

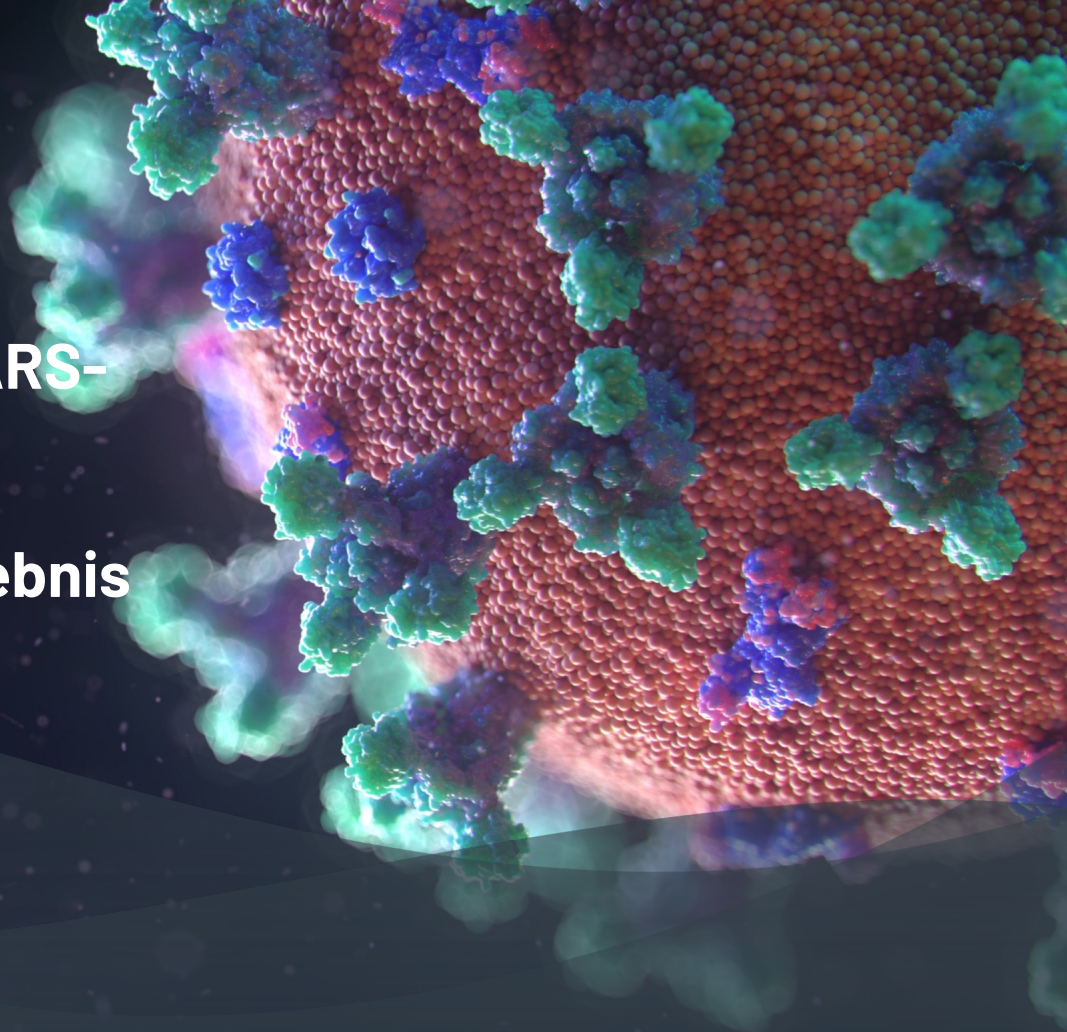


Innovative digitale SARS- CoV-2 Analytik: In 15 Minuten zum molekularen Testergebnis im Nephrologischen Zentrum

Dr. Markus Riester

4. Dezember 2021, 34. Berliner DialyseSeminar

midge medical is the future of diagnostics.



