510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k051087

B. Purpose for Submission:

510(k) premarket notification package to manufacture and market the **Dimension Vista™ integrated system** and seven (7) reagent test methods with their associated calibrators and IGG controls. The methods included in this submission are representative of the Dimension Vista™ system analytical functional areas (photometry, turbidimetry, chemiluminescence, nephelometry and ion selective multisensors for electrolytes).

C. Measurand:

Urea nitrogen, immunoglobulin G, Phenobarbital, creatine kinase MB isoenzyme, sodium, potassium, and chloride

D. Type of Test:

Quantitative, photometry, turbidimetry, chemiluminescence, nephelometry and ion selective multisensors

E. Applicant:

DADE BEHRING, INC.

F. Proprietary and Established Names:

Dimension Vista™ Integrated System
Dimension Vista™ Urea Nitrogen (BUN) Flex® reagent cartridge
Dimension Vista™ Chemistry 1 Calibrator
Dimension Vista™ Immunoglobulin G (IGG) Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Controls, H, M, L
Dimension Vista™ Phenobarbital (PHNO) Flex® reagent cartridge
Dimension Vista™ Drug 1 Calibrator
Dimension Vista™ Mass creatine kinase MB isoenzyme (MMB) Flex® reagent cartridge
Dimension Vista™ MMB Calibrator
Dimension Vista™ V-LYTE™ Integrated Multisensor Na+/K+/Cl
Dimension Vista™ V-LYTE ™ Standard A
Dimension Vista™ V-LYTE ™ Standard B

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1770-Urea nitrogen test system
   21 CFR §862.1600-Potassium test system
   21 CFR §866.5510-Immunoglobulins A, G, M, D, and E immunological test system
   21 CFR §862.1170-Chloride test system
   21 CFR §862.3660-Phenobarbital test system
   21 CFR §862.1665-Sodium test system
   21 CFR §862.1215-Creatine phosphokinase/creatine kinase or isoenzymes test system.
   21 CFR §862.1150-Calibrator
   21 CFR §862.1660-Quality control material (assayed and unassayed)
   21 CFR §862.1030-Alanine amino transferase (ALT/SGPT) test system (exempt from 510(k) review)
   21 CFR §862.2160-Discrete Photometric Chemistry Analyzer for Clinical Use

2. Classification:

   Class II, II, II, II, II, II, II, II, I reserved, I, and I, respectively

3. Product code:

CDQ	Urease and glutamic dehydrogenase, urea nitrogen
CEM	Electrode, ion specific, potassium
CFQ	Radioimmunoassay, immunoglobulins (G, A, M)
CGZ	Electrode, ion-specific, chloride
DLZ	Enzyme immunoassay, Phenobarbital
JGS	Electrode, ion specific, sodium
JHY	Colorimetric method, cpk or isoenzymes
JIT	Calibrator, secondary
JIX	Calibrator, multi-analyte mixture
JJY	Multi-analyte controls, all kinds (assayed and unassayed)
CKA	NADH oxidation/NAD reduction, alt/sgpt
JJE	Analyzer, chemistry (photometric, discrete), for clinical use

4. Panel:

   (75) Chemistry
   (81) Toxicology

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

The Dade Behring Dimension Vista™ Integrated system is an in vitro diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Vista™ system chemical and immunochemical applications utilize photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion selective multisensor technology for clinical use.

The Dimension Vista™ Urea Nitrogen Flex® reagent cartridge (BUN) is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

The Dimension Vista™ Chem I Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of urea nitrogen in human specimens.

The Dimension Vista™ V-LYTE ™ Potassium test system is intended to measure potassium in serum, plasma and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions, characterized by low or high blood potassium levels.

The Dimension Vista™ Immunoglobulin G Flex® reagent cartridge (IGG) is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin G (serum antibody) in serum and plasma. Measurement of immunoglobulin G aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

The Dimension Vista™ Protein 1 Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of IgG in human specimens.

The Dimension Vista™ Protein 1 Controls, H, M, L, are intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation.

The Dimension Vista™ V-LYTE ™ Chloride test system is intended to measure chloride in serum, plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Dimension Vista™ Phenobarbital Flex® reagent cartridge (PHNO) is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

Dimension Vista™ Drug 1 Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of phenobarbital in human specimens.

