterations would be limited to using a substitute canister which had a similar character sequence that could be altered by script addition, for example: 0 → 8. Even then, the change is clearly apparent when the canister is viewed off axis.

Table 3 – Code alteration results

Code alteration	
Ease of tamper detection	Easy
Tool sophistication / difficulty	Low
Test time (minutes)	10

Figure 5 – Serial number remains visible after abrasion

7.2.2 Open and repair

The damage to the lid (small fragmentation of the latches) during removal made it's repair very awkward. However the broken latches could be replaced using solvent adhesives such as methyl ethyl ketone (butanone) or tetrahydrofuran. Figure 6 shows the

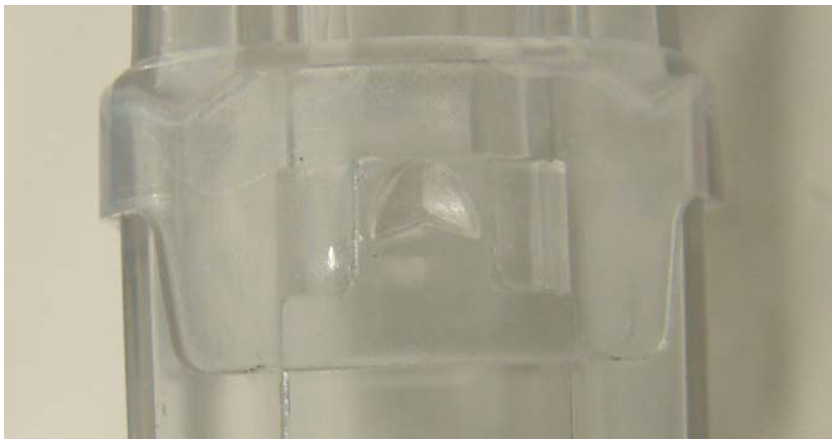
broken latches being replaced in their original positions. The solvents caused some visible whitening in the regions applied.

Figure 6 – Reattaching the broken latches, some whitening is visible in the bonded area

Based on a subjective assessment, the repaired canisters were noticeably easier to open than untampered canisters.

Alternatively, the lid could simply be glued back in place without repairing the latches, by applying solvent / adhesive around the rim of the lid and body of the canister as shown in Figure 7.

Figure 7 – Reclosed lid bonded to the canister body without repairing/replacing the latch features



This method of repair is considerably quicker and easier to perform but also more easily detected.

Table 4 – Open and repair results

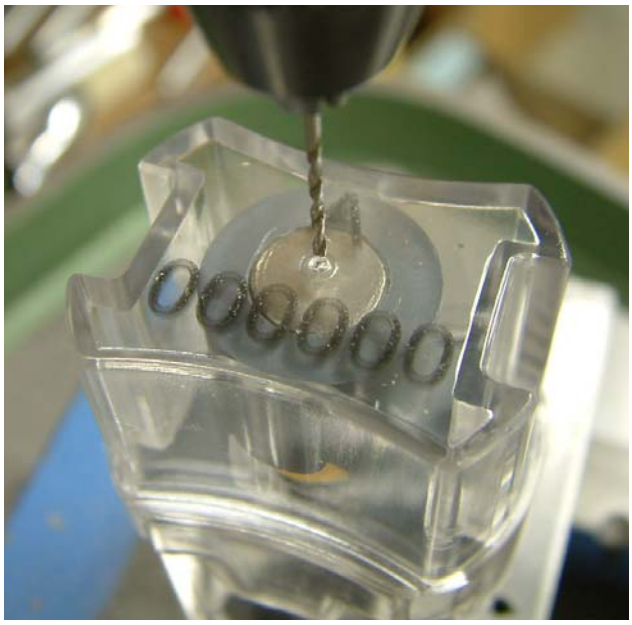
Open and repair	
Ease of tamper detection	Easy - Moderate *
Tool sophistication / difficulty	Easy - Difficult *
Test time (minutes)	5 – 60 *

** Dependant on the quality of the repair*

7.2.3 Concealed violation

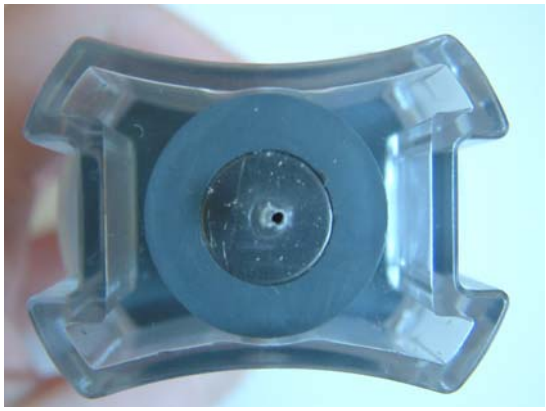
To gain access the sample Vacutainer, a 1mm diameter hole was drilled into the lid of the canister as shown in Figure 8.

Figure 8 – Hole drilled into the lid of the canister



The hole was made at the gate location of the mould cavity as shown in Figure 9. This creates an opening directly above the rubber cap of the Vacutainer.

Figure 9 – 1mm hole drilled in the canister lid



A needle fitted to a syringe can be passed through the hole in the lid and metal insert. The rubber cap of the Vacutainer can then be accessed allowing its contents to be altered, removed or replaced. This is shown in Figure 10.