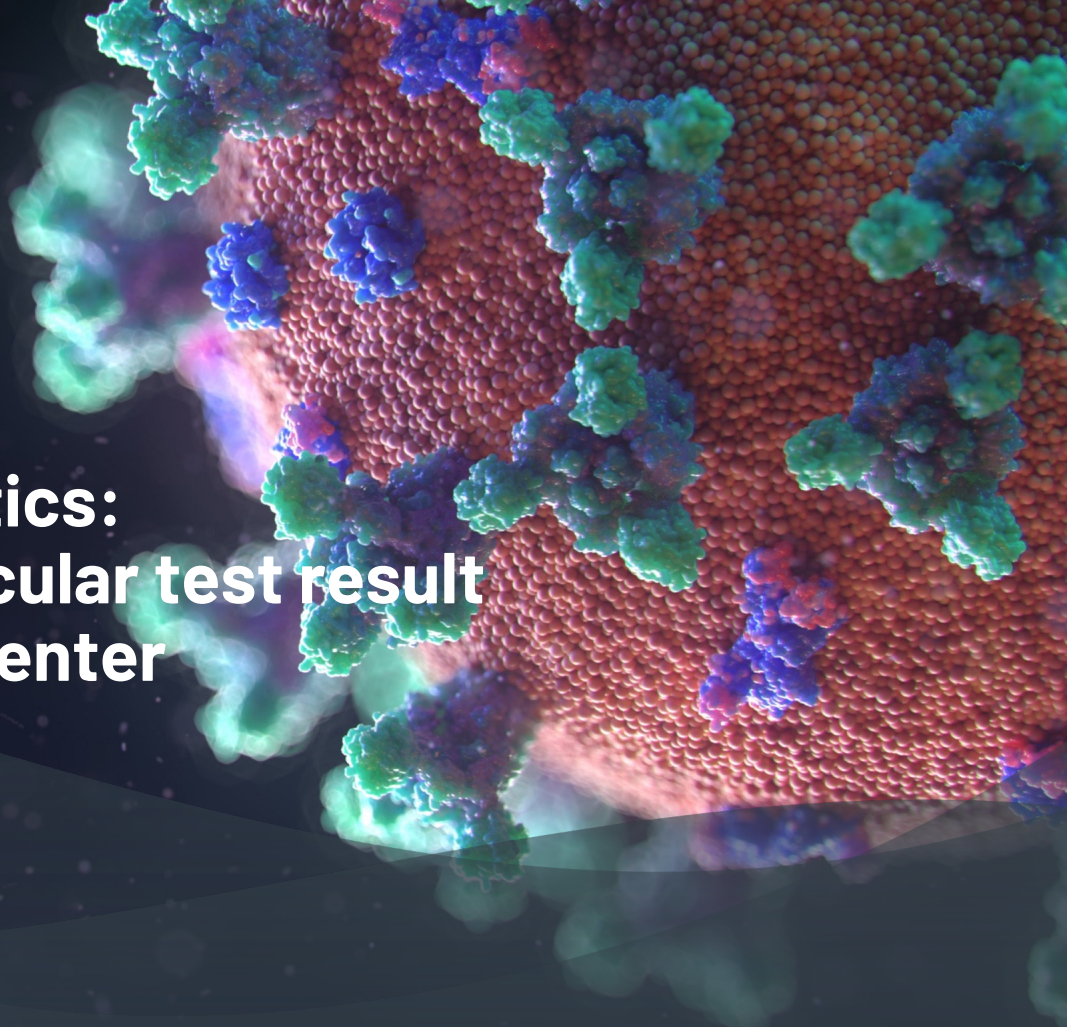


Innovative digital SARS-CoV-2 analytics: 15 minutes to molecular test result in the nephrology center

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Geschäftsführer

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It is pointed out that the SARS-CoV-2 test developed by midge medical GmbH has not yet been approved and is not offered for sale. midge medical GmbH plans to obtain approval of the test as an IVD according to the Medical Devices Act.

