An analysis of the use of pictograms on the packaging of a medical device.

Discussion paper for the PicPac project. The main aim of this text is to question if pictograms are 'effective visual communication' and 'if they are 'really beneficial for patients'.

Example: Packaging of a Covid-19 test.

Preliminary conclusions:

- ISO-pictograms/symbols without accompanying text are misunderstood - even by healthcare professionals.
- The standardised pictograms/symbols are mainly 'descriptive'. The relation between the visual (what is depicted?), and what needs to be done (what should a user/patient do?) is poor.
- The use of visuals/pictograms/symbols is possible within the current European regulatory framework. The interpretation of the legal texts 'clarifying certain information', 'compatible with the SmPC', and 'promotional nature' needs to be described in more detail.
- The Readability Guideline needs to be modified to accommodate for visuals/pictograms/symbols.
- The focus for the development of visuals/pictograms/symbols might need to be on 'enabling people to act appropriately'. This encompasses 'treatment adherence' and includes all the actions that patients/consumers/professionals must undertake to use medicines.

In other words: we might need to look at the approach and process first before we select 'pictograms/symbols' as the best option? Other forms of visuals or pictorial information might be more suitable in some circumstances and contexts.

Are these conclusions correct?

Discussion paper: Packaging Covid-19 test.

An analysis of the use of pictograms on the packaging of a medical device.

The main reason to look at the pictograms on packaging of medical devices is that the regulations, guidelines, and standards were fairly recently updated in the USA and in Europe. This approach might therefore be interesting to consider if it could be used as an example for the use of pictograms or symbols on packaging for medicines.

Below a detailed description of a box for a 'Rapid SARS-CoV-2 Antigen Test Card'. There are 8 symbols on these two sides of the packaging (figure 1). These are explained in the package leaflet (figure 2)

Figure 1: Example packaging with 8 pictograms, a barcode, and a QR-code.

ACCESSORIES:

Accessory	*Manufacturer*	*EC-Representative*	*CE-Mark*
Swab A	Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District Yangzhou 225109 Jiangsu P.R. China	Llins Service & Consulting GmbH Obere Seegasse 34/2,69124 Heidelberg Germany	CE 0197 acc. 93/42/EEC
Swab B	Goodwood Medical Care Ltd. 1-2 Floor, 3-919 Yonzheng Street Jinzhou District Dalian 116100 Liaoning China	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo No18, CP 29006, Màlaga, Spain	CE 0197 acc. 93/42/EEC
Swab C	Zhejiang Gongdong Medical Technology Co., Ltd. No. 10 Beiyuan Ave., Huangyan 318020 Taizhou, Zhejiang, P.R.China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany	CE 0123 acc. 93/42/EEC
Swab D	Jiangsu Hanheng Medical Technology Co.,Ltd. 16-B4,#1 North Qingyang Road, Tianning District, 213017, Changzhou, Jiangsu, China	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany	CE 0197 acc. 93/42/EEC

EXPLANATION FOR SYMBOLS

IVD	*In Vitro Diagnostics Use*		See Instructions for Use		Expiry Date
Σ	Tests per Kit		Keep dry	LOT	Batch Number
EC REP	Authorized Representative		Keep away from sunlight		Manufacturer
	Do not reuse		Do not use if package is damaged	4°C 30°C	Store between 4- 30 °C
CE 0123	CE Mark	REF	Catalogue Number		Warning, please refer to the instruction
Warning	H317: Warning! Liquid component may cause an allergic skin reaction.				

Manufacturer: Xiamen Boson Biotech Co., Ltd. 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian, 361021, P.R.China.

Authorized Representative: Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Version 5.1 Date: April 25th, 2021

Figure 2: Detail of the package leaflet with the descriptions of the symbols.

The symbols or pictograms in figure 1.

1- Warning.
The package leaflet has two versions: one in a diamond shape, one in a triangle (figure 2). It is not clear why there are two types of warnings. This warning is for: '*Liquid component may cause an allergic skin reaction*'.
- Does this symbol reduce or prevent the number or severity of allergic skin reactions?

2 - IVD (In Vitro Diagnostics Use).
Do patients need to know this? What is the alternative? What can they do with this? How should they act?
- How does the IVD-descriptor help patients?