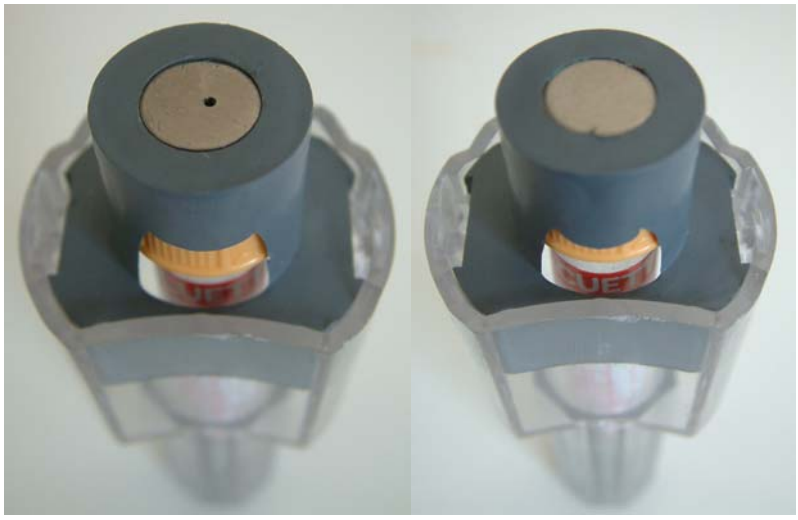
Figure 10 – Vacutainer contents violated

After violation, the hole in the canister lid was filled with grease or silicon sealant making the breach difficult to detect. Figure 11 shows a comparison between an untampered and repaired canister which at first inspection appear almost identical.

Figure 11 – Comparison of tampered and repaired canister (left), and untampered canister (right)

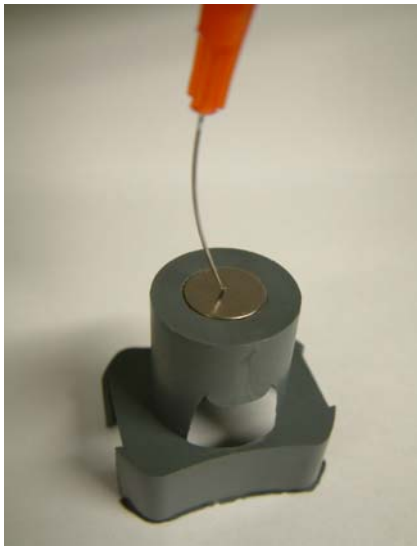
After removal of the canister lid, an inspection of the grey cap found that damage caused by the drill was visible.

Figure 12 – Comparison of untampered grey cap (left), and tampered grey cap (right)



In order to determine whether the ‘vacutainer’ could be accessed without drilling through the metal insert, a syringe needle was driven into the top of the cap insert. However, the metal inserts prevented access by bending the 25 GA1 0.5 x 25mm syringe needle as shown in Figure 13.

Figure 13– Metal insert causing needle to bend



Examination of the cap inserts revealed that inconsistent mould filling had occurred within the batch of sample supplied. This is shown in Figure 14, where support for the metal insert is not consistent when viewed from below.

Figure 14 – Variation in metal insert embedment in caps

Although the metal insert which is least embedded (left in Figure 14) could not be displaced by a syringe needle whilst assembled, it could be displaced easily by hand. If the insert became detached the sample would become vulnerable to concealed violation.

Table 6 – Concealed violation results

Concealed violation	
Ease of tamper detection	Easy
Tool sophistication / difficulty	Moderate
Test time (minutes)	20-30

7.2.4 Opening assessment

The opening performance of the canisters at a range of temperatures is shown in Table 7 below.

Table 7 – Canister opening performance

Replicate	Peak opening force (N)		
	-20°C	**23°C**	**80°C**
1	298	253	192
2	264	311	172
3	230	310	179
Mean	**264**	**291**	**181**
St Dev	*34*	*33*	*10*

Under all opening conditions, the latch features located in the lid of the canister were found to fracture, preventing conventional reclosure. Some other minor cracking of the lids was also observed in some replicates. No damage was present in any of canister bodies.

A damage assessment of the opened canister replicates showed that the latch features of canisters opened at -20 and 23°C were more likely to fracture at the base of the latch – as shown on the left in Figure 15 – while the canisters opened at 80°C were more likely to fracture at the tip of the latch – shown on the right in Figure 15.

Figure 15 – Typical latch damage after cold and ambient opening (left) and hot opening (right)

The polymer used in the construction of the canister was found to deform at a temperature of approximately 90°C and above – as shown in Figure 16.

Figure 16 – Comparison of canister appearance before (left) and after heating to 90°C (right)

8 Conclusions

Under the test conditions employed, the canisters were impossible to open without evidence of tampering.

It was possible to drill a hole through the canister lid and metal insert to allow violation of the 'vacutainer' using a syringe. The hole in the canister lid could be convincingly repaired, but evidence of tampering was obvious on inspection of the grey cap's metal insert.

The damage caused by opening the canister conventionally could also be effectively repaired using solvent adhesives, although evidence of tampering remained.

It was not possible to convincingly alter the serial number printed on the lid or canister body due to print penetration through the sidewall and lid of the canister.

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