The Dimension Vista™ V-LYTE ™ Sodium test system is intended to measure sodium in serum, plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The Dimension Vista™ V-LYTE ™ Standard A and Standard B are intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

The Dimension Vista™ Mass creatine kinase MB isoenzyme Flex® reagent cartridge (MMB) is a device intended to measure the activity of the MB isoenzyme of creatine phosphokinase in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction.

The Dimension Vista™ MMB Calibrator is intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of mass creatine kinase MB isoenzyme in human specimens.

3. Special conditions for use statement(s):

   Prescription use only

4. Special instrument requirements:

   Dimension Vista™ Integrated System

I. Device Description:

The Dade Behring Dimension Vista™ Integrated System is a floor model, fully automated, microprocessor-controlled, integrated instrument system that uses prepackaged Dade Behring Flex reagent test cartridges to measure a variety of analytes in human body fluids. The system is a multi-functional analytical tool that processes chemical and immunochemical methodologies, utilizing photometric, turbidimetric, chemiluminescence, nephelometric, and integrated ion selective multisensor detection technologies for clinical use. The Dimension Vista™ system can analyze up to 1500 tests/hour (typical, depending on the method mix) using a variety of analytical detection capabilities. Dimension Vista™ system detection

technologies and the corresponding methods representative of the system are:

Photometric	- Urea Nitrogen (BUN)
Turbidimetric	- Phenobarbital (PHNO)
Chemiluminescent	- mass creatine kinase MB isoenzyme (MMB)
Nephelometric	- Immunoglobulin G (IGG)
Multisensor, ion selective technology	- Na^+, K^+, and Cl^- electrolytes (V-LYTE™)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® BUN Flex® reagent cartridge/ Dimension® Indirect IMT system/ (QuikLYTE®) Na+/K+/Cl/ Dimension ® IGG/ Flex® reagent cartridge/ Dimension ® PHNO/ Flex® reagent cartridge/ Dimension® MMB/ Flex® reagent cartridge/ Dimension® MMB/ Calibrator/ Dimension® QuikLYTE®/ Standard A & Standard B/ Dimension® Chem 1 Calibrator/ N Protein Standard SL/ Dimension® Drug / Calibrator / Dimension® XL/RxL/ clinical chemistry analyzer/ N/T Protein Controls SL

2. Predicate 510(k) number(s):

   k860021/ k970330/ k990551/ k944932/ k970343/ k970336/ k860021/ k860021/ k012470/ k011035/ k944093/ k012468 – respectively

3. Comparison with predicate:

   Both the Dimension Vista™ Integrated system and the predicate Dimension RxL clinical chemistry system employ prepackaged reagents in flexible plastic, Dade Behring Flex reagent cartridges. Both systems automatically process and analyze clinical samples using a variety of in vitro diagnostic test methods. Both systems utilize integrated, ion selective multisensor detection technology for analysis of sodium, potassium and chloride electrolytes. A comparison of the similarities and differences of these two automated analyzer systems is provided in the following table:

Feature	**Dimension Vista™ System**	**Dimension® RxL Analyzer**
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
System Control	Fully automatic, microprocessor controlled	Fully automatic, microprocessor controlled
User Interface	Keyboard control Hand held barcode reader Stationary barcode scanners Graphical user interface On line help	Keyboard control ---------- Stationary barcode scanners Graphical user interface On line help

Feature	Dimension Vista™ System	Dimension® RxL Analyzer
Detection Technologies	photometric turbidimetric chemiluminescence nephelometric multisensor electrodes, ion selective	photometric turbidimetric ---------- ---------- multisensor electrodes, ion selective
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges, stored on board	Prepackaged, 6 & 8 well plastic, Dade Behring Flex® reagent cartridges stored on board
Calibrators	Stored on board	User places on system as needed
System fluids and Supplies	Stored on board	Stored on board
Reaction Vessels	hard plastic cuvettes & plastic reaction vessels	soft, plastic cuvettes & plastic reaction vessels
Temperature control	Reactions are controlled at 37°C Reagents are stored at 2 to 8 °C	Reactions are controlled at 37°C Reagents are stored at 2 to 8 °C
Spectral Selection	Interference filters - xenon flash lamp source	Interference filters - quartz/halogen lamp source
Test Throughput (typical)	Up to 1500 tests/hr	Up to 500 tests/hr
LIS external connectivity capability	Yes	Yes
System Performance Monitoring	Automatic preventive maintenance (usage - based)	Traditional preventative maintenance (time-based)
Sample Level Detection Capability	Automatic	Automatic
Calibration/QC	Automatic and Manual calibration/QC	Manual calibration/QC
Sample Integrity (hemolysis, icterus, lipemia) Monitoring	Yes - spectral interference monitoring (optional)	Yes- spectral interference monitoring (optional)

