DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 13, 2017

BODITECH MED INC.
HYUNG-JU OH
GENERAL MANAGER (REGULATORY AFFAIRS)
43, GEODUDANJI 1-GIL, DONGNAE-MYEON
CHUNCHEON-SI, GANG-WON-DO,
SOUTH KOREA 200-883

Re: K170232
Trade/Device Name: AFIAS TSH-SP, AFIAS-6/SP Analyzer
AFIAS TSH-VB, AFIAS-6/VB Analyzer
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: II
Product Code: JLW, KHO
Dated: August 31, 2017
Received: September 5, 2017

Dear Hyung-Ju Oh:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K170232

Device Name

AFIAS TSH-SP, AFIAS-6/SP Analyzer

Indications for Use *(Describe)*

AFIAS TSH-SP, for use in conjunction with the AFIAS-6/SP Analyzer, is an immunofluorometric test system intended for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites for the quantitative measurement of thyroid stimulating hormone (TSH) levels in serum, sodium-heparinized plasma, or EDTA plasma samples. The test system is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.

AFIAS-6/SP Analyzer is a fluorescence-scanning instrument for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in serum or plasma samples.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K170232

Device Name

AFIAS TSH-VB, AFIAS-6/VB Analyzer

Indications for Use *(Describe)*

AFIAS TSH-VB, for use in conjunction with the AFIAS-6/VB Analyzer, is an immunofluorometric test system intended for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites for the quantitative measurement of thyroid stimulating hormone (TSH) levels in sodium-heparinized or EDTA venous whole blood samples. The test system is intended for the monitoring of TSH levels in euthyroid and hypothyroid individuals.

AFIAS-6/VB Analyzer is a fluorescence-scanning instrument for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in venous whole blood samples.

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.

510(k) number: k170232

Preparation date: October 6, 2017

Device Type/Common Name: Radioimmunoassay, Thyroid-Stimulating Hormone

Trade/Proprietary Name : AFIAS TSH-SP, AFIAS-6/SP Analyzer
AFIAS TSH-VB, AFIAS-6/VB Analyzer

Type of Submission : Traditional 510(k) Submission

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

Submitter : Boditech Med Inc.
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Website: www.boditech.co.kr

Contact Person : Hyung-Ju Oh/General Manager (Regulatory Affairs)

Classification Regulation: 21CFR § 862.1690 Thyroid stimulating hormone test system

Class : II (for AFIAS TSH-SP Test Cartridge)
II (for AFIAS TSH-VB Test Cartridge)
I (for AFIAS-6/SP Analyzer)
I (for AFIAS-6/VB Analyzer)

Panel : Clinical Chemistry

Product Code : JLW; Thyroid stimulating hormone test system
KHO; Fluorometer for Clinical Use

Predicate Device : Access Fast hTSH with Access 2 System

Predicate Device 'K' Number : K042281

Intended Use/Indication for Use of AFIAS TSH-SP Test:

AFIAS TSH-SP, for use in conjunction with the AFIAS-6/SP Analyzer, is an immunofluorometric test system intended for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites for the quantitative measurement of thyroid stimulating hormone (TSH) levels in serum, sodium-heparinized plasma, or EDTA

plasma samples. The test system is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.

Intended Use/Indication for Use of AFIAS-6/SP Analyzer:

AFIAS-6/SP Analyzer is a fluorescence-scanning instrument for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in serum or plasma samples.

Intended Use/Indication for Use of AFIAS TSH-VB Test:

AFIAS TSH-VB, for use in conjunction with the AFIAS-6/VB Analyzer, is an immunofluorometric test system intended for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites for the quantitative measurement of thyroid stimulating hormone (TSH) levels in sodium-heparinized or EDTA venous whole blood samples. The test system is intended for the monitoring of TSH levels in euthyroid and hypothyroid individuals.

