# INSTAND

# CERTIFICATE

Survey of 28 April 2020

You have fulfilled the requirements of the External Quality Assessment with the following analysis

**Virus Genome Detection - Coronaviruses (340):**

Validity 12 months:

**SARS-CoV-2 (RNA) - qualitative**

(R) analysis is subject to the RiliBÄK

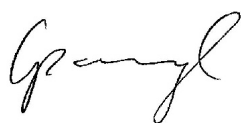**Participant:**
**68045**
**Drª Conceição Barreira**
**LAC Fernanda Galo**
**Edificio TomarLab**
**Rua Coronel Garçês Teixeira, 15**
**2300-463 Tomar**

Düsseldorf, 01 May 2020

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Deutsche
Akkreditierungsstelle
D-EP-15027-02-00

INSTAND
Qualitätskontrolle
und Ringversuch
Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V.
DÜSSELDORF

Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)

Prof. Dr. rer. nat. Heinz Zeichhardt
(Adviser)

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in medizinischen Laboratorien e.V.
Ubierstr. 20 | 40223 Düsseldorf

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# CERTIFICATE OF PARTICIPATION

Survey of 28 April 2020

You have participated in the External Quality Assessment with the following analysis

**Virus Genome Detection - Coronaviruses (340):**

SARS-CoV-2 (RNA) - qualitative

(R) analysis is subject to the RiliBÄK
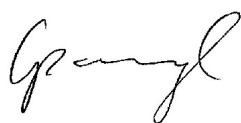
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| Adviser: | **Prof. Dr. rer. nat. Heinz Zeichhardt** | |
|---|---|---|
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## 340  Virus Genome Detection - Coronaviruses

**SARS-CoV-2 (RNA) - qualitative**                                                                                                                    +

| Name of test | Unit | Method | Manufacturer | | | | |
|---|---|---|---|---|---|---|---|
| GeneFinder COVID-19 Plus | | PCR / NAT (395) | ELITech (ET) | | | | |
| Result (qual) | Sample | Your specification(s) | Correct specification(s) | TV-Type | | Meets criteria | |
| | 340059 | positive (3) | | | | | Sample not evaluated |
| | 340060 | below detection limit/negative (1) | | | | | Sample not evaluated |
| (1) | 340061 | below detection limit/negative (1) | positive (3) | SV | | | |
| | 340062 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| | 340063 | positive (3) | positive (3) | SV | | + | |
| | 340064 | positive (3) | | | | | Sample not evaluated |
| | 340065 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| Primer / Gene region | Sample | Your value | | | | | |
| | 340059 | RdRP gene | | | | | |
| | 340060 | RdRP gene | | | | | |
| | 340061 | RdRP gene | | | | | |
| | 340062 | RdRP gene | | | | | |
| | 340063 | RdRP gene | | | | | |
| | 340064 | RdRP gene | | | | | |
| | 340065 | RdRP gene | | | | | |
| Name of test | Unit | Method | Manufacturer | | | | |
| GeneFinder COVID-19 Plus | | PCR / NAT (395) | ELITech (ET) | | | | |
| Result (qual) | Sample | Your specification(s) | Correct specification(s) | TV-Type | | Meets criteria | |
| | 340059 | positive (3) | | | | | Sample not evaluated |
| | 340060 | below detection limit/negative (1) | | | | | Sample not evaluated |
| | 340061 | positive (3) | positive (3) | SV | | + | |
| | 340062 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| | 340063 | positive (3) | positive (3) | SV | | + | |
| | 340064 | positive (3) | | | | | Sample not evaluated |
| | 340065 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| Primer / Gene region | Sample | Your value | | | | | |
| | 340059 | N gene | | | | | |
| | 340060 | N gene | | | | | |
| | 340061 | N gene | | | | | |
| | 340062 | N gene | | | | | |
| | 340063 | N gene | | | | | |
| | 340064 | N gene | | | | | |
| | 340065 | N gene | | | | | |

**SARS-CoV-2 (RNA) - qualitative**                                                                          +

| Name of test | Unit | Method | Manufacturer | | | |
|---|---|---|---|---|---|---|
| GeneFinder COVID-19 Plus | | PCR / NAT (395) | ELITech (ET) | | | |
| Result (qual) | Sample | Your specification(s) | Correct specification(s) | TV-Type | | Meets criteria | |
| | 340059 | positive (3) | | | | | Sample not evaluated |
| | 340060 | below detection limit/negative (1) | | | | | Sample not evaluated |
| (1) | 340061 | below detection limit/negative (1) | positive (3) | SV | | | |
| | 340062 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| | 340063 | positive (3) | positive (3) | SV | | + | |
| | 340064 | positive (3) | | | | | Sample not evaluated |
| | 340065 | below detection limit/negative (1) | below detection limit/negative (1) | SV | | + | |
| Primer / Gene region | Sample | Your value | | | | | |
| | 340059 | E gene | | | | | |
| | 340060 | E gene | | | | | |
| | 340061 | E gene | | | | | |
| | 340062 | E gene | | | | | |
| | 340063 | E gene | | | | | |
| | 340064 | E gene | | | | | |
| | 340065 | E gene | | | | | |

(1)    This result was not taken into account for the granting of the certificate.