K. Standard/Guidance Document Referenced (if applicable):

CSLI/ NCCLS Approved Guideline for Method Comparison and Bias Estimation Using Patient Samples; EP9 - A2
CSLI/NCCLS Approved Guideline for Evaluation of Precision Performance of Clinical Devices; EP5-A2
CLSI/NCCLS, Approved Guideline for Interference testing in Clinical Chemistry; EP7-A

L. Test Principle:

BUN: Urease specifically hydrolyzes urea to form ammonia and carbon dioxide. The ammonia is used by the enzyme glutamate dehydrogenase (GLDH) to reductively aminate α-ketoglutarate(α-KG), with simultaneous oxidation of reduced nicotinamide-adenine dinucleotide (NADH). The change in absorbance at 340 nm due to the disappearance of NADH is directly proportional to the urea nitrogen concentration in the sample and is measured using a bichromatic (340, 383 nm) rate technique.

Na^+ K^+ CL^- methods use indirect V-LYTE™ Integrated Multisensor Technology (IMT). There are four electrodes used to measure electrolytes on the Dimension® V-LYTE™ system. Three of these electrodes are ion selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensor. Diluted sample (1:10 with V-LYTE™ Diluent) is positioned in the sensor and Na^+, K^+ or Cl^- ions establish equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

IgG: Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Pheno: The phenobarbital method is based on a particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique. The phenobarbital method is a homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a latex particle-phenobarbital reagent (PR) and phenobarbital-specific monoclonal antibody (Ab). Phenobarbital present in the sample competes with the particles for the antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of phenobarbital in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm. The concentration is determined by means of a mathematical function.

CKMB: The MMB method is a homogenous sandwich chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI™) technology. LOCI™ reagents include two latex bead reagents and a biotinylated anti-mass creatine kinase MB isoenzyme monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The second bead reagent (Chemibeads) is coated with a second anti-mass creatine kinase MB isoenzyme monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a bead - mass creatine kinase MB isoenzyme - biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the mass creatine kinase MB isoenzyme concentration in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was done in accordance with NCCLS Approved Guideline for Evaluation of Precision Performance of Clinical Devices; EP5-A2. Specimens at each level were analyzed in duplicate, twice a day, for 20 days. The within-run and total standard deviations (SD) and percent coefficient of variation (%CV) were calculated by the analysis of variance method. The data are summarized below:

BUN

	Mean	Standard Deviation (%CV)	
	mg/dL [mmol/L]	Repeatability	Within-Lab Precision
Multiqual® Unassayed Control			
Level 1	14 [5.0]	0.5 [0.2] (3.4)	0.6 [0.2] (4.1)
Level 2	43 [15.4]	1.0 [0.4] (2.3)	1.3 [0.5] (2.9)
Level 3	78 [27.8]	1.9 [0.7] (2.4)	3.3 [1.2] (4.2)
Calibrator Level	133 [47.5]	2.9 [1.0] (2.2)	3.5 [1.2] (2.7)

IGG

	Mean	Standard Deviation (%CV)	
	g/L	Repeatability	Within-Lab Precision
PROT 1 CON L	5.81	0.17 (3.0)	0.20 (3.5)
PROT 1 CON M	8.63	0.24 (2.7)	0.27 (3.2)
PROT 1 CON H	11.86	0.42 (3.5)	0.42 (3.5)
Serum pool	23.23	0.81 (3.5)	0.87 (3.8)

PHNO

	Mean	Standard Deviation (%CV)	
	µg/mL [µmol/L]	Repeatability	Within-Lab Precision
BioRad Liquichek™ TDM Control			
Level 1	11.9 [51.2]	0.71 [3.1] (5.9)	0.86 [3.7] (7.2)
Level 2	30.6 [131.6]	0.93 [4.0] (3.0)	1.29 [5.6] (4.2)
Level 3	61.4 [264.0]	2.05 [8.8] (3.3)	3.70 [15.9] (6.0)