Intended Use/Indication for Use of AFIAS-6/VB Analyzer:

AFIAS-6/VB Analyzer is a fluorescence-scanning instrument for in vitro diagnostic use at clinical laboratories and Point-of-Care (POC) sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in venous whole blood samples.

Description of AFIAS TSH-SP and AFIAS TSH-VB Test Cartridges:

AFIAS TSH-SP as well as AFIAS TSH-VB Test Cartridge is a plastic structure molded in the form of a disposable, self-contained, unitized device which houses the 'lyophilized detection buffer', the 'diluent i.e. reconstitution buffer' as well as the 'test strip'; all of which are integral components of the test.

The test cartridge is an elongated structure having 140 mm length, 17 mm width and 17 mm height.

Description of AFIAS TSH-SP and AFIAS TSH-VB ID Chips:

'AFIAS TSH-SP ID Chip' as well as 'AFIAS TSH-VB ID Chip' is a flat, rectangular device with its main body measuring 24 mm × 20 mm × 3 mm. Another rectangular portion measuring 12 mm × 10 mm × 2 mm protrudes out from the apical side of the main body.

The ID Chip is an electronic memory device fitted into a plastic matrix. Lot-specific 'ID Chip' is an integral component of the test.

Before initiating the test run for testing a clinical sample or a calibrator/control using AFIAS TSH-SP or AFIAS TSH-VB test cartridge belonging to a new lot, the operator needs to mandatorily insert the lot-specific AFIAS TSH-SP or AFIAS TSH-VB ID Chip into one of the 'ID Chip Ports' of the AFIAS-6/SP or AFIAS-6/VB analyzer respectively.

Description of AFIAS-6/SP and AFIAS-6/VB Analyzer:

For performing AFIAS TSH-SP test on a clinical serum/plasma sample or a calibrator/control, AFIAS TSH-SP test cartridge needs to be used in conjunction with the AFIAS-6/SP analyzer.

Similarly, for performing AFIAS TSH-VB test on a clinical venous whole blood sample or a calibrator/control, AFIAS TSH-VB test cartridge needs to be used in conjunction with the AFIAS-6/VB analyzer.

AFIAS-6/SP as well as AFIAS-6/VB analyzer is a compact, bench-top, automated, fluorometric analyzer measuring 42 cm (L) x 33.6 cm (W) x 29.3 cm (H). AFIAS-6 weighs 15.1 kg.

Either analyzer is a flourometer 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).

Similarities between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH (with Access 2 System):

Following table shows the similarities between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH with Access 2 System

Similarities between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH (with Access 2 System)			
No.	**Comparison Parameter**	**Candidate Device/Test AFIAS TSH-SP (with AFIAS-6/SP Analyzer)**	**Predicate Device/Test (Access hTSH Assay with Access 2 Immunoassay System)**
1	Nature of the test	Quantitative *in vitro* diagnostic test system for human TSH	Quantitative *in vitro* diagnostic test system for human TSH
2	Intended use	Quantitative measurement of Thyroid Stimulating Hormone (TSH) in human serum and plasma samples	Quantitative determination of thyroid stimulating hormone (thyrotropin, hTSH) levels in human serum and plasma
3	Indications for use(s)	Indicated for use as an aid in the diagnosis of thyroid or pituitary disorders.	Indicated for use with patients where an assessment of their thyroid status is desired
4	Intended use sites	Clinical laboratories and POC sites (e.g. near-the-patient laboratories of hospitals, out-patient clinics, physician offices etc.)	Clinical laboratories and hospitals

5	Assay methodology	Sandwich immunoassay	Sandwich immunoassay
6	Result unit	µIU/ml (= mIU/l)	µIU/ml (= mIU/l)

Differences between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH (with Access 2 System):

Following table shows the differences between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH with Access 2 System.

