

EVALUATION OF THE FUJI DRI-CHEM NX700I CLINICAL CHEMISTRY ANALYZER INCLUDING INTERFERENCE STUDIES



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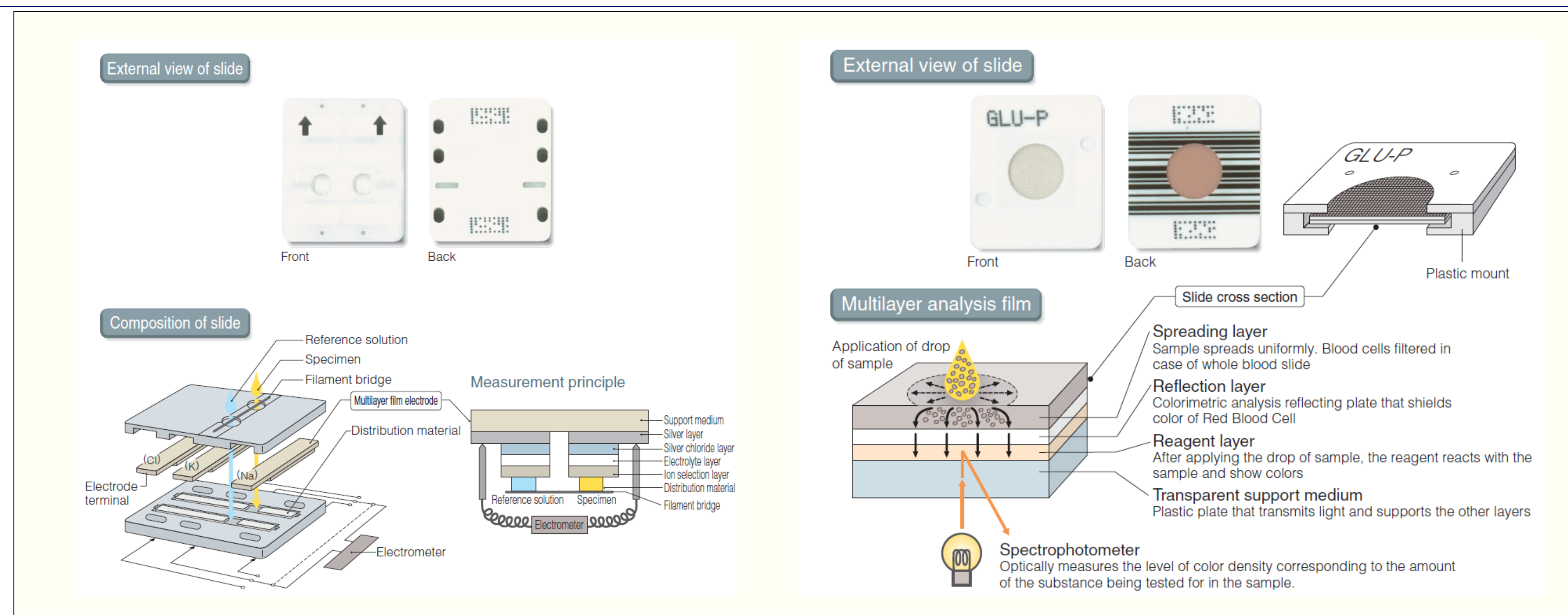
Background

The FUJI DRI-CHEM NX700i holds 28 colorimetric and 3 electrolyte test assays and analyzes up to 190 tests/hour (colorimetry + electrolytes). A STAT testing position is available. The colorimetric method slide is a multilayered slide composed of dry chemical ingredients needed for the reaction quantifying enzymes and substrates by colorimetric methods. The potentiometric method slide contains ion selective film electrodes. Calibration is done with QC cards except for CRP working with a calibrator. Each test needs 10µL of sample except for CRP (5µL) and ISE (50µL for all 3 tests).

Methods

In this study the Fuji Dri-Chem NX700i was evaluated using serum samples. The parameters investigated were albumin (ALB), blood urea nitrogen (BUN), creatinine (CRE), total bilirubin (TBIL), aspartate aminotransferase (AST/GOT), Alanine Aminotransferase (ALT/GPT), γ-glutamyltransferase (GGT), C-reactive protein (CRP), lipase (LIP), triglycerides (TG) and ammonia (NH₃). Interferences from hemolytic, lipemic, icteric or highly elevated total protein samples were excluded according to the manufacturers method specific declarations and studied separately. Method comparison was done by measuring 50 samples for each analyte at the same time on the NX700i and the Siemens Atellica CH

analyzer. For each parameter inter- (controls, n=10) and intra-assay (patient samples, n=10) coefficients of variation (CV) were calculated for low, medium and high concentrations. The manufacturer lists known interfering substances for every analyte. The measurement of CRP involves Glucose as part of the reactions and is listed as interfering substance above the concentration of 400 mg/dl (22.2 mmol/L). This was tested by measuring CRP at glucose concentrations from 150 mg/dl to 860 mg/dl. The effect of very low and high protein concentrations and haemolytic, icteric and lipemic samples were tested.



