3-STAGE-TEST-STRATEGY

for Companies and Institutions

- Rapid breaking of infection chains
- Enable an Exit out of Lockdown
- Easy testing of employees 2-3 times per week

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Objectives and Goals

Since the 2nd of November 2020, i.e., for 167 days, Germany has been in Lockdown. Despite ongoing vaccinations efforts and testing (so far uncoordinated), there is no end in sight of the Lockdown. On the contrary, terms such as "curfew" and the so-called "emergency-brake" are currently the terms that all citizens hear daily. Every week, rules and now also laws are changed, which is a clear sign that today's approaches and strategies are not (yet) working properly.

To return to an acceptable level of normality in a timely and safe manner, a different and, above all, better strategy is needed, which serves to reliably, quickly, and easily break infection chains.

The strategy must have lasting effects. It should be easy and quick to use, so that every citizen can reliably and demonstrably perform testing her- or himself. Further, no insurmountable logistical or organizational effort should be required for the already battered and weakened systems and citizen's morale. Such a new strategy must provide a useful complement to the proven hygiene rules, laboratory-based PCR tests, vaccinations, and the various antigen tests, that already have been ordered in gigantic quantities.

The Basis

The basis of the improved strategy is to strategically combine available, clinically tested and approved, but methodically different test methods in a 3-stage-test-chain.

The safety, effort, costs and, above all, the methodology of the respective test procedure are considered, without disregarding the maximum possible safety for the citizens.

The Goals

1. Scalable testing that does not overwhelm our citizens and systems.
2. Use of such test methods, where they are most effective within the defined chain of tests.
3. Breaking infection chains through early and user-friendly screening testing.
4. Protect the precious and vital PCR test systems and intensive-care-bed capacities.
5. Successive and safe exit from the lockdown.

3-Stage-Test-Strategy

Stage 1 - Screening						
Test Method	**Test Frequency**	**Acceptable Sensitivity**	**Acceptable Specificity**	**Desired Proof of Results**	**Example by numbers**	
					100,000 (with 1% Infected)	*100,000 (with 0.5% Infected)*
Symptom Screening Tests for all citizens filters as shown	2-3-time per week	~ 80%	~ 90%		**10,000** are suspected of Infection of those there are **800** / 1000 Infected	**10,000** are suspected of Infection of those there are **400** / 500 Infected
Number of citizens screened					100,000	100,000
Number of Infected in this filtered group					800	400
Number of those "suspected of Infection" that will go to **Stage 2**					10,000	10,000

Examples / Discussion:

- The Corowell Symptom Screening Test, has no limit of production capacity
- Sensitivity = 88.8% und Specificity = 91.1% (better than in the example above)

Stage 2 – Antigen Rapid Testing						
Test Method	**Test Frequency**	**Acceptable Sensitivity**	**Acceptable Specificity**	**Desired Proof of Results**	**Examples**	
					10,000 (suspected of Infection with 800 Infected)	*10,000 (suspected of Infection with 400 Infected)*
Qualified Antigen Tests for those "suspected of Infection"	1 x per **Screening** that was **NOT Passed**	**90%**	**95%**	Electronic Pass	**720** True Positive **500** False Positive **8700** True Negative **80** False Negative	**360** True Positive **500** False Positive **9100** True Negative **40** False Negative
Number of those suspected of Infection test with Antigen					**10,000**	**10,000**
Number of Infected in this filtered group					**720**	**360**
Number of Antigen Positives that will go to **Stage 3**					**1220**	**860**

Examples / Discussion:

- If extrapolated, of 83 million citizens ~ 10% are "screened-out". There is a need for ~ 8.3 Mio. antigen tests per screening day. Germany has sufficient antigen test availability for this.
- 1220 (True & False) Positives per 100,000 people, per screening day are sent to Stage 3 (RT-PCR). Extrapolated to 83 million citizens this would be ~ 1.0 Mio. 1 Mio. is already close to weekly our RT-PCR test capacity. Fortunately, not all citizens will test 2-3 times per week.
- There is an urgent need for electronic pass verification systems, such as those offered by pass.me or already implemented by COROWELL.

ATTENTION:

If ALL citizens were tested 100% **only** with antigen test, as it appears to be the current plan of the German Government, without any symptom screening in advance, then with a sensitivity of 90% and specificity of 95% for antigen tests in the above examples, almost 5 million citizens per test day would be sent to the RT-PCR (747,000 True Positive and 4.25 million False Positives), i.e. 20-30 times of our current daily RT-PCR test capacity.

Our RT-PCR test capacities will collapse short-term

Stage 3 – RT-PCR Testing						
Test Method	**Test Frequency**	**Acceptable Sensitivity**	**Acceptable Specificity**	**Desired Proof of Results**	**Examples**	
					1220 (those in Stage 2 Positive)	*860 (those in Stage 2 Positive)*
RT-PCR Testing for ALL POSITIVES of Stage 2	1 x per citizen that was Antigen **Positive** in Stage 2	**98%**	**99%**	Electronic Pass	**706** True Positive **7** False Positive **493** True Negative **14** False Negative	**353** True Positive **4** False Positive **496** True Negative **7** False Negative
Number of those tested Positive with Antigen					**1220**	**860**
Total Number of TRUE Infected in this filtered Group					**706**	**353**

Examples / Discussion:

- With this staged test process there is **no "dark number"** and **over 70% of all infected** in the test group **per test day are found** and can be isolated.
- Frequent repeating of this process will allow to **quickly isolate infected from non-infected** citizens.

