August 30, 2019

Fujirebio Diagnostics, Inc.
Stacey Dolan
Senior Manager, Regulatory Affairs
201 Great Valley Pkwy
Malvern, PA 19355

Re: K190702
Trade/Device Name: Lumipulse G whole PTH
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: July 29, 2019
Received: July 30, 2019

Dear Stacey Dolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie Kelm, Ph.D.,
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k190702

Device Name
Lumipulse G whole PTH

Indications for Use *(Describe)*
For in vitro diagnostic use

Lumipulse G whole PTH is a Chemiluminescent Enzyme Immunoassay (CLEIA) for the quantitative measurement of PTH (1-84) in human serum and plasma on the LUMIPULSE G System. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510(k) SUMMARY

A. GENERAL INFORMATION

Submission Date: August 20, 2019

510(k) Number: k190702

Submitter Information:

Submitted By: Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

Contact Person: Stacey Dolan, RAC (US)
Senior Manager, Regulatory Affairs
Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Office: (610)-240-3843
dolans@fdi.com

B. PURPOSE FOR SUBMISSION

To obtain a substantial equivalence determination for the Lumipulse ***G*** whole PTH

C. MEASURAND

Parathyroid Hormone

D. TYPE OF TEST

Quantitative, Chemiluminescent Immunoassay

E. APPLICANT

Fujirebio Diagnostics, Inc.

F. PROPRIETARY AND ESTABLISHED NAMES

Lumipulse® ***G*** whole PTH
Lumipulse® ***G*** whole PTH Immunoreaction Cartridges

G. REGULATORY INFORMATION

Trade Name: Lumipulse ***G*** whole PTH

Classification: Class II
Regulation: 21 CFR § 862.1545
Regulation Name: Parathyroid hormone test system
Product Code: CEW – Radioimmunoassay, Parathyroid Hormone
Panel: 75, Clinical Chemistry

H. INTENDED USE / INDICATIONS FOR USE

1. Intended Use / Indications for use
   For in vitro diagnostic use.

   Lumipulse ***G*** whole PTH is a Chemiluminescent Enzyme Immunoassay (CLEIA) for the quantitative measurement of PTH (1-84) in human serum and plasma on the LUMIPULSE ***G*** System. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.

2. Special conditions for use statement(s):
   For prescription use only.

3. Special instrument requirements:
   LUMIPULSE ***G*** System

I. INDICATIONS FOR USE

Same as Intended Use.

J. DEVICE DESCRIPTION

Reagents
The Lumipulse ***G*** whole PTH Immunoreaction Cartridges consists of 3 × 14 tests. Each kit contains the following:

1) Antibody-Coated Particle Solution
   (Liquid when used, 200 µL/Immunoreaction Cartridge)
   Contains 200 µg/mL anti-PTH polyclonal antibodies (goat)-coated ferrite particles, protein stabilizers (bovine and goat) and chemical stabilizers in MES buffer. This solution contains gelatin and turns into gel at 15 °C or lower.
   Preservative: ProClin 300

2) Enzyme-Labeled Antibody Solution
   (Liquid, 120 µL/Immunoreaction Cartridge)
   Contains 0.2 µg/mL alkaline phosphatase (ALP: calf)-labeled anti-PTH polyclonal antibody (goat), protein stabilizers (bovine) and chemical stabilizers in MES buffer.
   Preservative: ProClin 300