Differences between AFIAS TSH-SP (with AFIAS-6/SP Analyzer) and the predicate device Access Fast hTSH (with Access 2 System)			
No.	**Comparison Parameter**	**Candidate Device/Test AFIAS TSH-SP (with AFIAS-6/SP Analyzer)**	**Predicate Device/Test (Access hTSH Assay with Access 2 Immunoassay System)**
1	Intended use sites	- Clinical laboratories - Central laboratories of hospitals - Near-the-patient/POC laboratories of hospitals - Out-patient clinics - Physician offices	- Clinical laboratories - Central laboratories of hospitals
2	Assay principle	Immunofluorometric assay	Paramagnetic particle chemiluminiscent immunoassay
3	Test device	Self-contained, unitized, ready-to-use, disposable test cartridge	Ready to use reaction vessel containing reagents
4	Associated instrument	AFIAS-6/SP Analyzer	Access 2 Immunoassay System
5	Test throughput	1-6 samples at a time	Batch testing with random access
6	Turnaround time	Reaction/incubation time =15 minutes Time for first result in a batch of 6 samples = ~16 minutes Time to last result in batch of 6 samples = ~18 minutes	20 min for Fast hTSH 45 min for HYPERsensitive hTSH
7	Sample volume required per test	**For serum and plasma samples:** 200 µl (minimum 150 µl) **For Calibrators/Controls** 200 µl (minimum 150 µl)	Minimum 300 µL
8	Sample volume utilized per test	**For serum and plasma samples:** 100 µl **For Calibrators/Controls:** 100 µl	55 µL for Fast hTSH 110 µL for HYPERsensitive hTSH
9	Limit of Quantitation /Functional Sensitivity	0.07 µIU/ml with inter-assay CV ≤ 20%	0.03 µIU/ml for Fast hTSH assay 0.01 µIU/ml for HYPERsensitive hTSH assay

10	Measuring/ reportable range	0.07-80.00 µIU/ml	0.03-100 µIU/ml for Fast hTSH assay 0.01-100 µIU/ml for HYPERsensitive hTSH assay
11	Calibration	Lot-specific master calibration curve/equation is encoded in the 'Lot-specific AFIAS TSH-SP ID Chip' which needs to be inserted in one of the 'ID Chip Ports' of AFIAS-6/SP analyzer prior to using that AFIAS TSH-SP test cartridge lot for the first time. AFIAS-6/SP can store the information of up to 100 ID Chips most recently inserted in it for performing AFIAS TSH-SP or other AFIAS tests. This AFIAS TSH-SP test cartridge lot-specific master calibration curve is further automatically adjusted by periodic duplicate testing of two levels of AFIAS TSH Calibrators by the user at its discretion.	Manual calibration by testing Access HYPERsensitive hTSH Calibrators is required every 28 days
12	Operational environment	Ambient temperature 15~35℃ Internal/system temperature 33-37℃	15~30℃

Similarities between AFIAS TSH-VB (with AFIAS-6/VB Analyzer) and the predicate device Access Fast hTSH (with Access 2 System):

Following table shows the similarities between AFIAS TSH-VB (with AFIAS-6/VB Analyzer) and the predicate device Access Fast hTSH with Access 2 System

Similarities between AFIAS TSH-VB (with AFIAS-6/VB Analyzer) and the predicate device Access Fast hTSH (with Access 2 System)			
No.	**Comparison Parameter**	**Candidate Device/Test AFIAS TSH-VB (with AFIAS-6/VB Analyzer)**	**Predicate Device/Test (Access hTSH Assay with Access 2 Immunoassay System)**
1	Nature of the test	Quantitative *in vitro* diagnostic test system for human TSH	Quantitative *in vitro* diagnostic test system for human TSH
2	Intended use	Quantitative measurement of Thyroid Stimulating Hormone (TSH) in Sodium heparinized or EDTA venous whole blood samples	Quantitative determination of thyroid stimulating hormone (thyrotropin, hTSH) levels in human serum and plasma
3	Indications for use(s)	Indicated for monitoring TSH levels in euthyroid and hypothyroid individuals.	Indicated for use with patients where an assessment of their thyroid status is desired

