

K970921

APR - 8 1997

510(k) Summary
ALKO Standards A,B, and C
for Dade Dimension[®] Chemistry Systems
with MultiPLY[™] Integrated Multisensor module Installed

The products encompassed by this 510(k) submission are Class II (75JIX) In Vitro Diagnostic Solutions manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The A,B ,C Standards are intended for use in calibrating Na⁺, K⁺, Cl⁻ and TCO₂ analytes on the Dade Dimension[®] Chemistry Systems. Dade Chemistry Systems Inc. is the original equipment manufacturer (OEM) of the system and of predicate Standard Reagents which are necessary for the continued operation and use of the system.

The ALKO products stated are currently cleared under docket K:926518. Information herein will support ALKO's position to extend the intended use of these products to the Dade Dimension[®] Chemistry System with MultiPLY[™] Integrated Multisensor module installed. The MultiPLY[™] Integrated Multisensor module measures Na⁺, K⁺, Cl⁻ by using Integrated Multiple Technology means. The TCO₂ analyte is measured by the system's Ion Selective Electrode. The ALKO Standard Reagents are intended to serve as direct replacements to like named products manufactured by Dade Chemistry Systems Inc.(formally Dupont International). ALKO Product A202-0 (Standard A) is equivalent to Dade Dimension[®] Chemistry System product S540 (MultiPLY[™] Standard A). ALKO product A103-0 (Standard B) is equivalent to Dade Dimension[®] Chemistry System product S550 (MultiPLY[™] Standard B). ALKO product A200-0 (Standard C) is equivalent to Dade Dimension[®] Chemistry System product S560 (MultiPLY[™] Standard C). For marketing purposes ALKO will assign new product numbers for the extended use labeling.

ALKO uses a similar composition, description and packaging design as that used by Dade Chemistry Systems Inc. in its products. ALKO has shown performance equivalence of its products to Dade Chemistry Systems products in the following manner:

- Through a method comparison where results obtained on a Dade Dimension[®] Chemistry System with IMT installed, calibrated with ALKO products and compared with results obtained on the same analyzer calibrated with Dade products; and
- Through a precision study where ALKO products were installed on a Dade Dimension[®] Chemistry System with IMT installed and samples were measured over 20 runs.

A summary of the results of these studies follows:

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Precision Data

Precision data was collected from the analysis of two levels of serum controls measured three runs per day, three times per run for 5 days on a Dade Dimension[®] System with IMT installed for Na⁺, K⁺, Cl⁻, TCO₂ calibrated with ALKO reagents.

Level 1

| Analyte | | N | Mean | STD | CV% | Min | Max |
|------------------|------------|----|-------|--------|--------|------|------|
| Na ⁺ | Total | 45 | 121.0 | 1.2285 | 1.0149 | 120 | 124 |
| | Run to Run | 15 | 121.0 | 0.7588 | 0.6269 | 120 | 122 |
| K ⁺ | Total | 45 | 2.70 | 0.0494 | 1.8308 | 2.6 | 2.8 |
| | Run to Run | 15 | 2.70 | 0.0333 | 1.2328 | 2.6 | 2.7 |
| Cl ⁻ | Total | 45 | 78.5 | 0.4999 | 0.6367 | 78 | 79 |
| | Run to Run | 15 | 78.5 | 0.3189 | 0.4062 | 78 | 79 |
| TCO ₂ | Total | 45 | 16.59 | 0.7824 | 4.7153 | 14.6 | 18.0 |
| | Run to Run | 15 | 16.59 | 0.7373 | 4.4432 | 14.8 | 17.5 |

Level 2

| Analyte | | N | Mean | STD | CV% | Min | Max |
|------------------|------------|----|-------|--------|--------|------|------|
| Na ⁺ | Total | 45 | 180.0 | 1.0217 | 0.5677 | 178 | 183 |
| | Run to Run | 15 | 180.0 | 0.7350 | 0.4084 | 179 | 181 |
| K ⁺ | Total | 45 | 6.45 | 0.0542 | 0.8393 | 6.4 | 6.6 |
| | Run to Run | 15 | 6.45 | 0.0361 | 0.5595 | 6.4 | 6.5 |
| Cl ⁻ | Total | 45 | 120.6 | 0.6070 | 0.5032 | 119 | 122 |
| | Run to Run | 15 | 120.6 | 0.5287 | 0.4383 | 120 | 122 |
| TCO ₂ | Total | 45 | 34.24 | 1.8110 | 5.2894 | 29.7 | 39.3 |
| | Run to Run | 15 | 34.24 | 1.6119 | 4.7079 | 31.0 | 37.1 |

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Accuracy by Correlation with Dade MultiPLY[™] Standard Reagents

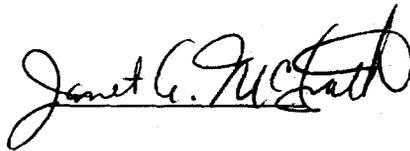
Correlation data was collected from 156 patient serum samples and 12 control samples for Na⁺, K⁺, Cl⁻ and from 76 patient serum samples for TCO₂, measured on a Dade Dimension[®] System with IMT installed, calibrated with ALKO reagents as compared with Dade reagents separately. A Linear Regression Analysis was performed using the Dade data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation $Y = a + bX$.

| Analyte | N | Slope | Intercept | R* | Range |
|-------------------|-----|-------|-----------|-------|------------|
| Na ⁺ | 168 | 0.998 | 2.699 | 0.982 | 120 - 180 |
| K ⁺ ** | 166 | 0.989 | 0.173 | 0.991 | 2.6 - 7.6 |
| Cl ⁻ | 168 | 0.960 | 4.091 | 0.966 | 78 - 122 |
| TCO ₂ | 76 | 0.909 | 2.037 | 0.975 | 4.8 - 34.4 |

*R = Correlation Coefficient

** Two outliers excluded

I hope that you find this information useful and informative.



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Regulatory Affairs

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(date prepared)