K. SUBSTANTIAL EQUIVALENCE INFORMATION

1. Predicate device name(s):
   LIAISON® 1-84 PTH Assay

2. Predicate 510(k) number:
   K150879

3. Comparison with predicate:

	Lumipulse *G* whole PTH (Proposed Device)	**LIAISON® 1-84 PTH Assay (K150879) (Predicate)**
Assay Intended Use	Lumipulse ***G*** whole PTH is a Chemiluminescent Enzyme Immunoassay (CLEIA) for the quantitative measurement of PTH (1-84) in human serum and plasma on the LUMIPULSE ***G*** System. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.	The DiaSorin LIAISON 1-84 PTH Assay is an in vitro chemiluminescent immunoassay (CLIA) intended for the quantitative determination of parathyroid hormone (1-84) in human serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism. The test has to be performed on the LIAISON® Analyzer family.
SIMILARITIES		
Classification	Class II	Same
Product Code	CEW	Same
Regulation	21 CFR § 862.1545	Same
Sample Type	human serum and plasma	Same
Antibody	Goat polyclonal	Same
Reagent Storage	Store at 2-10°C	Store at 2-8°C
Measuring Range	4.0 – 1800.0 pg/mL	4.0 - 1800 pg/mL
Sample Size	150 µL (for Sample Cups) 300 µL (for Sample Tubes)	150 µL
DIFFERENCES		
Instrument	LUMIPULSE ***G*** System	LIAISON Analyzer
Methodology	CLEIA	CLIA
Calibrators	2 level set (1 vial/level): • Level 1: 0 pg/mL • Level 2: 5000 pg/mL	4 level set (1 vial/level): • Level 1: 10 pg/mL • Level 2: 80 pg/mL • Level 3: 400 pg/mL • Level 4: 1450 pg/mL

L. STANDARDS/GUIDANCE DOCUMENTS REFERENCED

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition
- CLSI EP09c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition
- CLSI EP14-A2, Evaluation of Matrix Effects; Approved Guideline-Second Edition
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline
- CLSI EP25-A, Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline
- CLSI C28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline-Third Edition

M. TEST PRINICIPLE

Lumipulse ***G*** whole PTH is an assay system, including a set of immunoassay reagents and calibrators, for the quantitative measurement of whole parathyroid hormone (whole PTH) in specimens based on Chemiluminescent Enzyme Immunoassay (CLEIA) technology by a one-step sandwich immunoassay method on the LUMIPULSE ***G*** System. In the first reaction, alkaline phosphatase (ALP: calf)-labelled anti-PTH polyclonal antibody (goat), PTH in specimens, and anti-PTH polyclonal antibody (goat) - coated ferrite particles specifically bind to form antigen-antibody immunocomplexes. The particles are washed and rinsed to remove unbound materials. The Substrate Solution is then added and mixed with the particles in the enzyme reaction. AMPPD* contained in the Substrate Solution is dephosphorylated by the catalysis of ALP indirectly conjugated to particles. Finally, the Luminescence (at a maximum wavelength of 477 nm) is generated by the cleavage reaction of the dephosphorylated AMPPD. The Luminescent signal reflects the amount of whole PTH.

*AMPPD: 3-(2'-spiroadmantane)-4-methoxy-4-(3''-phosphoryloxy)phenyl-1,2-dioxetane disodium salt

N. PERFORMANCE CHARACTERISTICS

1. Analytical Performance

a. Reproducibility/Precision

<u>20-Day Precision</u>
The single site precision study was conducted using the Lumipulse ***G*** whole PTH at the internal laboratory according to CLSI *EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures*. A panel of seven native human serum

samples targeting the measuring range were assayed in replicates of two at two separate times of the day for 20 days (n=80 for each sample) using one LUMIPULSE ***G***1200 System and one lot of Lumipulse ***G*** whole PTH. Lumipulse ***G*** whole PTH demonstrated precision ≤4 % (total %CV). Within-Laboratory (Total) precision combines Within-run, Between-run and Between-day precision data. The data are presented below.

Sample	Mean (pg/mL) n=80	Within-Run		Between Run Within Day		Between-Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control Level 1	38.7	1.10	3%	0.28	1%	0.25	1%	1.16	3%
Control Level 2	291.7	4.62	2%	3.43	1%	2.30	1%	6.19	2%
Serum 1	8.4	0.34	4%	0.00	0%	0.00	0%	0.34	4%
Serum 2	37.2	0.85	2%	0.78	2%	0.00	0%	1.15	3%
Serum 3	84.8	1.72	2%	0.57	1%	0.25	0%	1.83	2%
Serum 4	258.8	5.37	2%	1.90	1%	2.60	1%	6.26	2%
Serum 5	404.7	7.91	2%	5.28	1%	5.41	1%	10.94	3%
Serum 6	813.6	15.35	2%	14.31	2%	9.65	1%	23.10	3%
Serum 7	1385.3	30.80	2%	28.47	2%	12.87	1%	43.88	3%

Lot-to-Lot Precision

The lot-to-lot study was conducted using three lots of Lumipulse ***G*** whole PTH and Calibrators at the internal laboratory according to CLSI *EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures*. Each lot combination was tested on a different LUMIPULSE ***G***1200 System (n=3). A panel of four native human serum samples targeting the measuring range and two levels of controls were assayed in duplicate in two runs per day across 8 days (n=32) replicates per lot). Lumipulse ***G*** whole PTH demonstrated precision ≤4% (inter-lot %CV).

