September 22, 2023

Immunostics Inc.
℅ Parag Bhurchandi
Principal Research Scientist (Regulatory Affairs)
Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do 24398
Korea, South

Re: K221817
Trade/Device Name: ALFIS Vitamin D, ALFIS-3 Analyzer
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Code: MRG, KHO
Dated: March 24, 2023
Received: March 27, 2023

Dear Parag Bhurchandi:

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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k221817

Device Name

ALFIS Vitamin D, ALFIS-3 Analyzer

Indications for Use *(Describe)*

ALFIS Vitamin D in conjunction with ALFIS-3 Analyzer is an enzyme-linked fluorescence immunoassay intended for in vitro diagnostic use at clinical laboratories for the quantitative measurement of Total 25-hydroxy Vitamin D (25-OH Vitamin D) in human serum, lithium heparin plasma and sodium heparin plasma.

ALFIS Vitamin D is indicated to be used as an aid in the determination of Vitamin D sufficiency in adults.

ALFIS-3 Analyzer is a fluorescence-scanning instrument using magnetic beads and alkaline phosphatase enzyme system for in vitro diagnostic use in conjunction with various ALFIS immunoassays intended for measuring the concentration of designated analytes in human blood and other specimens.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Device Type/Common Name: Radioimmunoassay, Vitamin D Test System

Trade/Proprietary Name **:** ALFIS Vitamin D
ALFIS-3 Analyzer

Type of Submission **:** Traditional 510(k)

Basis for Submission **:** Traditional 510(k) Submission for a New Device

Submitter/Applicant /Sponsor **: Immunostics Inc.**
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Applicant Contact Person **: Dr. Young Mi Kim**
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Classification Regulation: 21CFR § 862.1825 Vitamin D test system

Class **:** II (for ALFIS Vitamin D Test Cartridges)
I (for ALFIS-3 Analyzer)

Panel **:** Clinical Chemistry

Product Code **:** MRG; Vitamin D Test System

KHO; Fluorometer for Clinical Use

Predicate Device : Elecsys Vitamin D Total III with cobas e 601 analzyer
Roche Diagnostics GMBH
Sandhofer Strasse 116
Mannheim Baden-Wurttenberg,
DE D-68305

Predicate Device 'K' Number : K210901

Predicate Device Product Code: MRG, Vitamin D Test System

Intended use of ALFIS Vitamin D:

ALFIS Vitamin D in conjunction with ALFIS-3 Analyzer is an enzyme-linked fluorescence immunoassay intended for in vitro diagnostic use at clinical laboratories for the quantitative measurement of Total 25-hydroxy Vitamin D (25-OH Vitamin D) in human serum, lithium heparin plasma and sodium heparin plasma.

Indications for use of ALFIS Vitamin D:

ALFIS Vitamin D is indicated to be used as an aid in the determination of Vitamin D sufficiency in adults.

Intended use/indication for use of ALFIS-3 Analyzer:

ALFIS-3 Analyzer is a fluorescence-scanning instrument using magnetic beads and alkaline phosphatase enzyme system for in vitro diagnostic use in conjunction with various ALFIS immunoassays intended for measuring the concentration of designated analytes in human blood and other specimens.

Description of ALFIS Vitamin D Test Cartridges:

ALFIS Vitamin D Test Cartridge is a plastic structure molded in the form of a disposable, self-contained, unitized device which houses the 'magnetic bead', 'antibody-alkaline phosphatase-conjugator (Ab-ALP)', 'sample diluent', 'diethanolamine (DEA)', '4-Methylumbelliferyl phosphate (MUP)', 'washing buffer'; all of which are integral components of ALFIS Vitamin D test.

ALFIS Vitamin D test cartridge is an elongated structure having 150.8 mm length, 17 mm width and 16 mm height.

Description of ALFIS Vitamin D Test ID Chip:

'ALFIS Vitamin D Test ID Chip' is a flat, rectangular device with its main body measuring 23 mm × 27 mm. Half of the portion along the breadth of the main body is 5 mm thick while remaining half is 3 mm in thickness.

Another rectangular portion measuring 12 mm × 10 mm × 2 mm protrudes out from the breadth of apical side of the 3 mm-thick portion of the main body.

ALFIS Vitamin D Test ID Chip is an electronic memory device fitted into a plastic matrix. Lot-specific 'ALFIS Vitamin D Test ID Chip' is an integral component of ALFIS Vitamin D test system.