3 - See instructions for use.
It is not possible to do this test without using the instructions. Even if many similar tests have been done before, it is still necessary to check the details. [26,6% of 293 participants understood this. In context, this increases to 28,7% (Hermans et al, 2011)]
- Does this symbol increase the use of instructions?

4 - Store between 4 and 30 °C.
Storing temperature is necessary. However, a consumer/patient cannot check if the test-pack has been out of this range. [64,5% of 293 participants understood this. In context, this increased to 73,7% (Hermans et al, 2011)]
- Does this symbol increase the use of correct storage?

5 - Do not reuse.
This is essential. [11,3% of 293 participants understood this. In context, this decreases to 10,9% when it was shown in context (Hermans et al, 2011)]
- Does this symbol prevent the repeated use of this test?
- How often are these covid tests re-used? Which parts of the test are re-used?

6 - Tests per kit.
This is essential. [8,9% of 293 participants understood this. In context, this increases to 20,5% (Hermans et al, 2011)]
- How many consumers are not sure about the number of tests in this package?

7 - CE-mark 0123.
CE 0123 shows that TÜV SÜD was the Notified Body involved in conformity assessment. This sign should indicate for consumers: 'that a product is in conformity with the relevant directives.'
- For how many consumers is this the case?

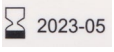
8 - The manufacturer.
[The QR-code links directly to the website of the manufacturer.] [25,6% of 293 participants understood this. In context, this increases to 54,3% (Hermans et al, 2011)]
- Do consumers check the name of the manufacturer?

Symbols not shown in figure 1.

9 - Authorised Representative symbols in the European Union.
An address in The Hague, The Netherlands.
- Do consumers contact the Authorised Representative?

10 - Catalogue number.
This is for the identification of the specific medical device.
- This might be useful if the test fails

11 - Batch number.
This is for the identification of the specific medical device.
- This might be useful if the test fails



12 - Expiry date.
This indicates the month and year until which the test can be used reliably.
- Consumers/patients need to know this. Especially if the test is stored for a few years.

Some discussion points beforehand.

1. Terminology?
The 'visual elements' are called 'pictograms' in the medicines-regulations. In the medical devices regulations and ISO-standards, they are called 'symbols'.

There are four 'symbols' that consist of a black rectangular outline with text in it: IVD, EC | REP, REF, and LOT. These are not really 'visual representations' because they don't represent anything.

Also the words 'user', 'patient', and 'consumer' needs to be described in more detail. For this Covid test, a person who buys it is a 'consumer', those who conduct the test are 'users', and depending on the outcome the same person becomes a 'patient' or remains a 'consumer'.
-> Terminology needs to be clarified.

2. Sequence? Do people need to learn the meaning of these symbols/pictograms?
The order in which the pictograms are shown on the outer packaging differs from the order in the package leaflet. This forces readers to 'search, compare, and search again'. Not all symbols that appear in the package leaflet appear on the outer packaging. There is no indicator which pictograms are 'most relevant', nor is there a grouping that helps people to decide 'these ones are for me', and 'those ones are not for me'.
-> Do people look at these explanations? Is this line of pictograms the easiest way to 'use' these?

3. The symbols are used without words?
The pictograms on the outer package appear without descriptors. In the 2016 FDA-regulations, this is called 'stand alone'. Only the 'Warning pictogram' is accompanied by the word 'Warning'. This is is conflict with the recommendations of the Dutch MEB who stipulates that approved pictograms must always be used with the approved text.
-> What is the motivation to make this difference between 'stand alone' and 'with text'?

4. Colour or black?
The outer packaging uses mainly black pictograms. The exception is the 'Warning' diagram that has a red outline. This red outline is printed in black in the package leaflet. Again a conflict with the recommendations of the Dutch MEB who stipulates that approved pictograms must always be used in colour.
-> In which situations are colours beneficial?