MMB

	Mean	Standard Deviation (%CV)	
	ng/mL [µg /L]	Repeatability	Within-Lab Precision
Liquichek™ Cardiac Control			
Level 1	5.5	0.32 (5.8)	0.38 (6.8)
Level 2	91.6	1.89 (2.1)	3.24 (3.5)
Serum Pool	282.5	5.24 (1.9)	9.24 (3.3)

Na^+

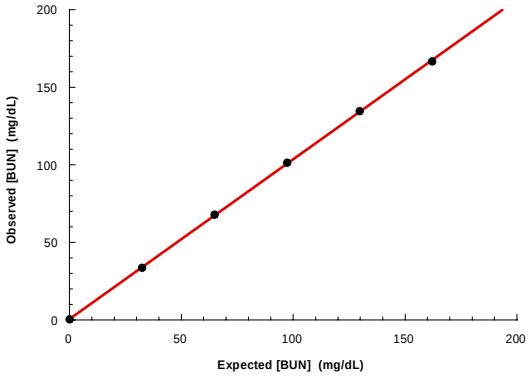
	Mean	Standard Deviation (%CV)	
	mmol/L	Repeatability	Within-Lab Precision
Serum pool	201	1.3 (0.7)	2.1 (1.1)
Multiqual® Unassayed L2	140	1.3 (0.9)	1.8 (1.3)
Multiqual® Unassayed L3	164	1.2 (0.7)	1.7 (1.0)
Liquichek™ Urine Chemistry Control Level 1	85	0.8 (0.9)	1.1 (1.3)

K^+	Mean	Standard Deviation (%CV)	
	mmol/L	Repeatability	Within-Lab Precision
Serum pool	9.0	0.07 (0.8)	0.10 (1.1)
Multiqual® Unassayed L2	4.0	0.04 (1.0)	0.06 (1.4)
Multiqual® Unassayed L3	7.4	0.07 (0.9)	0.10 (1.4)
Liquichek™ Urine Chemistry Control Level 1	31.4	0.47 (1.5)	0.58 (1.9)

Cl^-	Mean	Standard Deviation (%CV)	
	mmol/L	Repeatability	Within-Lab Precision
Serum pool	174	1.6 (0.9)	2.0 (1.2)
Mutiqual® Unassayed L2	99	1.0 (1.0)	1.5 (1.5)
Multiqual® Unassayed L3	123	1.2 (1.0)	1.6 (1.3)
Liquichek™ Urine Chemistry Control Level 1	102	1.0 (1.0)	3.1 (3.0)

b. Linearity/assay reportable range:

Dimension Vista™ BUN Method

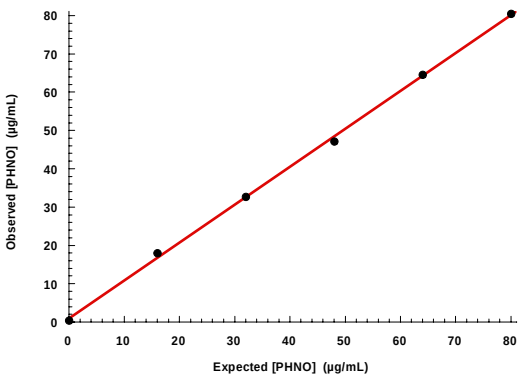


Expected (mg/dL)	Mean Observed (mg/dL)
0	0
33	33
66	68
100	101
133	134
166	166

Regression Statistics

Slope:	1.00
Y-int:	0.53
r:	1.000

Dimension Vista™ PHNO Method

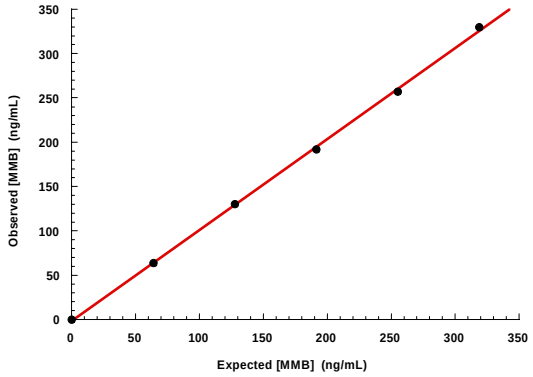


Expected (µg/dL)	Mean Observed (µg/dL)
0.0	0.0
16.0	18.1
32.0	32.7
48.0	47.2
64.0	64.6
80.0	80.5