Before initiating the test run for testing a clinical sample or calibrator/control using ALFIS Vitamin D Test Cartridge belonging to a new lot for the first time, the operator needs to mandatorily insert the lot-specific ALFIS Vitamin D Test ID Chip into the 'ID Chip Port' of the ALFIS-3 analyzer.

Description of ALFIS-3 Analyzer:

For performing ALFIS Vitamin D test on a clinical sample or an ALFIS Vitamin D Control, ALFIS Vitamin D test cartridge needs to be used in conjunction with the ALFIS-3 analyzer.

ALFIS-3 analyzer is a compact, bench-top, automated, fluorometric analyzer measuring 422 mm (L) x 270 mm (W) x 292 mm (H). ALFIS-3 weighs 13.0 kg.

ALFIS-3 analyzer is a fluorometer instrument of closed-system analyzer type. The operator does not have access to those configuration parameters that could affect the assay process, test analysis or result calculation or any other parameter that could affect test result outcome. These and other operational parameters can only be configured by the 'System Administrator' through software and/or firmware upgrade and modification of operational settings in consultation with the manufacturer or an authorized service provider.

With a simple computerized touchscreen user interface, the analyzer enables the operator to initiate the test run which is completed automatically and terminates with display of test result or an error message alert (in case of any procedural error and/or system malfunction).

Description of ALFIS Vitamin D Calibrators:

'ALFIS Vitamin D Calibrators' needs to be tested by user laboratories for periodic calibration of ALFIS Vitamin D test system.

Considering the reportable range of ALFIS Vitamin D test (6-100 ng/mL), the sponsor provides ALFIS Vitamin D Calibrators with following approximate assigned 25-OH Vitamin D levels:

Analyte levels of ALFIS Vitamin D Calibrators

No.	ALFIS Vitamin D Calibrator	Approximate Assigned /Target 25(OH)D Level
1	ALFIS Vitamin D Calibrator Level 1	10 ng/mL
2	ALFIS Vitamin D Calibrator Level 2	40 ng/mL

The sponsor would market a set of 'ALFIS Vitamin D Calibrator Level 1 and Level 2' separately from the ALFIS Vitamin D test product on demand by the user laboratories.

Description of ALFIS Vitamin D Controls:

'ALFIS Vitamin D Controls' needs to be tested by user laboratories periodically for monitoring the performance of ALFIS Vitamin D test system.

Considering the reportable range (6 – 100 ng/mL) of ALFIS Vitamin D and usual adult reference intervals of 25(OH)D IVD tests, the sponsor provides ALFIS Vitamin D Controls with following approximate assigned 25-OH Vitamin D levels:

Analyte levels and reference ranges of ALFIS Vitamin D Controls

No.	ALFIS Vitamin D Control	Approximate Assigned /Target 25(OH)D Level	Acceptable Range
1	ALFIS Vitamin D Control Level 1	15 ng/mL	13.5 ~ 16.5 ng/mL
2	ALFIS Vitamin D Control Level 2	35 ng/mL	31.5~38.5 ng/mL

The sponsor would market a set of 'ALFIS Vitamin D Control Level 1 and Level 2' separately from the ALFIS Vitamin D test product on demand by the user laboratories.

Similarities between ALFIS Vitamin D (with ALFIS-3 analyzer) and the predicate device Elecsys Vitamin D Total III:

Following table shows the similarities between ALFIS Vitamin D (with ALFIS-3 analyzer) and the predicate device Elecsys Vitamin D Total III

Table 5.1: Similarities between ALFIS Vitamin D (with ALFIS-3 analyzer) and the predicate device Elecsys Vitamin D Total III

No.	Comparison Parameter	Candidate Device/Test ALFIS Vitamin D (with ALFIS-3 Analyzer)	Elecsys Vitamin D Total III
1	Nature of the test	Quantitative *in vitro* diagnostic test system for total 25-hydroxyvitamin D	Same
2	Indications for use(s)	As an aid in the assessment of Vitamin D sufficiency in adults	Same
3	Intended use sites	Clinical laboratories	Same
4	Sample type	Serum or plasma	Same
5	Result unit	ng/mL	Same

Differences between ALFIS Vitamin D (with ALFIS-3 Analyzer) and the predicate device Elecsys Vitamin D Total III.

Following table shows the differences between ALFIS Vitamin D (with ALFIS-3 Analyzer) and the predicate device Elecsys Vitamin D Total III.