5. What are the reasons to use pictograms/symbols?
The explanation of the symbols takes substantial space in the package leaflet. Doesn't this challenge the aims of 'no need to translate', 'takes less space', and 'easy to understand'? The descriptions are given in four languages and the table is repeated four times in the package leaflet, and the necessity of the description prove that these pictograms are not 'easy to understand'. This is confirmed by two research studies: Hermans et al. (2011) and Seo et al. (2016).
-> What does the literature say about the aims, colours, accompanying text, sequence, and terminology?

What is the aim of the symbols on this packaging?

There seem to be eight different activities of customers/users/patients. Each of these activities might be supported by pictograms or illustrations:

1. People need to be able to purchase the right test.
People need to recognise what the package is for. It is an 'anterior nasal swab self-test to detect COVID 19'. Are these tests suitable for all ages?
[Is there any confusion that people buy the wrong type of test?]
An illustration might help here? (What does it show?) Is it interpreted correctly (What does it mean?)

2. People need to be able to buy the right number of tests.
Make sure people realise that there is only one test in the whole package. This is necessary at the 'point-of-purchase' and especially relevant for households with more than one person.
[Do people see this?]

3. People need to use a test only once.
Make sure people do not use a test twice. It needs to be discarded after use.
[How often does this happen? Which parts of the test could be re-used?]

4. People need to be able to follow the instructions.
Make sure people read the instructions.
[Is it possible to do this test without reading the instructions?]

5. People need to store these tests between 4 and 30 °C.
[What is the consequence if this is not followed? Does the test fail? False positive?]

6. People must not use this test after May 2023.
[How many people do use tests after the expiry date? What are the consequences and risks?]

7. People need to contact the manufacturer or representative for questions?
The pack mentions the postal addresses of Xiamen Boson Biotech Co and Lotus NL B.V.. It also mentions the website and QR-code for the Xiamen Boston website. There are no phone-numbers and no e-mail addresses?
[Should people contact the manufacturer or the representative? In which situations?]

8. People need to be aware of the risk of a potential allergic skin reaction?
[Should consumers know this before they buy this test?]

In order to be sure that pictograms/visuals/symbols have any effect, we need data about these eight activities:
1 - Do people confuse this COVID-19 test with other tests?
2 - Do people realise that they need one box for every person to be tested?
3 - Do people use these tests more than once? What are the risks if so?
4 - Do people consult the instructions? What are the risks if they do not?
5 - Where do people store these tests?
6 - Do people use these tests after the expiry date? Do people check the expiry date?
7 - Do people need to contact the importer or the manufacturer? If not, why is the address mentioned? If yes, why are there no phonenumbers and e-mail addresses?
8 - Do people need a warning about a potential allergic skin reaction? How serious can this get?

A shift from 'descriptive' to 'performative'.
In the list above, I've made a shift from 'the description of symbols' to 'activities of people'. The main reason to do this is that it is possible to investigate and check each of these activities. Interviews, observation studies, contextual inquiries and so on can provide some evidence. This will give a quantitative motivation to select, modify, or delete these symbols on the outside of medical device packaging.

Provisional conclusions

The symbols on medical device packaging of a COVID-19 test do not seem to be effective for consumers/users/patients. They follow the regulations and standards, but don't optimally enable people to use this test appropriately.

Five provisional concluding points can be drawn:

Point 1: Understanding pictograms.
The ISO-pictograms/symbols without accompanying text are misunderstood - even by healthcare professionals. Veerle Hermans stated in 2011: *'In conclusion, comprehension of IVD symbols on RDTs among laboratory staff in four international settings was unsatisfactory.'* Do Chan Seo concluded in 2016: '*Our work suggests that symbols commonly incorporated into the labeling of medical devices may not be readily understood at present*.'

> This might signal that 'symbols/pictograms' are not optimally performing. Even though some of these symbols/pictograms have been around for a long time, they are not recognised, remembered, or understood.

Point 2: Descriptive or action oriented?
The standardised pictograms/symbols are mainly 'descriptive'. The relation between the visual (what is depicted?), and what needs to be done (what should a consumer/user/patient do?) is poor.

The pictograms for IVD, EC | REP, REF, and LOT do not follow the definitions of a pictogram or symbol. Text inside a rectangular frame is not a pictogram.