Results

For the colorimetric assays inter-assay CVs (n=10) were 1.4 to 7.7% (Low), 1.1 to 5.5% (Medium) and 1.1 to 3.9% (High). Intra-assay CVs (n=10) were 1.2 to 4.1% (Low), 1.1 to 3.7% (Medium) and 0.8 to 3.3% (High). Method comparison (Passing-Bablok Regression) of routine samples from hospital patients showed good agreement of the two methods with correlation coefficients of r = 0.98 and higher except for LIP (0.83), NH₃ (0.87) and Alb (0.93). For the potentiometric assays inter-assay CVs (n=10) were 1.1 to 1.6% (Low), 0.7 to 1.2% (Medium) and 0.8 to 1.0% (High). Intra-assay CVs (n=10) were 0.1 to 0.5% (Low), 0.3 to 1.3% (Medium) and 0.7 to 0.9% (High). Method comparison (Passing-Bablok Regression) of routine samples from hospital patients showed good agreement of the two methods with correlation coefficients of r = 0.98 except for Chloride (0.83).

| | Albumin | | | Ammonia | | |
|----------------|----------------|--------|------|-----------------|--------|------|
| | Low | Medium | High | Low | Medium | High |
| CV inter assay | 2.8% | 2.6% | 2.3% | 5.2% | | 2.4% |
| CV intra assay | 2.5% | 2.2% | 1.6% | 1.9% | 3.7% | 1.8% |
| PB Regression | y=1.141x-8.377 | | | y=0.828x+14.422 | | |
| R ² | 0.92 | | | 0.865 | | |

| | Bilirubin Total | | | Blood Urea Nitrogen | | |
|----------------|-----------------|--------|------|---------------------|--------|------|
| | Low | Medium | High | Low | Middle | High |
| CV inter assay | 7.7% | 2.1% | 1.1% | 1.4% | 1.7% | 2.2% |
| CV intra assay | 9.5% | 1.5% | 0.8% | 4.1% | 1.2% | 1.1% |
| PB Regression | y=1.031x-0.155 | | | y=1.160x+1.150 | | |
| R ² | 0.994 | | | 0.986 | | |

| | Creatinine | | | CRP | | |
|----------------|----------------|--------|------|----------------|--------|------|
| | Low | Middle | High | Low | Medium | High |
| CV inter assay | 2.6% | 2.3% | 1.7% | 5.7% | | 5.5% |
| CV intra assay | 2.3% | 2.6% | 2.1% | 11.1% | 2.5% | 3.3% |
| PB Regression | y=1.101x-0.041 | | | y=1.142x-0.128 | | |
| R ² | 0.996 | | | 0.996 | | |

| | GGT | | | GOT | | |
|----------------|----------------|--------|------|----------------|--------|------|
| | Low | Medium | High | Low | Medium | High |
| CV inter assay | 4.8% | 1.7% | 2.4% | 2.5% | 2.4% | 1.7% |
| CV intra assay | 1.5% | 1.3% | 1.4% | 1.6% | 0.0% | 1.1% |
| PB Regression | y=1.043x-1.769 | | | y=0.739x+1.875 | | |
| R ² | 0.997 | | | 0.988 | | |

| | GPT | | | Lipase | | |
|----------------|----------------|--------|------|----------------|--------|------|
| | Low | Medium | High | Low | Medium | High |
| CV inter assay | 4.4% | 3.9% | 2.6% | 1.9% | 2.9% | 3.9% |
| CV intra assay | 1.9% | 2.1% | 1.4% | 3.1% | 3.1% | 2.6% |
| PB Regression | y=0.860x+1.200 | | | y=0.881x+1.859 | | |
| R ² | 0.969 | | | 0.834 | | |

| | Triglyceride | | | Sodium | | |
|----------------|-----------------|--------|------|------------------|--------|------|
| | Low | Medium | High | Low | Medium | High |
| CV inter assay | 1.5% | 1.1% | 1.4% | 1.1% | 0.7% | 0.8% |
| CV intra assay | 1.2% | 1.1% | 1.3% | 0.5% | 0.3% | 0.8% |
| PB Regression | y=1.058x-15.724 | | | y=1.1385x+1.5922 | | |
| R ² | 0.988 | | | 0.985 | | |

| | Potassium | | | Chloride | | |
|----------------|------------------|--------|------|------------------|--------|------|
| | Low | Medium | High | Low | Medium | High |
| CV inter assay | 1.6% | 1.2% | 0.8% | 1.5% | 0.8% | 1.0% |
| CV intra assay | 0,0% | 1.3% | 0.9% | 0.5% | 0.6% | 0.7% |
| PB Regression | y=1.0876x-0.0775 | | | y=0.8627x+3.6568 | | |
| R ² | 0.9786 | | | 0.8335 | | |

CV: coefficients of variation PB: Passing Bablok Regression

Interferences : When looking at the principle of CRP measurement, Glucose takes part in the process leading to the final color change which is then measured as correlation to the CRP quantity in the sample. Glucose is listed as interfering substance for the CRP measurement when above the concentration of 400 mg/dl (22.2 mmol/L). In this study there were false low CRP values above Glucose values of 417 mg/dl. Vitamin C did not cause interferences up to 174 mg/l except for TG and GGT (84mg/l), Lip and GOT (63mg/l). Bilirubin did not cause interferences up to 24,4 mg/dl except for AP (24 mg/dl) and GGT (14,9 mg/dl). Total Protein should be in the range between 40 and 95 g/L.

Conclusion

The FUJI DRI-CHEM NX700i shows good intra- and inter-assay precision with low CVs and excellent correlation with the Siemens Atellica CH analyzer.