Sample	Replicates	Mean (pg/mL)	Inter-lot %CV
Control Level 1	96	39.1	4%
Control Level 2	96	293.0	2%
Serum 1	96	8.6	3%
Serum 2	96	38.0	3%
Serum 3	96	86.3	3%
Serum 4	96	261.2	3%

Site-to-site Precision:

The site-to-site precision studies were conducted using the Lumipulse ***G*** whole PTH at the internal laboratory and two additional sites according to CLSI *EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures*. A panel of five native serum samples targeting the measuring range were assayed in triplicate at two separate times of the day for five days using three LUMIPULSE ***G***1200 instruments (one per site). Two lots of reagents were utilized for testing, and the data from both 5-day precision studies for Panels 1-5 were combined for the site-to-site analysis. Lumipulse ***G*** whole PTH demonstrated precision ≤ 6.7% (total %CV). Within-Laboratory (Total)

precision combines within-run, between-run and between-day precision, and data are presented below.

Sample	Mean (pg/mL)	Between Sites		Between Days Within Sites		Between Runs Within Days Within Lots		Within Runs		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Serum 1	8.8	0.4	4.7%	0.1	1.1%	0.2	2.3%	0.3	3.4%	0.6	6.3%
Serum 2	36.8	1.2	3.4%	0.6	1.7%	1.8	4.9%	0.9	2.5%	2.5	6.7%
Serum 3	83.9	2.1	2.5%	0.9	1.0%	3.3	3.9%	2.2	2.6%	4.5	5.4%
Serum 4	254.6	5.3	2.1%	2.7	1.1%	12.3	4.8%	5.0	2.0%	14.5	5.7%
Serum 5	1270.1	39.0	3.1%	0.0	0.0%	44.8	3.5%	21.5	1.7%	63.2	5.0%

b. Linearity/Assay Reportable Range

Linearity:
Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 demonstrated linearity in a study consistent with the guidelines in CLSI *EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures.* High and low sample pools were created using patient serum samples that contained naturally expressed whole PTH. The linearity was found in the range 1.4 pg/mL – 2190.3 pg/mL. Lumipulse ***G*** whole PTH correlated with expected concentrations per the linear regression formula:

y= -0.36519+1.091572x; R^2=0.9984

The measuring range of the assay will be 4.0 pg/mL – 1800.0 pg/mL.

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

Expected Values:
Lumipulse ***G*** whole PTH Calibrators are for *in vitro* diagnostic use in the calibration of Lumipulse ***G*** whole PTH on the LUMIPULSE ***G*** System for the quantitative determination of whole PTH in human serum and plasma. Two bottles (1.5 mL and 3.0 mL each) are supplied for the Lumipulse ***G*** whole PTH Calibrator kit which contain MES buffer with protein (bovine) stabilizer. Preservative: mixture of 5-chloro-2-methyl-isothiazolin-3(2H)-one and 2-methyl-isothiazolin-3(2H)-one

The calibrators are at the following concentrations:

Calibrator	Concentration (pg/mL)
CAL 1	0
CAL 2	5000

Traceability:
Calibration of the Lumipulse ***G*** whole PTH is traceable to in-house reference calibrators whose values have been assigned to the 1st international standard for Parathyroid

Hormone 1-84 (code: 95/646) provided by the National Institute for Biological Standards and Controls (NIBSC).

Shelf life:
The shelf life for Lumipulse ***G*** whole PTH Immunoreaction Cartridges and the Lumipulse ***G*** whole PTH Calibrators is 12 months at 2–10°C. It is not recommended that the reagents are frozen.

On-board the LUMIPULSE ***G***1200:
The Lumipulse ***G*** whole PTH Immunoreaction Cartridges are sealed unit dose stored at 2–10°C. To reduce risk for any misuse, the package insert states "The Lumipulse ***G*** whole PTH Immunoreaction Cartridges can be stored (refrigerated unit) on-board the LUMIPULSE ***G*** System for a maximum of 30 days".