Table 5.2: Differences between ALFIS Vitamin D (with ALFIS-3) and the predicate device Elecsys Vitamin D Total III

No.	Comparison Parameter	Candidate Device/Test ALFIS Vitamin D (with ALFIS-3)	Predicate Device/Test Elecsys Vitamin D Total III
1	Detection protocol	Enzyme-linked fluorescence assay	Electrochemiluminescence
2	Measuring range	6-100 ng/mL	6-125 ng/mL 6-240 ng/mL (after dilution)
3	Associated instrument	ALFIS-3 Analyzer	Cobas e analyzers
4	Test format	Self-contained, unitized, ready-to-use, disposable cartridge to be used in conjunction with ALFIS-3 analyser	A kit for multiple use with three ready to use liquid assay reagents and two pretreatment reagents; capable of testing up to 43 samples at a time
5	Turnaround time	Total turnaround time = 36 minutes	Total duration of assay = 27 minutes
6	Sample volume required per test	100 µL	20 µl
7	Sample volume utilized per test	40 µL	20 µl
8	Limit of Quantitation /Functional Sensitivity	6.0 ng/mL (with imprecision of CV ≤ 20%)	6.0 ng/mL (with imprecision of CV ≤ 20%)
9	Calibration	Lot-specific master calibration curve/equation is encoded in the 'Lot-specific ALFIS Vitamin D Test ID Chip' which needs to be inserted in the 'ID Chip Port' of ALFIS-3 analyzer prior to using that ALFIS Vitamin D test cartridge lot for the first time. User-level periodic calibration to modify the pre-defined master calibration curve (encoded in the ID chip) needs to be performed by	Every Elecsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant calibrators.

		testing ALFIS Vitamin D Calibrators Level 1 and 2 with the ALFIS Vitamin D test system.	

Summary of Performance Evaluation Studies:

1) Limit of Blank:

- Limit of Blank (LoB) of ALFIS Vitamin D test has been evaluated as per CLSI EP 17-A2.
- 6 replicates of 4 blank (25-hydroxyvitamin D-depleted) serum samples were tested with 3 lots of test cartridges on 3 ALFIS-3 analyzers (1 lot/analyzer) for 3 successive days; thus testing 72 blank replicates per lot/analyzer pair.
- Limit of Blank (LoB) was calculated by non-parametric analysis of the data.
- Limit of Blank of ALFIS Vitamin D test is 1.82 ng/mL.

2) Limit of Detection:

- Limit of Detection (LoD) of ALFIS Vitamin D test has been evaluated as per CLSI EP 17-A2.
- 5 replicates each of 4 low 25-hydroxyvitamin D-spiked serum samples were tested with 3 lots of test cartridges on 3 respective analyzers (1 lot/analyzer) for 3 successive days; thus testing 15 replicates per lot/analyzer pair and total 45 replicates per sample.
- Limit of Detection (LoD) was calculated by parametric analysis of the data.
- Limit of Detection of ALFIS Vitamin D test is 3.76 ng/mL.

3) Limit of Quantitation:

- Limit of Quantitation (LoQ) of ALFIS Vitamin D has been evaluated as per CLSI EP 17-A2.
- 4 replicates of each of the 5 low 25-hydroxyvitamin D serum samples were tested with 3 lots of test cartridges on 3 respective analyzers (1 lot/analyzer) for 3 successive days; thus testing 12 replicates per lot/analyzer pair and total 36 replicates per sample.
- Limit of Quantitation (LoQ) was calculated by considering accuracy goal of inter-assay CV $\leq$ 20%.
- Limit of Quantitation of ALFIS Vitamin D test is 6.0 ng/mL

4) **Linearity and Reportable Range:**

- For evaluating linearity and measuring/reportable range of ALFIS Vitamin D test, a series of 19 25-hydroxyvitamin D-spiked serum samples spanning the concentration

range of 1.3 ng/mL – 130 ng/mL was tested in triplicate with the one lot of ALFIS Vitamin D test cartridges on one ALFIS-3 analyzer on the same day.

- Mean of the triplicate test results of each sample was plotted against its expected TSH concentration calculated mathematically.
-
- ALFIS Vitamin D test showed linearity over the entire claimed measuring/reportable range of 6-100 ng/mL with following linear regression equations.

  $y = 1.0708x – 0.0757$, $R^2 = 0.9998$

5) **Susceptibility to High-dose Hook Effect:**

- For evaluating susceptibility to high dose hook (prozone) effect, a series of spiked samples having approximate 25-hydroxyvitamin D concentrations 12.5 ng/mL, 25 ng/mL, 50 ng/mL, 75 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 500 ng/mL, 750, and 1000 ng/mL were tested in triplicate with one lot of test cartridges using one analyzer on the same day by the same operator.
- No hook/prozone effect was observed up to 25-hydroxyvitamin D concentration of 1000 ng/mL.