Advantages

- You will minimize the risks to your establishment because you will break through infection chains very early. Early detection means early action!

  A sudden change or a sudden loss in the sense of smell (anosmia) is the FIRST symptom of the disease in 86%* of those infected with COVID-19 as early as 2-3 days after infection. Anosmia is not always perceived by sufferers, because we do not smell consciously and thus sometimes do not notice the loss of the sense of smell. The app-supported COROWELL COVID-19 Symptom Screening System, tests exactly this symptom, and thus can test earlier than any other rapid test. In addition to the smell test, Corowell has also integrated a questionnaire into the Screening.

- You will always have sufficient tests available for all employees!

  COROWELL is produced in Germany and is available in large quantities within a very short time. COROWELL is therefore ideal for mass screenings!

- You have lasting success with regular testing of all employees every 2-3 days!
  Only with this test frequency you can permanently reduce the risk of infection.

- You can save money through lower product cost and a reduced need for antigen rapid tests

  COROWELL is more cost-effective than antigen rapid testing. The more expensive antigen rapid tests will only need to be used in less than 10% of the tests within this 3-stage test strategy.

- You will test fast and with “no-contact”!

  COROWELL is non-invasive and does not need to be carried out by colleagues or third parties. In addition, the speed of the test allows for it to be carried out before entering a building. The result is available after only about 60 seconds.

- You do not need trained personnel and you have very little effort

  COROWELL is easy and fast and can be done by anyone anytime, anywhere – especially also at home! Those who "pass" the screening test can prove this with an electronic pass. Anyone who is found to be "suspected of infection" by means of COROWELL is going directly to stage 2. This avoids contact between infected and non-infected people.

- You can allow non-infected employees to move freely!

  COROWELL has a high specificity of 91.1 %*, i.e., 91.1% of the screened as not "suspected of infection" can move freely (proof with a digital pass). COROWELL has a high sensitivity of 88.8 %*, i.e., 88.8% of ALL infected people in the overall group will be in the group screened as "suspected of infection". (see Annex - Clinical Assessment and Specific Performance Data)

- You will reduce plastic garbage!

  COROWELL is made of paper and can easily be recycled.

Clinically tested Medical Product

- BfArM - registered Medical Device (DE/CA71/21a/07/2.3/2021/0004)
- CE Mark (Class I Medical Device Product)
- FDA Registration (listing number D428183)
- Based on over 90 clinical und scientific Publications
- Clinically tested

Scientific and clinical Background

1. "Loss of smell and taste is now recognized as amongst the most common symptoms of COVID-19 and the best predictor of COVID-19 positivity." [1] (Dec. 2020)

   "Our results indicate that a continuous rating of current olfactory function is the single best predictor of COVID-19 ..." [2] (Dec. 2020)

   "Based on a realistic [estimated] prevalence of Olfactory Disfunction of ~ 75%, this model of 20,000 shows a Reduction of the Reproduction Rate of COVID-19 by over 60%, if standard olfaction testing was applied every 3 days". [3] (Dec. 2020)

2. In the clinical literature, there are reports linking Anosmia to COVID-19 of more than 100,000 patients (in around 670 publications).

3. The Robert Koch Institute[4] (RKI, Germany), as well as the Center of Disease Control[5] (CDC, US) lists the "New Loss of Sense of Smell" as "Key Symptom Screening Test Criteria" and "high predictive value".

4. Corowell clears those that are not suspected of COVID-19 Infection, with a Sensitivity of ~ 88.8%[6,7]. Anosmia has a Specificity of > 91.1%[8,9] for COVID-19 (und siehe Anhang)

5. Corowell is non-invasive, objective, low-cost, rapid (results < 90 sec) and suitable for mass-testing, without the need of a specific infrastructure.

6. The expected Reproduction Rate Reduction would be greater than those achieved when applying [ALL] Restriction Measures (55.1%10 vs. 48%)11.

1 *Claire Hopkins, December 15, 2020, Hopkins C, Surda P, Vaira LA, et al. Six-month follow-up of self-reported loss of smell during the COVID-19 pandemic. Rhinology 2020 Dec 15. doi: 10.4193/Rhin20.544.*

2 *Richard Gerkin, December 25, 2020 Gerkin RC, Ohla K, Veldhuizen MG, et al. Recent smell los sis the best predictor of COVID-19 among individuals with recent respiratory symptoms. Chem Senses 2020 Dec 25; bjaa081. doi: 10.1093/chemse/bjaa081*

3 *Larremore, et al. December 2, 2020, Modeling the effectiveness of olfactory testing to limit SARS-2-CoV transmission*

4 *www.rki.de/covid-19*

5 *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*

6 *Yan CH, Faraji F, Prajapati DP et al. Association of chemosensory dysfunction and Covid-19 in patients presenting withinfluenza-like symptoms. Int Forum Allergy Rhinol 2020;10(7):806-813.*

