



## Coronavirus Kontamination weltweit

Irina Korschineck

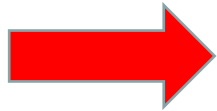
# Centers for Disease Control and Prevention (CDC)

Manufacturer	Product name	Catalog No.	Acceptable Lots
BioSearch Technologies <a href="http://www.biosearchtech.com">www.biosearchtech.com</a> 1-800-GENOME-1	2019-nCoV CDC Probe and Primer Kit for SARS-CoV-2	KIT-nCoV-PP1-1000	143503 143764 144000 144604
Integrated DNA Technologies (IDT) <a href="http://www.idtdna.com">www.idtdna.com</a> (800) 328-2661	2019-nCoV Kit, 500 rxn	10006606	0000500383 0000504847 0000505594 0000505969 0000507295 0000507509 0000508150 0000508785 0000509402 0000510344 0000510908 0000511393 0000512209 0000512692 0000513132
Integrated DNA Technologies (IDT) <a href="http://www.idtdna.com">www.idtdna.com</a> (800) 328-2661	2019-nCoV Kit, 1000 rxn	10006770	0000515825 0000522562



## Inhalt eines Real Time PCR Test Kits

### ViroReal® Kit SARS-CoV-2 & SARS



Beschriftung	Inhalt
SARS-CoV-2 & SARS + RNA IPC-3 Assay Mix (grüner Verschluss)	Primer und Sonde für Virus Detektion (FAM) und für RNA IPC Detektion (Cy5)
RNA IPC Target (oranger Verschluss)	Target für RNA IPC
SARS-CoV-2 Positive Control (roter Verschluss)	RNA Positivkontrolle (10 <sup>3</sup> Kopien/μl)
RNA Reaction Mix (weißer Verschluss)	RNA Reaktionsmix
Nuclease-free water (blauer Verschluss)	Nuklease-freies Wasser

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### In-house developed molecular assays

At the beginning of the outbreak, WHO supported access to COVID-19 in-house PCR protocols assays by posting them online on the WHO website. Protocols that have been shared can be accessed [here](#). Being listed in this document does not imply any endorsement or validation by WHO. These protocol postings online are not being updated and may not reflect subsequent refinements of the assays.

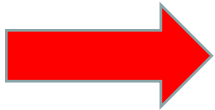
### Summary table of available protocols in this document

Institute	Gene targets
China CDC, China	ORF1ab and N
Institut Pasteur, Paris, France	Two targets in RdRP
US CDC, USA	Three targets in N gene
National Institute of Infectious Diseases, Japan	Pancorona and multiple targets, Spike protein
Charité, Germany	RdRP, E, N
HKU, Hong Kong SAR	ORF1b-nsp14, N
National Institute of Health, Thailand	N

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# Contamination at CDC lab delayed rollout of coronavirus tests

April 18, 2020 at 5:00 p.m. GMT+2



*The Washington Post*  
*Democracy Dies in Darkness*

The CDC facilities that assembled the kits violated sound manufacturing practices, resulting in contamination of one of the three test components used in the highly sensitive detection process, the scientists said.

The cross contamination most likely occurred because chemical mixtures were assembled into the kits within a lab space that was also handling synthetic coronavirus material.

# Contamination at CDC lab delayed rollout of coronavirus tests

April 18, 2020 at 5:00 p.m. GMT+2

## **Test kits manufactured in-house:**

Officials at the CDC chose to have the test kits manufactured in-house, instead of by an outside contractor.

Producing reliable test kits requires rigorous quality control.

The kits were developed in a specialty lab that focuses on disease research and *were assembled at the CDC's Biotechnology Core Facility Branch, located at the agency's headquarters in Atlanta.*

## **Multiplex:**

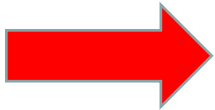
For reasons that have remained unexplained publicly, the CDC scientists chose *complexity over simplicity in the test's design.*

The *CDC's extra test component was not essential to detecting the novel coronavirus* and it complicated the test when speed was critical, many experts said.

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The Washington Post separately confirmed that Food and Drug Administration officials concluded that the CDC violated its own laboratory standards in making the kits. The substandard practices exposed the kits to contamination.

The troubled segment of the test was not critical to detecting the novel coronavirus, experts said. But after the difficulty emerged, CDC officials took more than a month to remove the unnecessary step from the kits, exacerbating nationwide delays in testing, according to an examination of federal documents and interviews with more than 30 present and former federal scientists and others familiar with the events. Many of them spoke on the condition of anonymity because they were not authorized to comment publicly.