4	Intended use sites	Clinical laboratories and POC sites (e.g. near-the-patient laboratories of hospitals, out-patient clinics, physician offices etc.)	Clinical laboratories and hospitals
5	Assay methodology	Sandwich immunoassay	Sandwich immunoassay
6	Result unit	µIU/ml (= mIU/l)	µIU/ml (= mIU/l)

Differences between AFIAS TSH-VB (with AFIAS-6/VBAnalyzer) and the predicate device Access Fast hTSH (with Access 2 System):

Following table shows the differences between AFIAS TSH-VB (with AFIAS-6/VB Analyzer) and the predicate device Access Fast hTSH with Access 2 System.

Differences between AFIAS TSH-VB (with AFIAS-6/VB Analyzer) and the predicate device Access Fast hTSH (with Access 2 System)			
No.	**Comparison Parameter**	**Candidate Device/Test AFIAS TSH-VB (with AFIAS-6/VB Analyzer)**	**Predicate Device/Test (Access hTSH Assay with Access 2 Immunoassay System)**
1	Intended use sites	- Clinical laboratories - Central laboratories of hospitals - Near-the-patient/POC laboratories of hospitals - Out-patient clinics - Physician offices	- Clinical laboratories - Central laboratories of hospitals
2	Assay principle	Immunofluorometric assay	Paramagnetic particle chemiluminiscent immunoassay
3	Test device	Self-contained, unitized, ready-to-use, disposable test cartridge	Ready to use reaction vessel containing reagents
4	Associated instrument	AFIAS-6/VB Analyzer	Access 2 Immunoassay System
5	Test throughput	1-6 samples at a time	Batch testing with random access
6	Turnaround time	Reaction/incubation time =15 minutes Time for first result in a batch of 6 samples = ~16 minutes Time to last result in batch of 6 samples = ~18 minutes	20 min for Fast hTSH 45 min for HYPERsensitive hTSH
7	Sample volume required per test	**For venous whole blood samples:** 150 µl (minimum 100 µl) **For Calibrators/Controls** 200 µl (minimum 150 µl)	Minimum 300 µL
8	Sample volume utilized per test	**For venous whole blood samples:** 50 µl **For Calibrators/Controls:** 100 µl	55 µL for Fast hTSH 110 µL for HYPERsensitive hTSH

9	Limit of Quantitation /Functional Sensitivity	0.3 µIU/ml with inter-assay CV ≤ 20%	0.03 µIU/ml for Fast hTSH assay 0.01 µIU/ml for HYPERsensitive hTSH assay
10	Measuring/ reportable range	0.3-80 µIU/ml	0.03-100 µIU/ml for Fast hTSH assay 0.01-100 µIU/ml for HYPERsensitive hTSH assay
11	Calibration	Lot-specific master calibration curve/equation is encoded in the 'Lot-specific AFIAS TSH-VB ID Chip' which needs to be inserted in one of the 'ID Chip Ports' of AFIAS-6/VB analyzer prior to using that AFIAS TSH-VB test cartridge lot for the first time. AFIAS-6/VB can store the information of up to 100 ID Chips most recently inserted in it for performing AFIAS TSH-VB or other AFIAS tests. Each AFIAS TSH-VB test cartridge lot-specific master calibration curve is further automatically adjusted by periodic duplicate testing of two levels of AFIAS TSH Calibrators by the user at its discretion.	Manual calibration by testing Access HYPERsensitive hTSH Calibrators is required every 28 days
12	Operational environment	Ambient temperature 15~35℃ Internal/system temperature 33-37℃	15~30℃

Summary of Performance Evaluation Studies:

1) Limit of Blank:

- Limit of Blank (LoB) of AFIAS TSH-SP and AFIAS TSH-VB tests have been evaluated as per CLSI EP 17-A2.
- 5 replicates each of 5 blank/TSH-depleted human serum as well as 5 blank/TSH-depleted whole blood samples were tested with 3 lots of test cartridges on 3 respective analyzers for 3 days; thus testing 75 replicates per lot/analyzer.
- Limit of Blank (LoB) was calculated by non-parametric analysis of the data.
- Limit of Blank of AFIAS TSH-SP test is 0.03 µIU/ml and that of AFIAS TSH-VB test is 0.13 µIU/ml.