7 *Maechler F, Gertler M, Hermes J et al. Epidemiological and clinical characteristics of SARS-CoV-2 infections at a testing sitein Berlin, Germany, March and April 2020 – A cross-sectional study. Clin Microbiol Infect 2020 Aug 19; S1198-743 X (20)30500-0. doi: 10.1016/j.cmi.2020.08.017.*

8 *Wells PM, Doores KJ, Couvreur S et al. Estimates of the rate of infection and asymptomatic COVID-19 disease in a populationsample from SE England. J Infect 2020 Oct 14: S0163-4453(20)30653-8. doi: 10.1016/j.jinf.2020.10.011.*

9 *Saussez S, Lechien JR, Hopkins C. Anosmia: an evolution of our understanding of its importance in COVID-19 and what questions remain to be answered. Eur Arch Otorhinolaryngol 2020 Sep 9. doi: 10.1007/s00405-020-06285-0.*

10 *Larremore, et alt. December 2, 2020, Modeling the effectiveness of olfactory testing to limit SARS-2-CoV transmission*

11 *Li, et alt. The temporal association of introducing and lifting non-pharmaceutical interventions with the time-varying reproduction number (R) of SARS-CoV-2: a modelling study across 131 countries*

12 *https://www.ifo.de/publikationen/2020/aufsatz-zeitschrift/die-volkswirtschaftlichen-kosten-des-corona-shutdown*

Annex

Specific performance data and clinical assessment

COROWELL
IF YOU CAN'T SMELL, YOU ARE NOT WELL!

Specific performance data
Clinical assessment

The Corowell Symptom Screening Test tests subjects for anosmia, typical flu symptoms (fever, cough, shortness of breath, sore throat, muscle pain and unusual fatigue) or a recent disorder of the sense of smell.

The clinical performance of the Corowell Symptom Screening Test for self-testing was evaluated on a total of 200 subjects in two (2) prospective studies at a clinical center in Lausanne, Switzerland.

Of these 200 subjects, symptom screening tests were performed on a first study cohort of 50 subjects, each of which was tested repeatedly once per day on 8 test days, within a total period of two (2) weeks. This study cohort included exclusively adult employees of a clinical center (aged 21 to 65 years) without any specific clinical suspicion of a SARS-CoV-2 infection. The 50 study subjects followed written and illustrated instructions from the official Corowell Symptom Screening Test Instructions for Use (IFU) and conducted the tests themselves. The tests wer observed by medical professionals without intervention. RT-PCR tests, using combined nasopharyngeal / oropharyngeal swab samples, were used as a comparison method, for those subjects identified by the symptom screening test as being suspected of a SARS-CoV-2 infection. During the eight (8) test days, a total of 387 symptom screening tests were carried out and a total of 10 subjects were detected as being suspected of a SARS-CoV-2 infection. These subjects were then immediately tested on the same test day with RT-PCR, where 3 of the 10 subjects were tested RT-PCR positive. In this study cohort, no other subjects were tested positive for RT-PCR during the eight test days. All 3 of the 3 RT-PCR positive subjects were initially correctly identified as being suspected of SARS-CoV-2 infection by means of the symptom screening tests.

The symptom screening tests were performed on a second study cohort of 150 subjects. This study cohort also included only adult subjects, however, in this case during initial clinical admission. The entire study cohort was randomly selected without any specific clinical suspicion of a SARS-CoV-2 infection, only based on the initial clinical admission. The 150 study participants followed written and illustrated instructions from the official Corowell Symptom Screening Test Instructions for Use (IFU) to conduct the test themselves. The tests were observed by medical professionals without intervention. RT-PCR tests, using combined nasopharyngeal / oropharyngeal swab samples, were used as a comparison method in all 150 subjects. Based on the 150 symptom screening tests, that were carried out, 16 subjects were detected as being suspected of a SARS-CoV-2 infection. These 16 subjects were then immediately tested on the same test day with RT-PCR, where 5 of the 16 subjects were tested RT-PCR positive. In this study cohort, one (1) further subject was tested RT-PCR positive, which the symptom screening test had previously not detected as being suspected of a SARS-CoV-2 infection. Thus, 5 out of the 6 RT-PCR positive subjects were initially correctly detected as being suspected of a SARS-CoV-2 infection by means of the symptom screening test.

This results in the following pooled performance assessment of the tests from the two study cohorts described above. The Corowell Symptom Screening Test demonstrated a
Sensitivity of 88.8% (8 subjects of the 9 RT-PCR positive subjects were correctly identified by the Corowell symptom screening test) and a
Specificity of 91.1% (174 subjects of the 191 RT-PCR negative subjects were correctly identified by the Corowell symptom screening test).

	RT-PCR positive	RT-PCR negative	Total
Symptom Screening Test suspected of SARS-CoV-2 infection	8	17	25
Symptom Screening Test not suspected of SARS-CoV-2 infection	1	174	175
Total	9	191	200
Sensitivity	**88.8 %**		
Specificity	**91.1 %**		