**RNA Positive Kontrolle**

# Keine Tests in USA verfügbar! & Europa?

Summary table of available protocols in this document

Institute	Gene targets
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US CDC, USA	Three targets in N gene
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Charité, Germany	RdRP, E, N
HKU, Hong Kong SAR	ORF1b-nsp14, N
National Institute of Health, Thailand	N

# RNA Positivkontrolle (10<sup>3</sup> Kopien/μl)

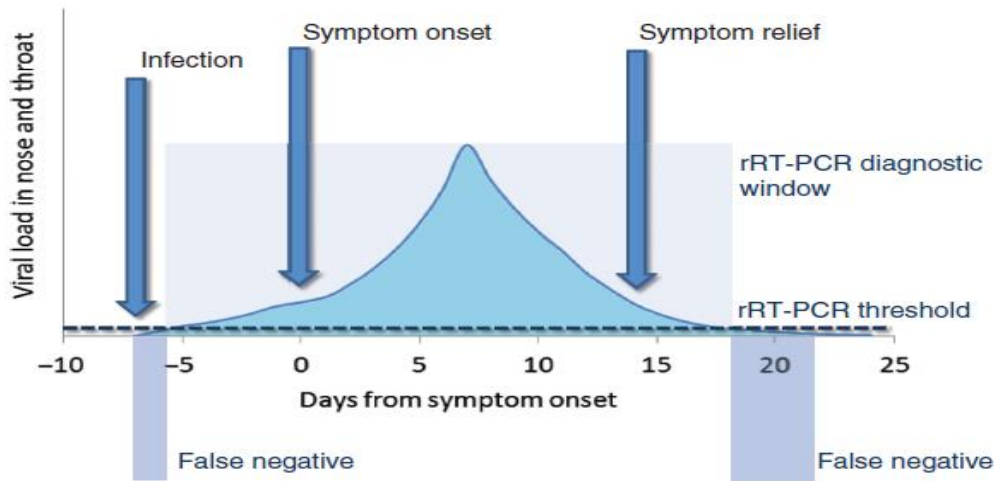
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Bei einer Bestellung in einem Synthese Labor:

1-10 nmol Syntheseausbeute



**Figure 1:** Correspondence between development of viral load during severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, clinical course and positivity of (real time) reverse transcription polymerase chain reaction (rRT-PCR) assays.

Lippi G, Simundic AM, Plebani M.  
 Potential preanalytical and analytical vulnerabilities in the laboratory diagnosis of coronavirus disease 2019 (COVID-19)  
*Clin Chem Lab Med.* 2020-0285

Infection: >100-500 Viren  
 False negative: Viren sind in den Zellen  
 Symptom onset: 5.000-10.000 Viren / Tropfen (Ct=24-25)  
 5 – 15 Tage: < 1-10 Million Viren / Tropfen (Ct=17-20)  
 Symptom relief: 5.000-10.000 Viren / Tropfen (Ct=24-25)  
 False negative: 1-10 Viren (Ct=33-35)

 Aerosol 100-1.000 Kopien

# RNA Positivkontrolle

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**Syntheseausbeute: 1-10 nmol**

**1 nmol: 600.000.000.000.000 Kopien (= 600.000.000 Millionen)**

Gelöst in 1 ml: 600.000 Millionen Kopien / µl

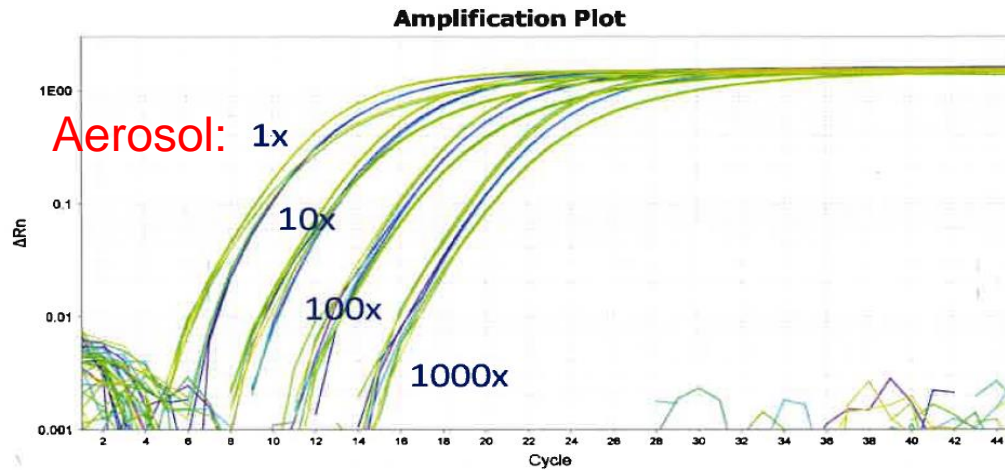
**Tropfen (10 µl): 6.000.000 Millionen Kopien / Tropfen**