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Questions may be directed to Michael Diebold (michael.diebold@midge-medical.com) or Dr. Markus Riester (markus.riester@midge-medical.com).

Slido Fragen

Gab es in ihrer Praxis bereits Fälle von Patienten oder Personal, die an Corona erkrankt waren oder in als Kontaktpersonen in Quarantäne mussten?

- ☐ Noch kein Fall
- ☐ Ein oder mehrere Fälle
- ☐ Der Betrieb musste eingeschränkt werden, da zu viele positive Fälle

Welche Coronatests werden bei ihnen für das Testen von Patienten oder Personal eingesetzt

- ☐ Antigen-Schnelltests
- ☐ Erst Antigen, falls positiv → Nachtesten mit PCR-Labortests
- ☐ Labor-PCR-Tests
- ☐ Wir machen die PCR-Analysen selber, haben dafür unsere eigene PCR-Analytik
- ☐ Wir setzen keine Tests ein

midge medical – handheld diagnostic device with molecular precision Made in Berlin.

Startup founded in Berlin

Goal Develop analytical procedures for bringing fully digital diagnostics to the health care professional

Step 1 Simplified, fast SARS-CoV-2 diagnostics for **nephrologists starting in 20/22**, for high-risk HD patients and ambulatory care

Step 2 2023: Bring diagnostics home for high risk and PD patients, with supervision of results by physicians

Founders

Michael Diebold

Dr. Markus Riester



CKD patients are at high risk in the SARS-CoV-2 pandemic

CHRONIC KIDNEY DISEASE

CKD is a key risk factor for COVID-19 mortality

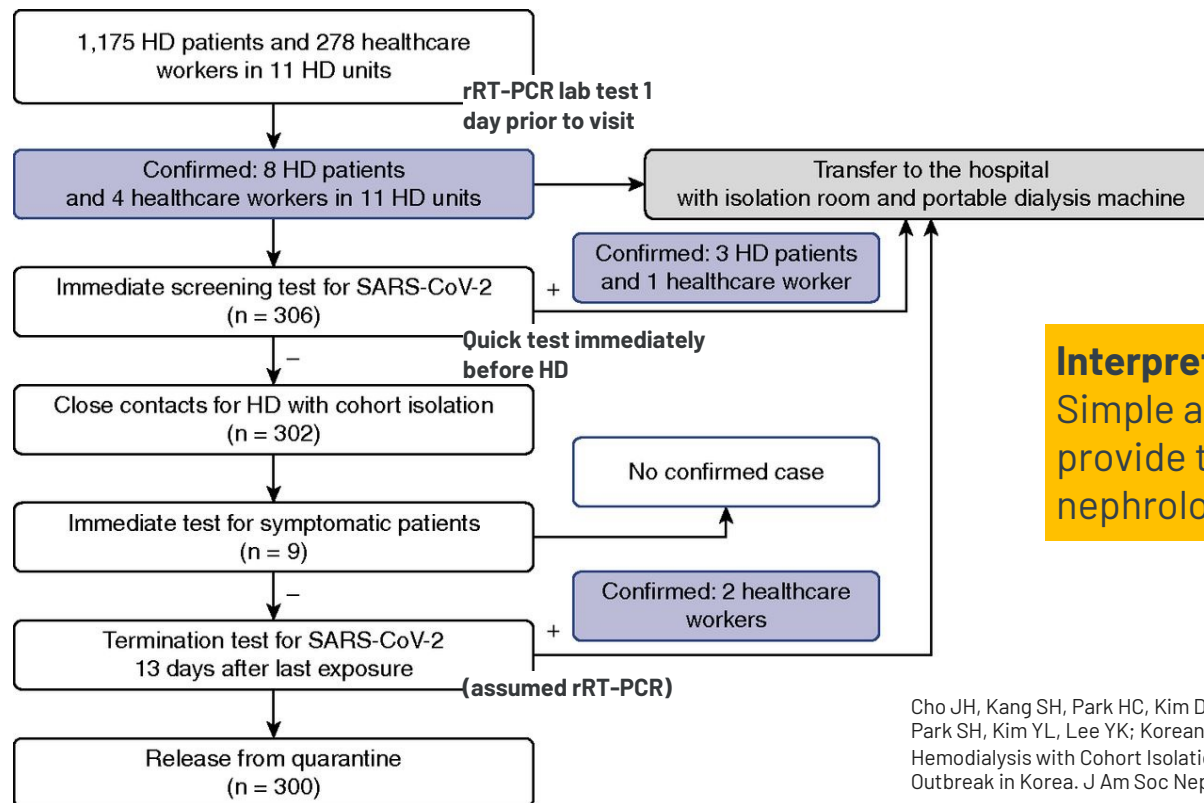
[Ron T. Gansevoort](#) ✉ & [Luuk B. Hilbrands](#) ✉

