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OUR RESPONSIBILITY FOR YOUR HEALTH



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|--------------------------------|---|
| Product | LEPU MEDICAL SARS-CoV-2 Antigen Rapid Testkit (nasopharyngeal-swab) |
| Article No. | cap-med-122, 1 package individually packed (suitable for personal use) |
| Registration | 2th September 2020, CE-InCG27 REV.06 |
| Downloads/Listing | BfArM, listing EU Health Security Committee >> click here << Product details >> click here <<, Price list >> click here << |
| Limit of Detection | 2 x 10 ² TCID ₅₀ /ml (200 TCID ₅₀ /ml) (gold standard values) |
| Sensitivity/Specificity | 94,37% (97,32% for samples with Ct-values ≤ 25), 99,62% |
| Packaging Unit (VPE) | 1 package individually packed, 150 pcs. per carton |

CAPULUS MEDICAL Services

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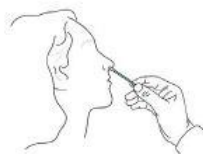
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Der Warenversand/-Abrechnung erfolgt über die BIOCHEM Bernburg GmbH (ISO 13485 zertifiziert), Neuer Weg 1, 06406 Bernburg.

BENEFITS AT A GLANCE / OPERATIONAL MANUAL

- October 01, 2020 – BfArM listed and 100% refundable
- February 17th, 2021 – Official listing by EU Health Security Committee
- Recommended by Paul-Ehrlich-Institute
- Category gold-standard-values (LOD-value under 500), tests with a LOD-value up to 1200 are BfArM listed
- Very good sensitivity- / specificity values
- Easy handling in application (booklet-structure, minimizes the use of staff)
- Nasal swabs are only taken from the middle turbinate (more comfortable for patients)
- Larger nasal swab area for the inclusion of more virus- / bacterial mass
- Upon request, free training courses for your staff can be carried out by our specialists (only in Germany)

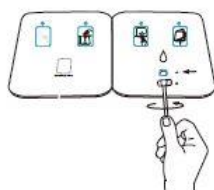
Instruction



Step 1: Use swab to collect sample.



Step 2: Add 5 drops of buffer to well A.



Step 3: Insert the sample through well B to well A, rotate the shaft clockwise first and counterclockwise, twice each.



Step 4: Peel off the adhesive, fold the left side over, and wait for 15 minutes.

Result Interpretation

Positive

(+)



Negative

(-)



Invalid



LEPU MEDICAL TECHNOLOGY (BEIJING) CO., LTD

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MANUAL IN COMPARISON

Booklet-structure minimizes the use of staff

Antigen Test Competitor



Antigen Test Competitor