> The development of visual materials such as pictograms, symbols and illustrations must follow 'best practice standards'. The processes that are recommended in the ISO-standards might not be compatible with the development processes of information about medicines for patients.

Point 3: The relations between images and text needs to be reconsidered.
EU Directive 2001/83/EU, article 62 states: '*The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful for the patient, to the exclusion of any element of a promotional nature*.'

'Clarifying certain information', 'compatible', and 'of a promotional nature' needs more detailed guidance. For example, 'Rapid' in the example on page 8 has been replaced by a symbol for '20 minutes'. Although this is mentioned in the instructions, this could be seen as 'promotional'. The symbol for 'See instructions for use' is an example of advice that might be 'useful for the patient'. However, this advice is not mentioned in the SmPC, and it is assumed that it is compatible with this summary.

> The interpretation of the current Regulatory framework needs to be reconsidered to allow for the inclusion of visual materials in the packaging, package leaflets, and especially digital presentations.

Point 4: The Readability guideline needs to be modified.
The Readability Guideline states: *'If there is any doubt about the meaning of a particular pictogram it will be considered inappropriate.'* (Readability Guideline, 2009: p 10).

None of the symbols for the Covid-19 test pack conforms to this requirement. Either the guideline needs to be modified, or the pictograms/symbols need to be improved.

> The Readability Guideline poorly support the use of visual materials.

Point 5: Focus on 'enabling people'.
EU Directive 2001/83/EU, article 63, paragraph 2 states: *'The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals.'*

Especially the phrase *'enabling the users to act appropriately'* can be used to develop visual information on the outer packaging. Four questions need to be answered in order to adhere to this requirement:
1 - which actions? - what do people need to do?
2 - which users? - who are the people? What is the context, what is the situation?
3 - what is 'appropriately'? - Which criteria are suitable to assess 'appropriate', and how do we measure these?
4 - and how do we enable? - What are the different ways to enable the actions of people in a context? Which information in which formats is most suitable?

The examples on page 8 start from these principles. The actions of consumers/users/patients are used as a basis. The original packaging (figure 1) and these prototypes can be used in dialogues with consumers/users/patients to collect answer the questions on page 5. Based on these answers, the design of the information can be modified in such a way that it increases the likelyhood that people are effectively enabled to act appropriately.

> The concept of 'adherence' might need to be extended to mean: 'act appropriately'. This applies to all the actions a patient/consumer must undertake to use medicines.

References:

Hermans et al. (2011) *Assessment of the knowledge of graphical symbols labelled on malaria rapid diagnostic tests in four international settings*. **Malaria Journal**. 10:331. doi:10.1186/1475-2875-10-331

Seo, Do Chan; Ladoni, Moslem; Brunk, Eric; Becker, Mark W.; Bix, Laura (2016). *Do Healthcare Professionals Comprehend Standardized Symbols Present on Medical Device Packaging?: An Important Factor in the Fight Over Label Space*. **Packaging Technology and Science.** doi:10.1002/pts.2199

Sletvold, H., Bjørnli Sagmo, LA., Torheim, EA. (2020). *Impact of pictograms on medication adherence: A systematic literature review*. **Patient Education and Counseling.** 103 (2020) 1095–1103. doi:10.1016/j.pec.2019.12.018

ISO 15223-1:2021 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements.

Figure 3: Package based on eight activities, without symbols/pictograms [front/back].
The visual of the 'nose-swab' indicates the type of test.

COVID-19 antigen test

This pack contains 1 test.

This test can be used once.

Follow the instructions.

You get a result in 20 minutes.

Store between 4 °C and 30 °C.

Use this pack before May 2023.

Instructions:
Scan:

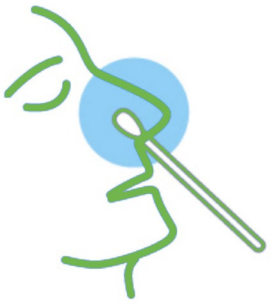
Webaddress:
youtu.be/XQlTGs6CIJo

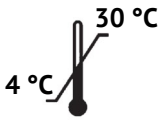
Contact details for questions and suggestions:
Lotus NL B.V., Koningin Julianaplein 10, 2595 AA The Hague, The Netherlands.
Telephone: 00 31 6 44168999 | e-mail: peter@lotusnl.com

Reference number: 1N40C5-2
Batch number: 21111711E

Figure 4: Package based on ISO-symbols/pictograms [front/back]. Consumers have to open the package, unfold the package insert, locate the right language, find the symbol in a table, read the explanation, consider its meaning, and act?