[Nature Reviews Nephrology](#) **16**, 705–706 (2020) | [Cite this article](#)

19k Accesses | **39** Citations | **49** Altmetric | [Metrics](#)

A new study uses the OpenSAFELY health analytics platform to identify risk factors for COVID-19 mortality. This analysis, which includes data for more than 17 million people in the UK, suggests that patients with chronic kidney disease are at higher risk than those with other known risk factors, including chronic heart and lung disease.

Multi-center study determined factors to limit exposure of HD clinics to SARS-CoV-2



Interpretation

Simple and fast molecular test can provide the required safety for the nephrological clinic

Cho JH, Kang SH, Park HC, Kim DK, Lee SH, Do JY, Park JW, Kim SN, Kim MS, Jin K, Kang GW, Park SH, Kim YL, Lee YK; Korean Society of Nephrology COVID-19 Task Force Team. Hemodialysis with Cohort Isolation to Prevent Secondary Transmission during a COVID-19 Outbreak in Korea. J Am Soc Nephrol. 2020 Jul;31(7):1398-1408. doi: 10.1681/ASN.2020040461.

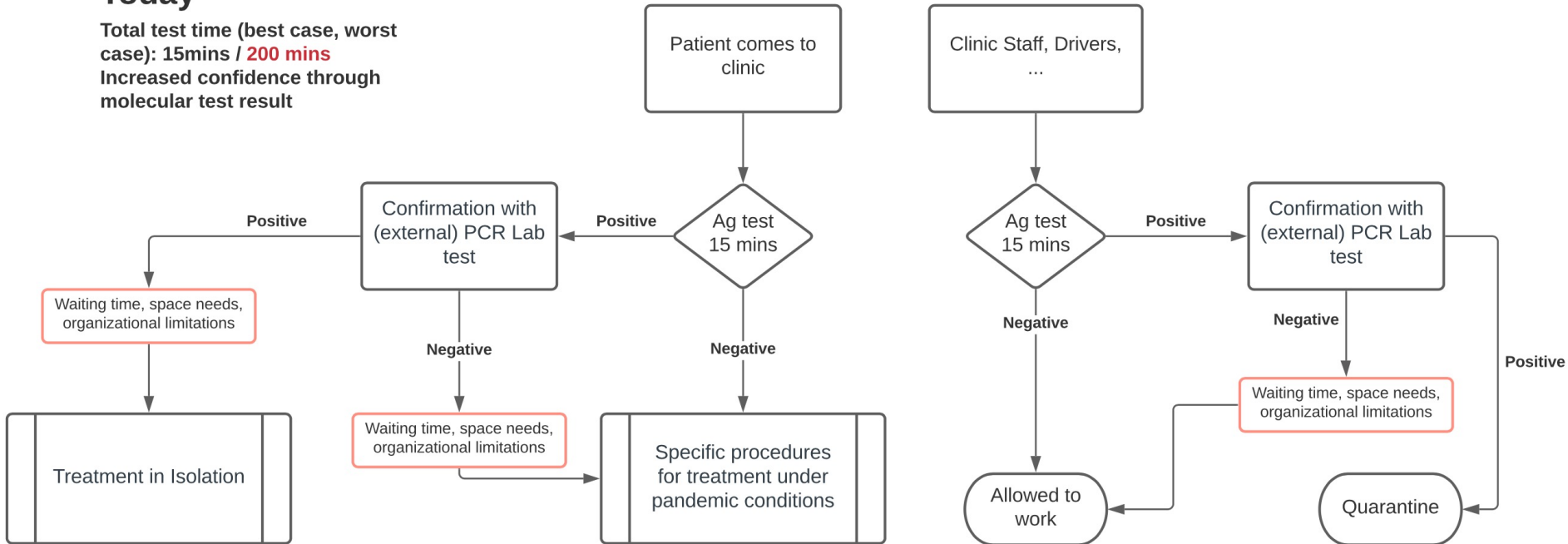
Conclusion: early detection is critical to limit exposure of HD clinics to SARS-CoV-2 infection

