Introduction

2-1: Monoclonal antibody, CSLEX-1 recognizes sialyl Lewis^a^ epitope

Type 1 sugar chain

Sialyl Lewis^a^ (NS-19-9)

NeuAcα2-3Galβ1-4GlcNAcβ1-3Galβ1-4Glcβ1-Cer

Type 2 sugar chain

Fucα1-2

Sialyl Lewis^a^ (CSLEX-1)

NeuAcα2-3Galβ1-4GlcNAcβ1-3Galβ1-4Glcβ1-Cer

Fucα1

2-2: Clinical Significance of serum Sialyl Lewis^x^ (CSLEX) positive rate of primary breast cancer comparing with other marker

Positive rate (%) in primary breast cancer

2-3: Positive Rate of Recurrent Breast Cancer Comparing with Other Marker

Positive rate (%) in recurrent breast cancer

2-4: Positive Rate of CSLEX in Benign Mammary disease

No. of positive (%) of CSLEX, CA15-3, CEA

Mammary dysplasia 2

Mastitis 4

2-5: CSLEX value before and after response to treatment

CR, PR NC PD

2-6: Monitoring after operation

Case 1

1. Methods

CSLEX assay (Nittoboseki Co., LTD) uses microplate coated with an anti-CSLEX specific monoclonal mouse antibody (CSLEX-1 established by P. Terasaki et al, UCLA) and HRP-conjugated mouse anti-human CSLEX antibody was used for detection after incubating a serum 20 U/ml in the anti-CSLEX antibody coated well. 40 U/ml CSLEX was used as calibrator and was calibrated using diluted calibrator in a standard dilution reagent.

1. Results

CVs of within run and between-day reproducibility for three samples ranging from 6.0-23.2 U/ml were 3.2-4.2% and 0.9-3.1%, respectively. No interference was observed from addition ascorbic acid (5g/L), rheumatoid factor (1500U/ml) and hemoglobin (5g/L) respectively. Dilution linearity of CSLEX using four samples (<40U/ml) and standard dilution reagent exhibited straight lines through origin. Analyzing five replicates of the zero standard, and then computing CSLEX concentration for the signal of mean+2SD determined the sensitivity of the automated assay. The analytical sensitivity was calculated this way and found to be 1.0 U/ml. A preliminary correlation study using sera sample (n=103) showed the following correlation coefficient, slope and intercept, respectively: 0.984, 1.06 and 1.6 using sera sample (n=103) showed the following correlation coefficient, slope and intercept, respectively: 0.984, 1.06 and 1.6.

1. Conclusions

Correlation between automated and manual assay showed on excellent agreement. This result indicates that our kit
4-3) Recovery test for CSLEX

<table>
<thead>
<tr>
<th>Added (U/ml)</th>
<th>Measured (U/ml)</th>
<th>Recovered (U/ml)</th>
<th>Recovery (%)</th>
</tr>
</thead>
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<tr>
<td>0</td>
<td>5.9</td>
<td>5.9</td>
<td>100</td>
</tr>
<tr>
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<td>15.6</td>
<td>12.2</td>
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<tr>
<td>100</td>
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<td>88</td>
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<td>100</td>
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<tr>
<td>10000</td>
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<td>115</td>
<td>44</td>
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</tbody>
</table>

4-4) Correlation between automated and manual

\[ Y = 1.057X + 0.01 \]

\[ r = 0.984 \]

4-5) Standard curve & Example of demonstration

5. Conclusion

1. The measurement of CSLEX is useful for monitoring after therapy of breast cancer.
2. The correlation between automated and manual assay showed on excellent agreement.
3. This result indicates that our kit for measurement of CSLEX is applicable assay to automate system.
4. This application is suitable for routine clinical use.