6) **Analytical specificity:**

- Analytical specificity of ALFIS Vitamin D has been evaluated as per CLSI EP07, 3rd edition.

Interference from endogenous and exogenous substances:

- Susceptibility of ALFIS Vitamin D test to interference from various endogenous and exogenous substances has been evaluated.
- Performance of ALFIS Vitamin D test has not been found to be significantly affected when the endogenous and exogenous substances were tested at specified highest concentrations as follows.
- ALFIS Vitamin D test showed analyte recovery within the acceptable range of 90-110% in presence of specified concentrations of above endogenous and exogenous interferants thereby indicating insignificant interference.

Potential endogenous interferent tested	Highest concentration tested at which no significant interference was observed
Albumin/Protein	12,000 mg/dL
Conjugated Bilirubin	40 mg/dL
Human hemoglobin	1,000 mg/dL
Triglycerides	2,000 mg/dL
HAMA	800 ng/mL
Rheumatoid Factor	200 IU/mL
Biotin	3,500 ng/mL

Potential exogenous interferent tested	Highest concentration tested at which no significant interference was observed
Acetaminopen	15.5 mg/dL
Acetylcysteine	15 mg/dL
Acetylsalicylic acid	3.0 mg/dL
Ampicillin-Na	7.5 mg/dL
Cyclosporin	180 µg/dL
Doxycycline	1.8 mg/dL
Ibuprofen	22 mg/dL
Itraconazole	3.0 mg/dL
Levodopa	750 µg/dL
Methyldopa	2.25 mg/dL
Rifampicin	4.8 mg/dL
Ascorbic acid	5.25 mg/dL

Cross-reactivity with structural analogs of 25-hydroxyvitamin D:

- Cross-reactivity of ALFIS Vitamin D test system with various structural analogs of 25-hydroxyvitamin D has been evaluated.
- The cross-reactivity was determined using the following formula:

  % cross reactivity = [(mean recovery of test samples) – (mean recovery of control samples) / (concentration of cross reactant] × 100
- Cross-reactivity of ALFIS Vitamin D test with various potential cross-reactants that were tested at specified highest concentration has been shown in the following table.

Potential cross-reactant tested	Concentration of the cross-reactant tested	Percent cross-reactivity observed
25-hydroxyvitamin D3	50 ng/mL	99.30 – 100.61 %
25-hydroxyvitamin D2	50 ng/mL	98.42 – 98.38 %
3-epi-25-hydroxyvitamin D3	50 ng/mL	20.24 – 22.18 %
24,25-dihydroxyvitamin D3	50 ng/mL	121.59 – 121.91 %
1,25-dihydroxyvitamin D3	100 ng/mL	0.81 – 0.27 %
1,25-dihydroxyvitamin D2	100 ng/mL	0.59 – - 0.05 %
Vitamin D3 (Cholecalciferol)	1000 ng/mL	0.1– - 0.04 %
Vitamin D2 (Ergocalciferol)	1000 ng/mL	0.06 – 0.08 %

7) In-house repeatability and reproducibility:

- In-house repeatability and reproducibility studies of ALFIS Vitamin D test system were performed as per CLSI EP05-A3 guideline.
- For evaluating in-house repeatability of ALFIS Vitamin D, 3 spiked serum samples having 25-hydroxyvitamin D concentrations 10, 30, 50 ng/mL were tested with 1 lot of ALFIS Vitamin D Cartridges and 1 ALFIS-3 Analyzer. Each sample was tested in duplicate daily for 20 successive days by the same operator.
- For evaluating in-house reproducibility of ALFIS Vitamin D, 3 spiked serum samples having 25-hydroxyvitamin D concentrations 10, 30, 50 ng/mL were tested with 3

cartridge lots and ALFIS-3 analyzer/operator pairs. Each sample was tested in quintuplicate daily for 5 successive days.

- In these in-house studies, ALFIS Vitamin D test system showed CV < 10% thereby indicating acceptable repeatability as well as reproducibility.

8) External site-to-site reproducibility:

- External site-to-site reproducibility study of ALFIS Vitamin D test system was performed at one in-house research laboratory and two external clinical laboratories in the US as per CLSI EP05-A3 guideline.
- 3 spiked serum samples having 25-hydroxyvitamin D concentrations 10, 30, 50 ng/mL were tested with 3 cartridge lots (one lot/site) and 3 ALFIS-3 analyzer-operator (one analyzer-operator per site). Each sample was tested in quintuplicate daily for 5 successive days.
- ALFIS Vitamin D test system showed CV < 10% thereby indicating acceptable site-to-site reproducibility.