Conclusions from study	Short term contribution of midge test	Propects for the clinic
pre-existing deployment plan before the epidemic		PoC molecular diagnostics included in planning
early detection with rapid rRT-PCR testing	Fast molecular test for testing patients, staff, drivers, doctors	Validation test can be done by minoo test in the nephrological clinic
collaboration between institutions	Enabled by digital connectivity, supported by midge test device	Nephrologist controls the diagnostic process to create a safe workplace and improve patient outcomes
continuous monitoring of infection	Enabled by rapid PoC minoo test done at the clinic	Control infections exposure by rapid PoC minoo test done at the clinic

Current patient journey

Today

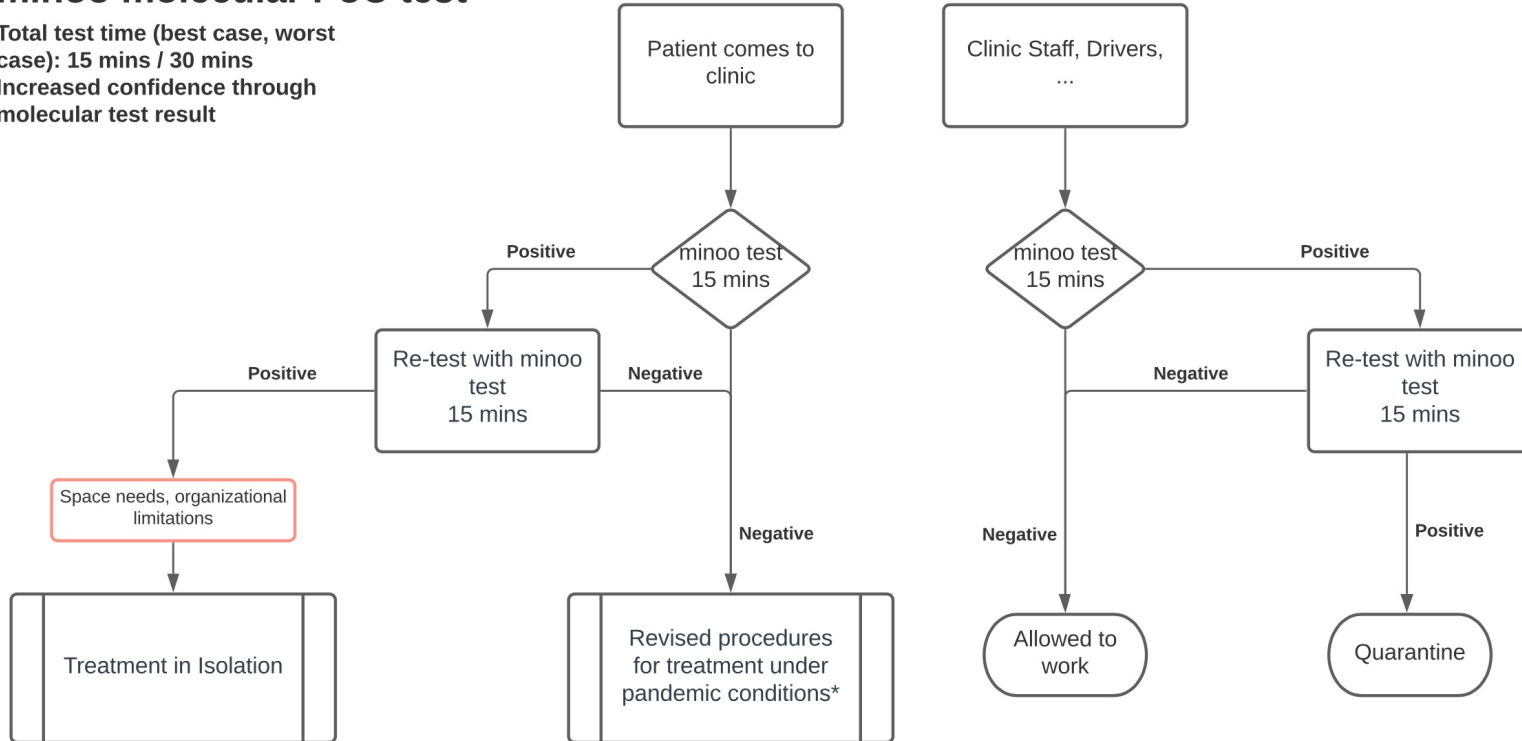
Total test time (best case, worst case): 15mins / **200 mins**
Increased confidence through molecular test result



