

## pH-Fix 4.5–10.0

Test strips for measuring pH values in urine in the range of pH 4.5–10.0

 0197  IVD for self-testing  Please refer to instruction for use

 92120

### Pack Content:

100 Test strips  
1 Color chart pH 4.5–10.0

### Application:

The pH-Fix 4.5–10.0 test strips are semi-quantitative indicator strips for measuring the pH value in urine by self-testing in the pH range 4.5–10.0 with a gradation of 0.5. The test strips can be read visually by comparison with the color chart.

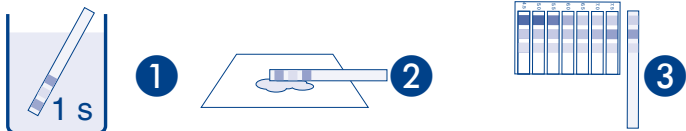
For quality control use commercially available pH buffer solution.

### Caution:

Refer to your GP to discuss the results. A pH value will only deliver a definitive diagnosis in conjunction with other medical findings and where necessary appropriate treatment. Only use thoroughly rinsed and clean containers to collect urine. Only collect urine in the morning and carry out testing immediately after collecting it wherever possible.

### Instructions for measuring the pH value of urine:

1. Dip the test strip with all its test fields into the urine sample for 1 second.
2. Dab the strip along the edge on an absorbent cloth to remove excess liquid.
3. Compare the test fields with the color scale (accuracy of reading  $\pm 0.2$  pH).



### Performance study:

A comparative study (N = 103) shows that in 99 % of all cases the pH values have been determined correctly with an accuracy of 0.5 pH units.

### Storage conditions:

Avoid exposing the strips to sunlight and/or moisture. Keep container cool and dry (store between 4–30 °C). The test strips are stable, when stored properly up to the date of expiry indicated.

### Disposal:

Used test strips may be disposed of as domestic waste.

### Note:

Do not touch the test fields.

Test strips are for single use only.

The use of the system is limited to samples that are not strongly colored.

Sample volume must be sufficient to properly wet all test pads according to the instructions for use.

Only for use outside of the body.

### Test principles:

The pH value of the sample generates a color change of the pH indicator dye that is chemically bound to the paper of the test fields.

### Reporting:

Please note that any serious incident that has occurred in relation to the product shall be reported immediately to the manufacturer and the competent authority of the European member state in which the incident occurred. European vigilance contact points: [http://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](http://ec.europa.eu/growth/sectors/medical-devices/contacts_en)

### Literature:

L. Thomas, *Labor und Diagnose*, TH-Books Verlagsgesellschaft, 2008.

 Statement of Conformity (Product corresponds to the In-Vitro Diagnostic Directive 98/79/EC of the European Union)

 In-vitro Diagnostic

 Please read instructions for use!

 Permitted storage temperature range

 Use by

 Batch identification

 Item number

 Manufacturer

 Do not reuse

### Technical Service

If you have any questions after reading the manual or if you need technical assistance, please contact  
MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6–8 · 52355 Düren · Deutschland  
Phone: +49 24 21 969-0  
Fax: +49 24 21 969-199  
e-mail: [info@mn-net.com](mailto:info@mn-net.com)  
[www.mn-net.com](http://www.mn-net.com)