Development and evaluation of Whole blood albumin test system for the Point of Care Testing - The test performance in home health nursing -
H Nozaka, H Sazawa, E Ozaki, M Nakano, H Takami, M Ooura
Hirosaki university Graduate school of health sciences

Background

1. Hospital to Home health care
   It is required that chronic phase medical care is converted into home therapy, because lack of medical resources has occurred in Japan.

2. Nutritional management
   It is reported that nutritional management is strongly related to patient prognosis, recovery period and survival rate.
   Albumin and Total protein levels are significant indicator of patient nutritional status.

Problem

Increase Protein energy malnutrition (PEM) patient in JAPAN
No POCT device for nutritional biochemical examination in home health nursing

The aim of this work is development and evaluation of POCT device for Albumin test with whole blood.

The requirements of system is following

- Minimally invasive with Lancet blood
- Low hardware price and running cost
- Maintenance free
- No need of centrifugal separation

Objectives

1. Low-invasive Low cost Easy treatment
2. New POCT device for home nursing

Auto analyzer vs POCT devices

<table>
<thead>
<tr>
<th>Method</th>
<th>Auto analyzer (Laboratory)</th>
<th>Dry chemistry (POCT)</th>
<th>Liquid POCT device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drawing/blood volume</td>
<td>1-200μl</td>
<td>200-300μl</td>
<td>(1-2μl) Whole blood</td>
</tr>
<tr>
<td>Accuracy</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Precision</td>
<td>△</td>
<td>△</td>
<td>X</td>
</tr>
<tr>
<td>Analyzetime</td>
<td>3-5min</td>
<td>3-5min</td>
<td>3-5min</td>
</tr>
<tr>
<td>Multi-channel</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Devicetime</td>
<td>$50,000~$100,000</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Portability</td>
<td>○</td>
<td>△</td>
<td>X</td>
</tr>
</tbody>
</table>

System configuration

The portable device was consisted of photo-transistor unit, LED unit, and data logger system “NI-USB DAQ”. Application software was developed with “NI-LabVIEW”. Albumin test principle was adopted BCG (Brom-Cresol Green) method.

System Block Diagram

ALB test process

Measurement of ALB level

- Control power supply
- Lab View
- Control

Measurement of Hb level

- Power supply
- Data Logger
- A/D converter

Remove Hb interference (Absorbance correction)

- DC/DC converter
- Power supply
- LED

Create calibration curve with Hb level correction

- DC/DC converter
- Power supply
- LED

Convert absorbance to ALB concentration

- DC/DC converter
- Power supply
- LED

Calculation of estimated serum ALB level

- ALB test unit
- LED
- Power supply

Study on calculation of estimated Ht level from Hb level

Method

- We measured Hb and Ht level with peripheral blood from brachial vein.
- Materials: 34 healthy persons

Results

1. The Ht level can be calculated by using the Hb level of the specimen and the prediction formula.
2. Hematocril volume correction of the whole blood ALB level can be performed with Hb level.

ACKNOWLEDGMENT

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