9) **Matrix Comparison:**

- Matching clinical serum, lithium heparin plasma, and sodium heparin plasm samples obtained from same study subjects were tested with one lot of ALFIS Vitamin D test cartridges on one ALFIS-3 analyzer. Additional 5 spiked samples were tested with the same lot of ALFIS Vitamin D test cartridges and ALFIS-3 analyzer to cover the entire measuring range of ALFIS Vitamin D Test System.
- Regression analysis of the matrix comparison study data showed acceptable commutability of ALFIS Vitamin D Test results across the tested matrices of clinical samples.

Sr. No.	**Sample matrices compared**	**Number of Samples**	**Linear regression equation**	**Correlation coefficient**
Measuring/reportable range of **ALFIS Vitamin D Test =** 6 – 100 ng/mL				
1	Serum vs. Li-heparin Plasma	45	y = 0.9797x + 0.3501	0.9982
2	Serum vs. Na-heparin Plasma	45	y = 0.98x + 0.3486	0.9981

9) **Reference Interval:**

- Reference interval of ALFIS Vitamin D test was evaluated by testing serum samples collected from 299 apparently healthy adults in the United States which comprised 149 and 150 samples meeting specified demographic criteria obtained respectively from two external clinical samples repositories.
- The sample sets procured for the reference interval study met the following criteria:

  • Age (adults): 21~70 years of age

• Approximately: 20% central, 20% northern, 60% southern State residents

• Approximately: 50% male, 50% female

• At least : 30% collected from African American and 30% from Caucasian

• Approximately: 50% collected during fall, 25% during winter and 25% during summer

• Individuals not taking vitamin D supplements; 30% of individuals did report to taking multivitamins. Note, the vitamin D dosage in multivitamins sold in the US is ≤ 2000 IU Vitamin D)

• Collected after June 2021

- Non-parametric reference interval encompassing the central 95% frequency distribution of study results was determined as per CLSI C28-A3c Standard.
- 2.5^{th} percentile and 97.5^{th} percentile of distribution of test results was taken as the lower limit and upper limit respectively of the reference interval.
- Adult reference intervals of ALFIS Vitamin D test have been found to be **8.75-43.66 ng/mL** for serum samples.
- The manufacturer claims 9.0 - 43.0 ng/mL as the adult reference interval of ALFIS Vitamin D test.
- However, the user laboratories should establish their own reference intervals for specific population and/or specific group(s) of population they may cater to.

10) **Method Comparison Study:**

- Method comparison study of ALFIS Vitamin D test was carried out at the in-house laboratory with the predicate device (Elecsys Vitamin D Total III) by testing 120 CDC VDSCP verification samples spanning Total 25-hydroxy Vitamin D concentrations from 6.45 ng/mL to 83.33 ng/mL as confirmed by the Reference Measurement Procedure (RMP) of 25-hydroxyvitamin D i.e., ID-LC-MS/MS at CDC certified laboratory with NIST standard reference material 2972.
- The samples were tested with one lot of ALFIS Vitamin D cartridges and one ALFIS-3 analyzer.
- ALFIS Vitamin D test measurements were compared with Total 25-hydroxy Vitamin D concentrations as per the Reference Measurement Procedure (RMP) as well as with the predicate device (Elecsys Vitamin D Total III) test results.
- Weighted Deming regression analysis of the method comparison study data revealed acceptable compatibility of ALFIS Vitamin D test results.

Sr. No.	Compared test results	Number of samples compared	Linear Regression Equation	Correlation Coefficient
Measuring/reportable range of **ALFIS Vitamin D test =** 6.0 - 100.0 ng/mL				
1	**Reference Measurement Procedure (RMP)** vs. **ALFIS Vitamin D test** (6.45 - 83.33 ng/mL)	**120**	$y = 0.997x + 0.4725$ (0.9449 – 1.049) (-1.006 – 1.951)	0.978
2	**Elecsys Vitamin D Total III** vs. **ALFIS Vitamin D test** (6.18 - 79.48 ng/mL)	**120**	$y = 1.006x + 0.05392$ (0.9756 – 1.036) (-0.7186 – 0.8265)	0.9844

Conclusion:

Based on the intended use, principle and non-clinical as well as clinical performance characteristics described above, ALFIS Vitamin D (with ALFIS-3 analyzer) test system is substantially equivalent to the predicate device Elecsys Vitamin D Total III Assay.