COVID-19 antigen test






Xiamen Boson Biotech Co., Ltd. Fujian, 361021, P.R. China.

EC REP Lotus NL B.V., 2595 AA The Hague, The Netherlands.

CE TÜV SÜD, 80686 München, Germany.

REF 1N40C5-2

LOT 21111711E

Two other examples.

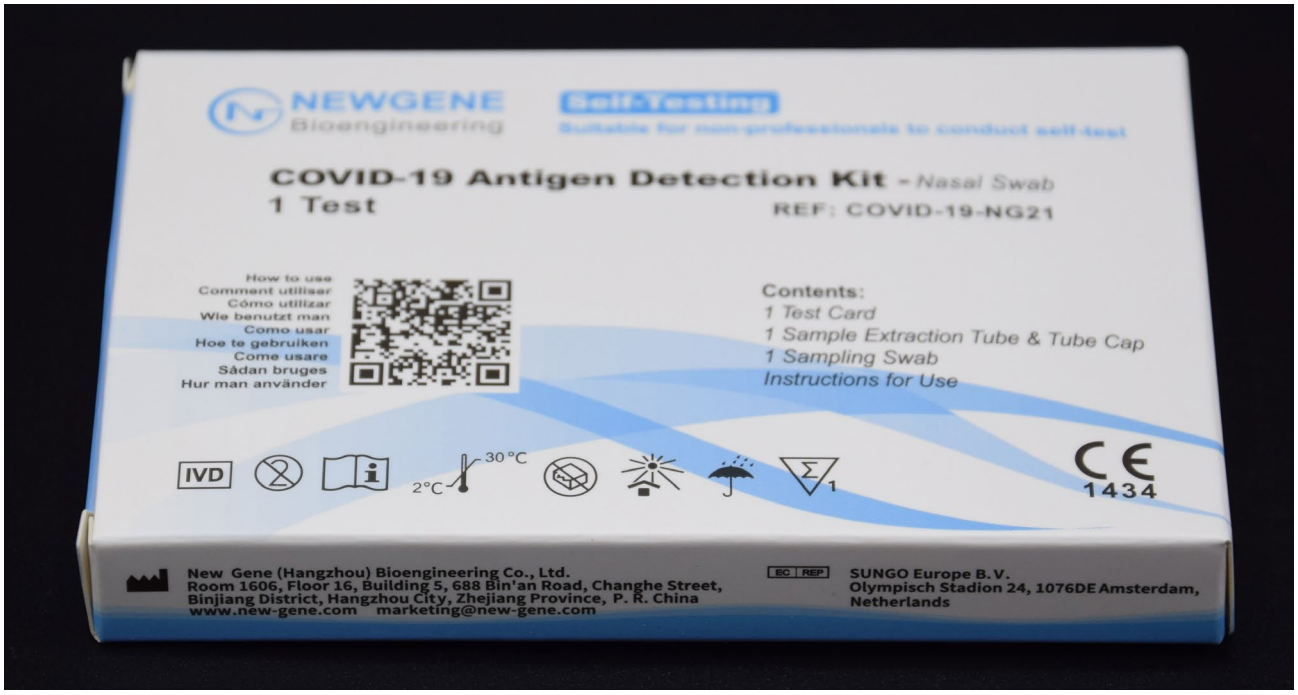


Figure 5: Packaging of another Covid-19 antigen test. This pack adds three more symbols:
- Do not use if package is damaged
- Keep away from sunlight
- Keep dry

Figure 6: Packaging for plasters.
- Pictograms in red and black?
- There are two explanations for symbols: ® = Registered trademark, and 'Do not use if package is damaged'. There is no tabel/outer packaging that explains these symbols …
- The balance between 'instructions' and 'non-instructions' is unclear. There is no real starting point to start 'reading', nor is it clear which information is relevant for whom.