Regression Statistics

Slope:	0.99
Y-int:	0.77
r:	1.000

Dimension Vista™ MMB Method

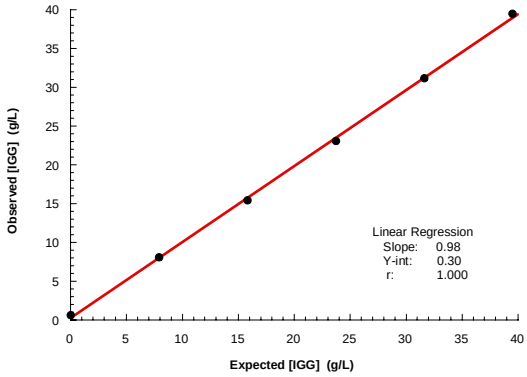


Expected (ng/mL)	Mean Observed (ng/mL)
0.0	0.0
63.8	64.0
127.6	130.5
191.3	192.3
255.1	257.5
318.9	329.9

Regression Statistics

Slope:	1.03
Y-int:	-1.35
r:	1.000

Dimension Vista™ IGG Method

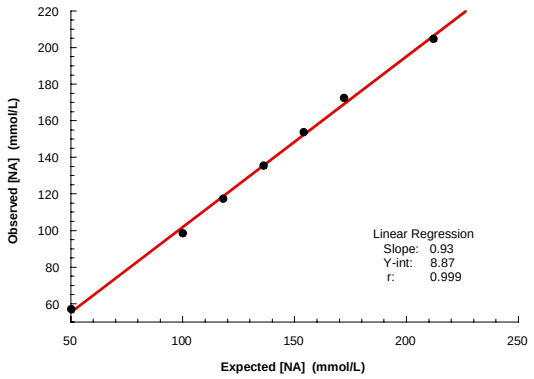


Expected (g/L)	Mean Observed (g/L)
0.00	0.68
7.90	8.09
15.80	15.45
23.70	23.09
31.60	31.21
39.49	39.49

Regression Statistics

Slope:	0.98
Y-int:	0.30
r:	1.000

Dimension Vista™ IMT NA Method

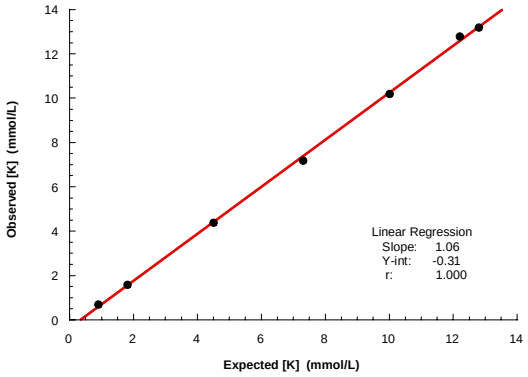


Expected (mmol/L)	Mean Observed (mmol/L)
50.0	57.3
100.0	98.7
118.0	117.6
136.0	135.5
154.0	153.8
172.0	172.5
212.0	204.8

Regression Statistics

Slope:	0.93
Y-int:	8.87
r:	0.999

Dimension Vista™ IMT K Method

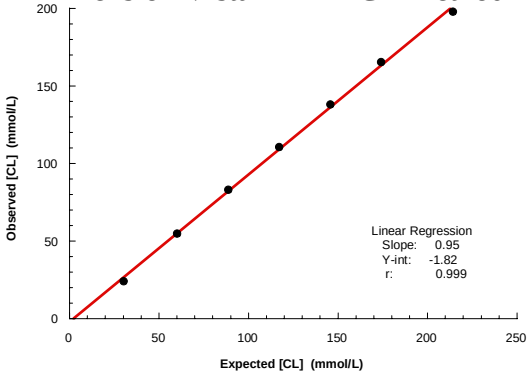


Expected (mmol/L)	Mean Observed (mmol/L)
0.9	0.7
1.8	1.6
4.5	4.4
7.3	7.2
10.0	10.2
12.2	12.8
12.8	13.2

Regression Statistics

Slope:	1.06
Y-int:	-0.31
r:	1.000

Dimension Vista™ IMT CL Method



Expected (mmol/L)	Mean Observed (mmol/L)
30.0	24.3
60.0	55.1
88.5	83.2
117.0	110.7
145.5	138.3
174.0	165.6
214.0	197.9

Regression Statistics

Slope:	0.95
Y-int:	-1.82
r:	0.999

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Value Assignment Chem 1 Calibrator (BUN)

Primary standards are gravimetrically prepared by adding NIST SRM 912 reference material to water and then assayed to confirm value assignment. Commercial lot - UREA is added gravimetrically to calibrator solution at target concentration. Verify that stock solution recovered value vs. previous commercial lot is within predetermined acceptance criteria.