Future patient journey

minoo molecular PoC test

Total test time (best case, worst case): 15 mins / 30 mins
Increased confidence through molecular test result



Test capacities again reaches the limits ... time-to-result on the rise

- Same situation as 2020
- In Germany about 2 million tests available per week!
- At least 5-fold amount of tests needed for combating the pandemic ... more is better

 tagesschau

Sendung verpasst? 

 [Wirtschaft](#) [Engpässe bei PCR-Tests: Laborbranche am Limit](#)



Engpässe bei PCR-Tests

Laborbranche am Limit

Stand: 30.11.2021 14:58 Uhr

Weil mit steigenden Infektionszahlen immer mehr PCR-Tests benötigt werden, stoßen Labore an ihre Grenzen. Ergebnisse lassen oft länger auf sich warten, vielerorts wird bereits priorisiert.

Von Stephan Lenhardt, SWR Mainz

Saving time and reducing costs by speeding up the testing process before patients start their dialysis

Reported mortality rate of 15% due to SARS-COV-2

As a high-risk patient group, they need to get PCR tested every time before starting their treatment

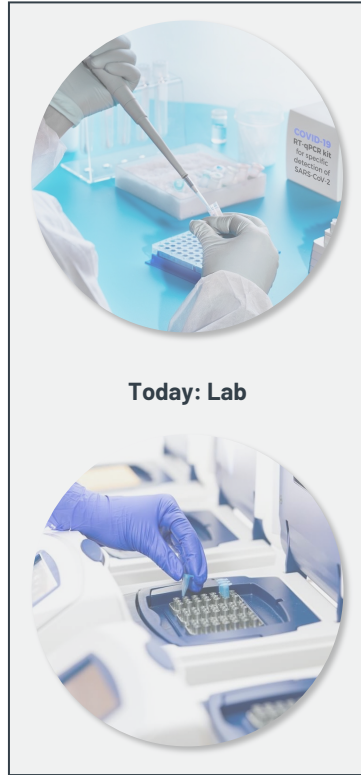
This additional effort takes 3 more hours out of staff and patient time