The package insert recommends calibrator curve storage on the LUMIPULSE ***G***1200 for a maximum of 30 days.

Transport Conditions:
Lumipulse ***G*** whole PTH Immunoreaction Cartridges and the Lumipulse ***G*** whole PTH Calibrators are shipped at 2-10°C. Materials will be shipped to the end user using an insulated container and a predetermined configuration of gel (cold and/or frozen) packs to maintain the product for up to 72 hours when stored at ambient temperature.

d. Detection Limit

The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) for the Lumipulse ***G*** whole PTH were determined in accordance with the CLSI Guideline *EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*. Four blank and four low level serum specimens were tested over three days with two Lumipulse ***G*** whole PTH lots giving 60 determinations for each panel per lot for the LoB and LoD Studies. For the LOQ Study, 5 low level serum were tested on 2 LUMIPULSE ***G***1200 Systems with 2 Lumipulse ***G*** whole PTH lots across several days.

The LoB for Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System was determined to be 0.0 pg/mL.

The LoD for Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System was determined to be 0.295 pg/mL.

The LoQ is defined as the concentration of PTH (1-84) that can be measured with an interassay CV of 10%. The LoQ for Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System was determined to be 2.128 pg/mL.

e. Analytical Specificity/Cross Reactivity

The cross reactivity study followed the guidance of CLSI *EP07-A2, Interference Testing in Clinical Chemistry*. Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System was evaluated for cross-reactivity of the assay with other substances that are

similar in structure to whole PTH and truncated versions of whole PTH. No cross reactivity was observed for the tested concentrations of each cross reactant listed below on a panel of serum samples with naturally occurring whole PTH (n=4 panel members).

Cross Reactant	Concentration Tested (pg/mL)	% Cross Reactivity
Calcitonin	500000	< 0.001%
Osteocalcin	500000	< 0.001%
C-Telopeptide (β-crosslaps)	500000	< 0.001%
PTH (7-84)	200000	< 0.002%
PTH (1-34)	200000	< 0.002%
PTH (39-84)	200000	< 0.002%
PTH (39-68)	200000	< 0.002%
PTH (44-68)	200000	< 0.002%
PTH (53-84)	200000	< 0.002%
PTH (13-34)	200000	< 0.002%

f. Interfering Substances

The endogenous and exogenous interference studies followed the guidance of CLSI *EP07-A2, Interference Testing in Clinical Chemistry*. Human serum specimen pools with whole PTH concentrations of approximately 35.1, 81.5, and 235.9 pg/mL were supplemented with potentially interfering compounds at levels listed in the table below. Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System demonstrated an average interference of ≤ 10% for each compound tested and were found not to interfere.

Endogenous Interferences	Test Concentration
Conjugated Bilirubin	44 mg/dL
Free Bilirubin (unconjugated)	20 mg/dL
Hemoglobin	510 mg/mL
Triglycerides (Intralipid 20% Emulsion)	3440 mg/mL
Cholesterol	503 mg/mL
Human Serum Albumin	4 – 12 g/dL
Human Anti-Mouse antibodies (HAMA)	4200 ng/mL
Rheumatoid Factor (RF)	5500 IU/mL
Alkaline Phosphatase	1500 U/mL

Therapeutic Drug Interferences	Test Concentration
Acetaminophen	22 mg/dL
Acetylsalicylic Acid	70 mg/dL
Salicylic Acid	71 mg/dL
Ibuprofen	53 mg/dL
Biotin	0.1 µg/dL
Alendronate	80.65 µg/mL
Etidronate	105 mg/dL
Pamidronate	19 mg/dL
Risedronate	6 mg/dL

Therapeutic Drug Interferences	Test Concentration
Vitamin D2	253 ng/mL
Vitamin D3	289 ng/mL
Calcitrol	1.8 ng/mL
Alfacalcidol	3 µg/mL
Calcium Acetate	41 mg/mL
Magnesium Chloride	40 mg/dL
Aluminium Sulfate	40 mg/dL
Lanthanum Chloride	41 mg/dL
Doxycycline	49.1 µg/mL
Lisinopril	33.9 µg/mL

g. High Dose Hook Effect

The Hook Effect was evaluated for the Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System. No high dose effect was observed for a spiked serum sample containing up to 80,000 pg/mL of whole PTH.

h. Assay Cut-off

See Clinical Cut-off Section 3 below.

i. Specimen Stability

The following storage conditions were tested in the specimen stability studies and the results are as follows.