Shelf life

Study duration is labeled product shelf life plus 6 days; i.e., 12 months shelf life requires testing a minimum of 6 days past 12 months.

Freeze – Thaw Testing
Product is frozen and thawed three times (3 cycles over three days) and then stored at 4^{o}C. Testing occurs on days 7, 35, 189 and 371.

Open and punctured vial
Vials are opened/punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2-8^{o}C. Open vials are tested on Day 31 vs. freshly opened vials.

The reference material (control) is stored at -20^{o}C. The method is calibrated from this stored material. The 4^{o}C material values are recovered vs. the calibrations. Recoveries vs. time are monitored and drift determined. Allowable drift is < 5%.

Value Assignment Vista™ Protein 1 Calibrator (IGG)

Master Calibrator Concentrated human serum pool assayed vs. CRM 470. Commercial Calibrator Lot - Preparation from Human serum pool at target concentration. Commercial Lot vs. Master Calibrator Lot – Using three reference curves, 4 runs, 3 vials, 4 replicates per vial tested on 2 nephelometers for a total of 144 values per instrument for value assignment.

Shelf life

Study duration is labeled product shelf life plus 1 month. 24 months shelf life requires testing a minimum of 1 month past 24 months. Product is stored at 2 - 8°C throughout testing cycle and tested on day 0 and after 6, 9, 12, 18, 24, and 25 months.

Open and punctured vial
Vials are stored on board the instrument and contents are tested in duplicate on day 0, 4, 7, 9, 11, and 14.

Results obtained must be within 85 – 115 % of the assigned value.

Vista Protein 1 Controls same as above, but results obtained must be within 80 – 120 % of the assigned value.

Value Assignment Vista Drug 1 Calibrator (PHNO)

USP Phenobarbital weighed into drug free normal human serum. Verification of Master Pool recovered values vs. Master Pool assigned values. Commercial lot Stock Solution - Phenobarbital added gravimetrically to stock solution at target concentration. Stock solution recovered value vs. Master Pool assigned values. Commercial Lot - Calculated quantities of stock Solution added to drug free normal human serum to target concentrations for two calibrator levels. The concentration of each level is within acceptable ranges using a Vista instrument calibrated with Master Pools. A previously released commercial lot is used as a control. Each level is tested on three Vista instruments, N= 45 total replicates.

Shelf life

Study duration is the labeled product shelf life plus 6 days. 12 months shelf life requires testing a minimum of 6 days past 12 months. Control Material Identical lot of calibrator product stored at -20^{o}C. Five replicates per level

Product is stored at 4^{o}C throughout testing cycle and tested on days 0, 3, 7, 35, 98, 189, 280, 325, and 371. The control material is stored at -20^{o}C and tested at the same frequency.

Freeze – Thaw Testing
Product is frozen and thawed three times (3 cycles over three days) and then stored at 4^{o}C. Testing occurs on days 7, 35, 189 and 371.

Open and punctured vial
Vials are opened/punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2-8^{o}C. Open vials are tested on Day 31 vs. freshly opened vials.

The reference material (control) is stored at -20^{o}C. The method is calibrated from this stored material. The 4^{o}C material values are recovered vs. the calibrations. Recoveries vs. time are monitored and drift determined. Allowable drift is < 8%.

Vista MMB Calibrator

Human heart CKMB added to 6%, buffered and preserved, bovine serum albumin. 6-levels liquid, stored at -70^{o}C. Verification of Master Pool recovered values vs. Master Pool assigned values. Commercial lot Stock

Solution Human heart CKMB added volumetrically to stock solution at target concentration Verification - Stock solution recovered value vs. Master Pool assigned values Commercial Lot - Calculated quantities of stock solution added to calibrator base matrix to target concentrations for three calibrator levels. Verify that the concentration of each level is within acceptable ranges using a Vista instrument calibrated with Master Pools. Assign final bottle values to each level of the Commercial Lot. A previously released commercial lot is used as a control. Each level is tested on three Vista instruments. N=45 total replicates.

Shelf life same as above, but Allowable drift is < 5%.