2) Limit of Detection:

- Limit of Detection (LoD) of AFIAS TSH-SP and AFIAS TSH-VB tests have been evaluated as per CLSI EP 17-A2.
- 5 replicates each of 5 low TSH-spiked human serum as well as 5 low TSH-spiked whole blood samples were tested with 3 lots of test cartridges on 3 respective analyzers for 3 days; thus testing 75 replicates per lot/analyzer.
- Limit of Detection (LoD) was calculated by parametric analysis of the data.
- Limit of Detection of AFIAS TSH-SP test is 0.05 µIU/ml and that of AFIAS TSH-VB test is 0.2 µIU/ml.

3) Limit of Quantitation:

- Limit of Quantitation (LoQ) of AFIAS TSH-SP and AFIAS TSH-VB tests have been evaluated as per CLSI EP 17-A2.
- For evaluating the LoQ of AFIAS TSH-SP test, 2 replicates of each of the 5 low TSH-spiked serum samples were tested daily in two different runs with two test cartridge lot/analyzer/operator combinations for 21 successive days.
- For evaluating the LoQ of AFIAS TSH-VB test, 5 replicates of each of the 4 low TSH-spiked venous whole blood samples were tested daily in two different runs with two test cartridge lot/analyzer/operator combinations for 5 successive days.
- Limit of Quantitation (LoQ) was calculated by considering accuracy goal of inter-assay CV $\leq$ 20%.
- Limit of Quantitation of AFIAS TSH-SP test is 0.07 µIU/ml and that of AFIAS TSH-VB test is 0.3 µIU/ml.

4) **Linearity and Reportable Range:**

- For evaluating linearity and measuring/reportable range of AFIAS TSH-SP test, a series of 22 test samples prepared by mixing a high TSH-spiked serum sample (TSH≈100 µIU/mL) and a TSH-depleted serum sample (TSH ≈ 0 µIU/mL) in various proportions, was tested in triplicate with the one lot of AFIAS TSH-SP test cartridges on one AFIAS-6/SP analyzer on the same day.
- Similarly, for evaluating linearity and measuring/reportable range of AFIAS TSH-VB test, a series of 22 test samples prepared by mixing a high TSH-spiked venous whole blood sample (TSH≈100 µIU/mL) and a TSH-depleted venous whole blood sample (TSH ≈ 0 µIU/mL) in various proportions, was tested in triplicate with the one lot of AFIAS TSH-VB test cartridges on one AFIAS-6/VB analyzer on the same day.
- Mean of the triplicate test results of each sample was plotted against its expected TSH concentration calculated mathematically.
- The following linear regression equations were obtained:

  Serum: $y = 1.0081x - 0.0785$, $R^2 = 0.9993$

  Na-heparinized whole blood: $y = 0.9824x + 0.216$, $R^2 = 0.9997$

- Both tests showed linearity over the entire TSH concentration range (0~100 µIU/ml) tested for the study.
- Measuring/reportable range of AFIAS TSH-SP test system has been programed as 0.07-80 µIU/ml while that of AFIAS TSH-VB test system has been programed as 0.3 -80.0 µIU/ml.

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

- For evaluating susceptibility to high dose hook (prozone) effect, a series of spiked samples having TSH concentrations 25, 50, 75, 100, 150, 200, 500, 1000, 1500, 2000, 2500 and 3000 µIU/ml was 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 TSH concentration of 3000 µIU/ml.