**Aerosol Tröpfchen(1:10.000): 600 Millionen Kopien / Aerosolpartikel**

# RNA Positivkontrolle EURM-019

10<sup>8</sup> Kopien/μl → Aerosol 10.000 Kopien



ANNEX 2: Sequence of the synthetic IVT RNA positive control (880 nt\*)

```
GGGAGACGAAUUGGGCCCUAGAUCAUGCUUGAGCGGGCCGACGGUAGUAGAAUUCUCG
AGAAUUCGCCUUUAUUCAGUAUUGAGUAAUUGGUAUUGUUGGCGGUUCACUAUUAUGUUA
AACCAAGUGGAACCUCAUCAGGAGAGCCCAACUCGUUAUUGCUAAUAGUGUUUUAAACAUU
UGUCAAGCUGUCCGGAAGAGACAGGUACGUAAUAGUUAUAGCGUAUCUUUUUUUUUUCU
UUCUGGGUUAUUCUAGUACACUAGCCAUCCUUAUCUGCGCUUCGACUUGUGGCGUACUG
CUGCAAUAUUGUUAACGUAAUUGGACCCCAAAAUCAGCGAAUUGCACCCCGCAUUAACGUUU
GGUGGACCCUCAGAUCAACUGGAGUAACCCAGAAUGGAGAACCCAUUGCAACUGAGGGAGC
CUAGAUAACCCAAAAGUACAUUGGCACCCGCAUCCUGCUAACAUAUGCUGCAUUCGUGC
UACAAUUCUUCUAGAAUUAUUGGGACCGACAAUUAUGACACAGCAACUAGUAUACAA
CAUUGCGCGCAAUUGCACAUAUUGCCCGACGCUUCAGCGUUCUUCGGAADGUUCGCGAU
UGGCAUUGGAAGUCACACCUUCGGGACGUUGUAGCCUACACAGGUGCCAUCAAUUGGAGU
GUGACAUACCCAUUGGUGCAGGUAAUUGCGUAGUUAUCAGACUCAGACUAAUUCUCCUCGG
CGGGCACGUAGUGUAGCUAGUCAACCGUUCUUGUCGCUUGGAUCCGAAUUCRAAGGUGAA
AUUGUUAUCCGCUACAAUUCACACAACUACGAGCCGGAAGCAUAAAGUUAAGCCUUG
GGUGCCUUAUGA
```

Diese EURM-019 Positive Kontrolle enthält alle Test der WHO Liste

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### ANNEX 2: Sequence of the synthetic IVT RNA positive control (880 nt\*)

```

GGGAGACGAAUUGGGCCCUCUAGAUGCAUGCUCGAGCGGCCGCCAGUGUGAUGGAUAUCUGC
AGAAUUCGCCC UUAUUC AAGUAUUGAGUGAAAUGGUC AUGUGUGCGGUUCACUAUAUGUUA
AACCAGGUGGAACCUC AU CAGGAGAU GCCACAACUGCUUAUGCUAAUAGUGUUUUUAACAUU
UGUCAAGCUGUCCGGAAGAGACAGGUACGUUAAUAGUUAAUAGCGUACUUCUUUUUCUUGC U
UUCGUGGU AUUCUUGCUAGUUA CACUAGCCAUCCUUA CUGCGCUUCGAUUGUGUGCGUACUG
CUGCAAUAUUGUUAACGUUAAUUGGACCCCAAAAUCAGCGAAAUGCACCCCGCAUUAACGUUU
GGUGGACCCUCAGAUUCAACUGGCAGUAACCAGAAUGGAGAACGCAUUGCAACUGAGGGAGC
CUUGAAUACACCAAAAAGAU CACA UUGGCACCCGCAAUCCUGCUAACAAUGCUGCAAUCGUGC
UACAACUCCUCAAGGAAAUUUUUGGGGACCAGGAACUAAUCAGACAAGGAACUGAUUACAAA
CAUUGGCCGCAAAUUGCACA AUUUGCCCCAGCGCUUCAGCGUUCUUCGGAAUGUCGCGCAU
UGGCAUGGAAGUCACACCUUCGGGAACGUGGUUUAUCUACACAGGUGCCAUCAAAUUGGAGU
GUGACAUAACCAUUGGUGCAGGUUAUAUGCGCUAUCUAGACUCAGACUAAUUCUCCUCGG
C → SUAGCUAGUCAACCCUGCUUUUGG →
AUUGUUAUCCGCUCACAAUUCACACAACAUAACGAGCCCGGAAGCAUAAAAGUGUAAAAGCCUGG
GGUGCCUAAUGA
  
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# DANKE

an Sie  
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an en.co.tec, LISAvienna, AWS  
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an das ingenetix Team X, Y, Z und E  
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an unsere Kunden und Lieferanten  
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