Clinics will significantly benefit by using our solution:

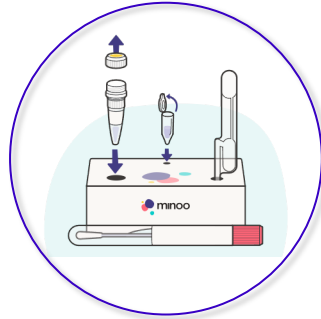
1. Results in less than 30 minutes
2. Optimal treatment planning
3. Testing at home to optimize flow in the dialysis clinics
4. Reimbursement for PCR test and for taking the test
5. Minimum effort
6. Mobile access for nephrologist



midge medical establishes test results in 15 min with reusable test device



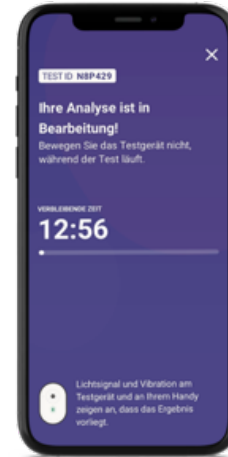
Today: Lab



Test kit
One simple pipetting step



Reader device Integrated multiple use
low-cost fluorometer (2 years lifetime)



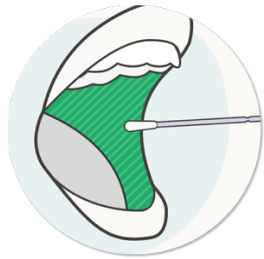
Mobile app
User interface



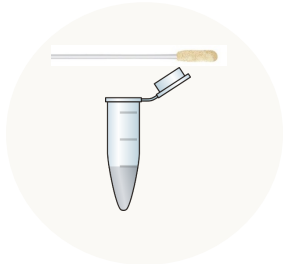
Cloud back-end

- GDPR compatible Data analysis and aggregation
- interface to healthcare systems
- post-market surveillance

Simple procedure for self-testing – fast and precise results



Take sample
Throat or nasal
swab

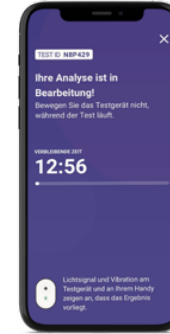


Process swab
Insert into lysis buffer,
mix with dry chemistry,
and transfer into test
container

Handling is similar to
antigen tests



**Place test container
onto device**
Sample is analyzed
and results are sent to
phone via Bluetooth



Get lab quality result
within 15 minutes

Digital monitoring of
process with
animated on-screen
instructions



Data connection
to cloud backend

Data aggregation for
healthcare systems
and possible real-time
disease mapping

Summary

midge medical provides a multiple-use handheld test device for molecular SARS-CoV-2 testing with PCR equivalent analytical sensitivity and selectivity

- **Test results in 15 mins**, with simple sample preparation by nurse or by patient under observation
- Test **simplifies the patient flow and creates a safe environment**
- **Reimbursement upside** for providing test to patients **assumed**
- **More assays** are available (respiratory: influenza, RSV, hemorrhagic fevers, ...)

Can you imagine using this test system in your clinic?

**We are looking for clinicians
to validate our test system in the clinic workflow,
to improve patient outcome,
to conquer the SARS-CoV-2 pandemic.**