6) **Analytical specificity:**

- Susceptibility of AFIAS TSH-SP and AFIAS TSH-VB test systems to interference from various endogenous substances, heterophiles and drugs as well as cross-reactivity with endogenous TSH structural analogs (hFSH, hLH, and hCG) has been evaluated at specified concentrations of the interferants/cross-reactants as follows:
  - Albumin/Protein (6 g/dL= 6000 mg/dL)
  - Conjugated Bilirubin (20 mg/dL)
  - Unconjugated Bilirubin (20 mg/dL)
  - Human hemoglobin (100 mg/dL and 500 mg/dL)
  - Triglycerides (3 g/dL= 3000 mg/dL)
  - HAMA (138 ng/mL)
  - Rheumatoid Factor (1500 IU/mL)
  - Biotin (56 ng/mL)
  - Levothyroxine (75 µg/L)
  - Methimazole (36 mg/L)
  - Metoprolol (4.99 mg/L)
  - Human Follicle-stimulating Hormone/hFSH (1,200 mIU/ml)
  - Human Luteinizing Hormone/hLH (1,200 mIU/ml)
  - Human Chorionic Gonadotropin/hCG (1,200 mIU/ml)
- AFIAS TSH-SP as well as AFIAS TSH-VB tests showed analyte recovery within the acceptable range of 90-110% in presence of specified concentrations of above substances thereby indicating insignificant interference/cross-reactivity.

7) **Site-to-Site Precision/Reproducibility:**

- Reproducibility of AFIAS TSH-SP test system was evaluated by testing 5 replicates of each of the 4 serum samples (TSH levels ≈0.5, ≈5.0, ≈15.0 & ≈55.0 µIU/ml) with 3 lots of AFIAS TSH-SP test cartridges on 3 AFIAS-6/SP analyzers (1 analyzer per site) at 3 external point-of-care sites at the hands of 9 intended POC operators (3 operators per site).

  The results are summarized in the following tables:

Site-wise Statistical Analysis of External POC Sites Precision Study Data of AFIAS TSH-SP Test									
Serum Sample Tested	**Precision Study Site**	**Number of Replicates (n)**	**Mean TSH (µIU/mL)**	**Lot-to-Lot Imprecision**		**Day-to-Day Imprecision**		**Total Imprecision**	
				SD	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Clinical Serum Sample 1	**Site 1**	15	0.49	0.003	0.7	0.006	1.3	0.020	4.2
	Site 2	15	0.49	0.003	0.7	0.009	1.8	0.018	3.7
	Site 3	15	0.50	0.009	1.8	0.011	2.2	0.021	4.2
Clinical Serum Sample 2	**Site 1**	15	4.91	0.034	0.7	0.187	3.8	0.288	5.9
	Site 2	15	4.96	0.057	1.1	0.154	3.1	0.318	6.4
	Site 3	15	5.03	0.029	0.6	0.145	2.9	0.233	4.6
Spiked Serum Sample 3	**Site 1**	15	14.96	0.423	2.8	0.658	4.4	1.008	6.7
	Site 2	15	14.93	0.240	1.6	0.280	1.9	0.749	5.0
	Site 3	15	15.26	0.423	2.8	0.277	1.8	0.604	4.0
Spiked Serum Sample 4	**Site 1**	15	54.26	0.496	0.9	1.385	2.6	3.003	5.5
	Site 2	15	54.35	2.136	3.9	1.381	2.5	3.141	5.8
	Site 3	15	53.53	0.596	1.1	2.306	4.3	2.883	5.4