V-LYTE™ Standard Solutions (A&B) (NA+/K+/Cl-)

NIST certified NaCL & KCl is weighed into aqueous solutions with buffer & preservative. Stored at 2-8 degrees C two levels (Std. A & Std. B) Verification – Master Lot recovered values vs. Master Lot assigned values using Atomic absorption analyzer. Commercial Lot - Reagent grade NaCL & KCl weighed into aqueous solutions with buffer & preservative. Two levels (Std. A & Std. B). Verify that the concentration of each level is within acceptable ranges using a Flame Photometer and Cl titrator calibrated with Master Lot solutions. 9 replicates each level Confirm measured concentrations are within specification.

Shelf life same as above, but additional 30 Day Onboard Stability testing where standards are installed on day zero. The V-LYTE™ system is calibrated & 5 Replicates of 3 QC products are assayed. Onboard standards are used for QC testing on Day 31 vs. freshly installed standards. Allowable drift is < 1%.

d. Detection limit:

Except for electrolytes, detection limit is based on the analytical sensitivity represents the lowest concentration of analyte that can be distinguished from zero. This sensitivity is defined as the mean value (n=20 replicates) plus two standard deviations of a zero level sample. Analytical sensitivity data is included for applicable methods.
BUN = 1 mg/dL, IgG = 0.8 g/L, Pheno = 2.0 g/mL, CKMB = 0.5 ng/mL
Electrolyte detection limit is based on linearity studies.

e. Analytical specificity:

Interference testing was performed using guidance supplied by CLSI/NCCLS, Document EP7-A, "Interference testing in Clinical Chemistry." Potential Interfering Substances section of product insert sheets for method specific interfering substances summary information.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Split sample method comparisons between the representative Dimension Vista™ flex® reagent cartridge methods and the Dimension® RxL Flex® reagent cartridge methods were performed, following CSLI/ NCCLS Approved Guideline for Method Comparison and Bias Estimation Using Patient Samples; EP9 - A2. The data are summarized below:

Dimension Vista™	**Predicate**	**Sample Type**	**Slope**	**Intercept**	**Correlation Coefficient (r)**	**n**
BUN	Dimension® BUN	Serum/Plasma Urine	1.03 0.92	0.92 18.6	0.998 0.988	111 75
IGG	Dimension ® IGG	Serum/Plasma	0.92	1.89	0.985	98
PHNO	Dimension ® PHNO	Serum/Plasma	1.04	1.7	0.995	75
MMB	Dimension ® MMB	Serum/Plasma	1.05	1.4	0.997	136
V-LYTE™ Na^+	Dimension ® QuikLYTE™ Na^+	Serum/Plasma Urine	1.02 0.98	-1.3 2.5	0.997 0.998	103 52
V-LYTE™ K^+	Dimension ® QuikLYTE™ K^+	Serum/Plasma Urine	1.01 1.00	-0.06 0.12	0.999 0.999	103 52
V-LYTE™ CL^-	Dimension ® QuikLYTE™ Cl^-	Serum/Plasma Urine	1.02 1.02	-0.3 -3.3	0.998 0.998	104 51

b. Matrix comparison:

See method comparison

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off**:**

   Not Applicable

5. Expected values/Reference range:

   Referenced literature

N. Instrument Name:

Dimension Vista™ integrated system

O. System Descriptions:

1. Modes of Operation:

   Random access multi-functional analytical tool that processes chemical and immunochemical methodologies, utilizing photometric, turbidimetric, chemiluminescence, nephelometric, and integrated ion selective multisensor detection technologies.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   Barcode sample cups

4. Specimen Sampling and Handling:

   Routine sampling is provided via a barcoded sample rack containing slots for up to six sample cups. Stat sampling utilizes the same sampling system using a separate stat lane which loads the tracks immediately and processes the samples as soon as possible.

5. Calibration:

   Onboard automatic and on demand calibration – utilizing the following result calculation capabilities: Linear, Logit, Linearized Logit, Logit-Log, Rational, Qualitative (+ or - cutoffs), Vlin Integral (Y= max slope of signal vs. time), and Combo Curve (2 step process first linear then Logit)

6. Quality Control:

   Automatic QC processing and alerts

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

The software documentation was prepared in accordance with the FDA guidance document "Guide for the Content of Premarket Submission for Software Contained in Medical Devices" and demonstrates the Dimension Vista™ integrated system was developed under good software lifecycle practices comparable to other medical devices of the same type.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.