- It is recommended to use fresh specimens.
- Whole PTH is known to be prone to degradation when stored at room temperature. Avoid keeping specimens at room temperature.
- Serum may be stored at 2-10°C for up to 24 hours.
- Plasma may stored at 2-10°C for up to 7 days.
- Both serum and plasma can be stored at -20°C ±10°C for up to 3 months.
- Avoid using heat-inactivated specimens.
- Specimens on-board the LUMIPULSE ***G*** System should be tested within 3 hours.
- Avoid successive freezing and thawing of specimens. Do not perform more than 1 freeze/thaw cycle.

j. Matrix Comparison

The Anticoagulant Matrix Comparison Study was executed per CLSI *EP14-A2, Evaluation of Matrix Effects* and *EP09c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples*. Lumipulse ***G*** whole PTH on the LUMIPULSE ***G***1200 System was evaluated for matrix differences by performing a study using seventy-one (71) matched sets of serum (red top and serum separator tubes (SST)) and plasma (K_2EDTA, sodium heparin and lithium heparin) samples. The results demonstrated equivalency between matrices and are presented in the following table.

Tube Type	n	Concentration Range (pg/mL)		Slope			Intercept			Pearson Correlation Coefficient
		Min	Max	Estimate	Lower 95%CI	Upper 95%CI	Estimate	Lower 95% CI	Upper 95% CI	
SST	71	7.2	1531.2	1.0128	0.9884	1.0372	-0.4836	-1.1220	0.1548	0.9995
K_2EDTA	71	5.1	1552.6	1.0117	0.9751	1.0482	-2.7210	-3.7703	-1.6717	0.9993
Lithium Heparin	71	6.5	1446.1	1.0062	0.9807	1.0317	-0.1995	-0.9244	0.5255	0.9984
Sodium Heparin	71	6.5	1487.4	1.0182	0.9783	1.0580	-0.3707	-1.4014	0.6601	0.9980

k. Method Comparison

The Lumipulse ***G*** whole PTH Method Comparison Study followed the guidance of CLSI *EP09c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples* and was performed on the LUMIPULSE ***G***1200 System. The weighted Deming regression method was used to compare the performance of the Lumipulse ***G*** whole PTH to the LIAISON® 1-84 PTH assay on a total of 275 matched human serum samples. The samples tested ranged from 7.200 to 1644.600 pg/mL for Lumipulse ***G*** whole PTH for Lumipulse ***G*** whole PTH and 6.480 to 1750.000 pg/mL for LIAISON 1-84 PTH. The data are summarized in the following table.

Lumipulse *G* whole PTH vs. LIAISON 1-84 PTH				
n	Correlation Coefficient (r)	Intercept (95% CI)	Slope (95% CI)	Average Bias (pg/mL)
275	0.9808	-0.5351 (-1.2821 to 0.2119)	0.9909 (0.9726 to 1.0093)	-6.271

2. Clinical Studies

Not Applicable.

3. Clinical Cut-Off

Not Applicable.

4. Expected Values/Reference Range

Serum specimens obtained from an apparently healthy adult population (22-72 years old) were tested using the Lumipulse ***G*** whole PTH per CLSI *EP28-A3c, Defining,*

Establishing, and Verifying Reference Intervals in the Clinical Laboratory. The observed ranges are listed below.

Group	n	Median (pg/mL)	Range (pg/mL) 5th and 95th Percentile
All	147	15.7	6.9 – 27.4
Apparently Healthy Females	68	16.2	8.7 – 29.7
Apparently Healthy Males	79	15.2	6.6 – 23.2

It is recommended that each laboratory establish its own range, which may be unique to the population it serves depending upon geographical, patient, and environmental factors.

O. INSTRUMENT NAME

LUMIPULSE ***G***1200 System (K142895)

P. PROPOSED LABELING

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

Q. CONCLUSION

The results of these nonclinical and clinical studies demonstrate that the Lumipulse ***G*** whole PTH is substantially equivalent to the performance of the DiaSorin LIAISON 1-84 PTH Assay (K150879).