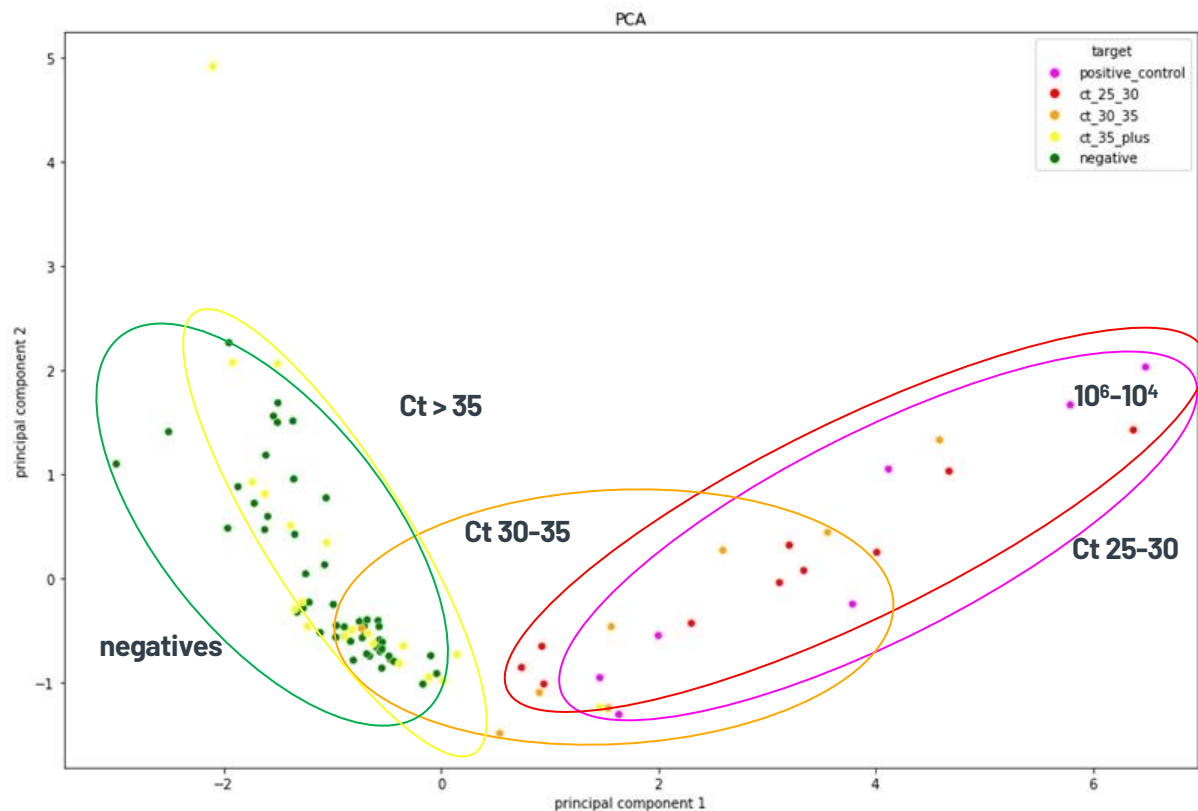


We love to hear from you.

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Clinical samples; LOD 8×10^2 copies/ reaction → equivalent to PCR up to CT=35



		Purification 1:2	
		PCR	RPA
Template volume		5µl/20µl	150µl/600µl
Total Dilution		1:8	
Device		RotorG	Minoo
CT 25-30	5555327357	25.74	+
	1941548797	26.27	+
	5562179767	26.49	+
	5562179197	26.74	+
	5015208497	26.92	+
	5015214997	28.1	+
	2079615717	28.53	+
	4263118057	28.99	+
	4263118007	29.08	+
	1909236637	29.15	+
CT 30-35	5555335137	30.57	+
	1202203387	32.05	+
	4269251867	32.96	+
	5562179037	32.98	+
	7502263737	33.22	-
	4269303787	33.32	-
	5562179837	34.3	+
	1939733757	34.53	+
CT 35-40	4269309297	35.5	+
	4269295417	36.35	+
	5015214747	36.69	-
	2079828497	37.27	-
	4263120457	38.07	-
	4269326397	38.46	-
	4269351807	38.49	-
	4269244557	38.51	+
	4269329867	38.79	-
	4269346527	38.98	+
	4269333017	39.5	-
	4269303777	40.02	-

Performance comparison Antigen vs. PCR vs. minoo test

