Newborn screening of Phenylketonuria

Fully quantitative fluorometric screening kit for PKU

- Simple and easy to perform
- Excellent analytical sensitivity
- Extensive experiences from worldwide customers
- Calibrated against international reference preparations
Neonatal Phenylalanine

Neonatal phenylalanine assay is a chemical method intended for the quantitative determination of phenylalanine from dried blood spots. Phenylalanine eluted from dried blood spots forms a fluorescent compound with ninhydrin. The fluorometric response is greatly enhanced by the presence of a dipeptide L-leucyl-L-alanine. The pH during the reaction is strictly controlled by succinate buffer at 5.8 ± 0.1 in order to optimize fluorescence and maximize specificity. Copper reagent is added to stabilize the fluorescent complex and enhance the signal. Fluorescence is measured with at 485 nm (excitation wavelength being 390 nm). The assay is calibrated against the European Working Standard for Phenylalanine (EWS-Phe) since 1996 and the 1st ISNS Reference Preparation for Neonatal Screening for TSH, phenylalanine and 17 α-hydroxyprogesterone in blood spots since 2005.

PKU Test procedure

1. Punch 3 mm sample disks, add 80 μl elution buffer
2. Incubate 30 min at RT on a shaker
3. Transfer 50 μl eluate, add 50 μl incubation mixture.
4. Incubate A) 1 h at 60 °C or B) 2 h at 37 °C
5. Add 200 μl copper reagent
6. Incubate 15 min at RT
7. Measure at ex. 390 nm, em. 485 nm

Comparison of calibration curves using two procedures and with linear regression curve fitting.

<table>
<thead>
<tr>
<th>Cat.no.</th>
<th>Product name</th>
<th>Plate type</th>
<th>Packing size</th>
<th>Regulatory status</th>
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<tbody>
<tr>
<td>6199895</td>
<td>Neonatal PKU, fluorometric test</td>
<td>96-well solid</td>
<td>480 wells</td>
<td>CE marked</td>
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<td>6199896</td>
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<td>4800 wells</td>
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<td>6190940</td>
<td>Neonatal Phenylalanine Calibrators</td>
<td>96-well solid</td>
<td>5 sets of 3 levels</td>
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Type 903 filter paper is used in all products.

*Please note: Product specifications are subject to change without prior notice owing to product modifications, improvements / up-gradation.