Combined-sites Statistical Analysis of External POC Sites Precision Study Data of AFIAS TSH-SP Test								
Serum Sample Tested	**Number of Replicates (n)**	**Mean TSH (µIU/mL)**	**Lot-to-Lot Imprecision**		**Day-to-Day Imprecision**		**Total Imprecision**	
			SD	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Clinical Serum Sample 1	45	0.49	0.005	1.0	0.007	1.5	0.020	4.0
Clinical Serum Sample 2	45	4.97	0.028	0.6	0.072	1.5	0.280	5.6
Spiked Serum Sample 3	45	15.05	0.297	2.0	0.244	1.6	0.801	5.3
Spiked Serum Sample 4	45	54.05	0.468	0.9	0.531	1.0	2.965	5.5

- Similarly, reproducibility of AFIAS TSH-VB test system was evaluated by testing 5 replicates of each of the 4 whole blood samples (TSH levels ≈0.5, ≈5.0, ≈15.0 & ≈55.0 µIU/ml) with 3 lots of AFIAS TSH-VB test cartridges on 3 AFIAS-6/VB analyzers (1 analyzer per site) at 3 external point-of-care sites at the hands of 9 intended POC operators (3 operators per site).

  The results are summarized in the following tables:

Site-wise Statistical Analysis of External POC Sites Precision Study Data of AFIAS TSH-VB Test									
Venous Whole Blood Sample	**Precision Study Site**	**Number of Replicates (n)**	**Mean TSH (µIU/mL)**	**Lot-to-Lot Imprecision**		**Day-to-Day Imprecision**		**Total Imprecision**	
				SD	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Clinical Venous Whole Blood Sample 1	**Site 1**	15	0.45	0.008	1.7	0.015	3.4	0.029	6.3
	Site 2	15	0.44	0.005	1.2	0.013	2.8	0.031	7.0
	Site 3	15	0.46	0.004	0.9	0.024	5.3	0.029	6.4
Clinical Venous Whole Blood Sample 2	**Site 1**	15	4.88	0.116	2.4	0.273	5.6	0.321	6.6
	Site 2	15	5.00	0.105	2.1	0.183	3.7	0.350	7.0
	Site 3	15	5.01	0.186	3.7	0.200	4.0	0.403	8.1
Spiked Venous Whole Blood Sample 3	**Site 1**	15	15.97	0.532	3.3	0.581	3.6	1.161	7.3
	Site 2	15	15.31	0.425	2.8	0.563	3.7	1.156	7.5
	Site 3	15	16.10	0.344	2.1	0.712	4.4	0.995	6.2
Spiked Venous Whole Blood Sample 4	**Site 1**	15	55.77	0.906	1.6	0.944	1.7	2.853	5.1
	Site 2	15	56.57	0.450	0.8	1.326	2.3	2.977	5.3
	Site 3	15	55.71	1.791	3.2	2.349	4.2	3.300	5.9

Combined-sites Statistical Analysis of External POC Sites Precision Study Data of AFIAS TSH-VB Test								
Venous Whole Blood Sample	**Number of Replicates (n)**	**Mean TSH (µIU/mL)**	**Lot-to-Lot Imprecision**		**Day-to-Day Imprecision**		**Total Imprecision**	
			SD	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Clinical Venous Whole Blood Sample 1	45	0.45	0.005	1.0	0.012	2.6	0.029	6.5
Clinical Venous Whole Blood Sample 2	45	4.96	0.125	2.5	0.103	2.1	0.356	7.2
Spiked Venous Whole Blood Sample 3	45	15.79	0.206	1.3	0.362	2.3	1.136	7.2
Spiked Venous Whole Blood Sample 4	45	56.02	0.199	0.4	0.750	1.3	3.005	5.4

8) **Matrix Comparison:**

- Matching clinical serum, sodium heparin plasma and di-potassium EDTA plasma samples obtained from same study subjects were tested with one lot of AFIAS TSH-SP test cartridges on one AFIAS-6/SP analyzer for evaluating the effect of these anti-coagulants on AFIAS TSH-SP test results.
- Similarly, matching clinical sodium heparin venous whole blood and di-potassium EDTA venous whole blood samples obtained from same study subjects were tested with one lot of AFIAS TSH-VB test cartridges on one AFIAS-6/VB analyzer for evaluating the effect of these anti-coagulants on AFIAS TSH-VB test results.
- The data and regression analysis are summarized below:

Sr. No.	**Sample matrices compared & TSH Range of Compared Results**	**Number of Samples**	**Linear Regression Equation**	**Correlation Coefficient**
Measuring/reportable range of **AFIAS TSH-SP Test =** 0.07-80.0 µIU/ml				
1	**Serum** vs. **Sodium heparin plasma** (0.09 – 77.52 µIU/mL)	**81**	$y = 0.9565x + 0.0424$	0.9998
2	**Serum** vs. **Di-Potassium EDTA plasma** (0.09 – 77.52 µIU/mL)	**79**	$y = 0.9654x + 0.0131$	0.9997
Measuring/reportable range of **AFIAS TSH-VB Test =** 0.3-80.0 µIU/ml				
3	**Sodium heparin venous whole blood** vs. **Di-Potassium EDTA venous whole blood** (0.40 – 71.74 µIU/mL)	**63**	$y = 0.993x + 0.0325$	0.9998

9) **Adult Reference Interval:**

- Adult reference interval of AFIAS TSH-SP test was evaluated by testing serum samples collected from total 128 apparently healthy adults (65 males and 63 females) in the age group of 21-70 years.
- Adult reference interval of AFIAS TSH-VB test was evaluated by testing sodium heparin venous whole blood samples collected from total 133 apparently healthy adults (69 males and 64 females) in the age group of 21-70 years.
- Non-parametric reference interval encompassing the central 95% frequency distribution of test 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 AFIAS TSH-SP and AFIAS TSH-VB tests have been found to be 0.45-4.49 µIU/mL and 0.41-4.06 µIU/mL respectively.

- The manufacturer claims 0.45-4.50 µIU/mL as adult reference interval of AFIAS TSH-SP test and 0.40-4.0 µIU/mL as the adult reference interval of AFIAS TSH-VB 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) **Clinical Method Comparison:**

- Method comparison studies of AFIAS TSH-SP and AFIAS TSH-VB tests were carried out at three point-of-care clinical sites at the hands of typical POC operators.
- 183 serum samples (including 22 spiked serum samples) were tested in singlet with one lot AFIAS TSH-SP test cartridges on one AFIAS-6/SP analyzer per site.

  Aliquot of each serum sample from across the three study sites was tested with the predicate device Access Fast hTSH (on the Access 2 system) at a centralized laboratory.
- Similarly, 157 sodium heparinized venous whole blood samples (including 22 spiked venous whole blood samples) were tested in singlet with one lot AFIAS TSH-VB test cartridges on one AFIAS-6/VB analyzer per site.

  Matching serum samples from across the three study sites were tested with the predicate device Access Fast hTSH (on the Access 2 system) at the centralized laboratory.
- Correlation/comparability between the candidate test results of the tested samples and predicate test results of matching serum samples was evaluated by performing weighted deming regression analysis of the data as summarized in the following table:

TSH Range of Candidate Test Results included in the Regression Analysis of Method Comparison Data	**Number of Samples**	**Weighted Deming Regression Equation (with 95% Confidence Intervals for Slope and Y-intercept)**	**Correlation Coefficient**
AFIAS TSH-SP 0.07 – 79.91 µIU/mL	Compared = **183**	**y = 0.976*x* - 0.003** (0.969 – 0.981) (-0.0055 – -0.0007)	**0.9994**
AFIAS TSH-VB 0.31 – 76.26 µIU/mL	Compared = **157**	**y = 0.909x + 0.012** (0.904 – 0.913) (0.006 – 0.017)	**0.9999**

Conclusion:

Based on the intended use, principle and non-clinical as well as clinical performance characteristics described above, AFIAS TSH-SP (with AFIAS-6/SP analyzer) and AFIAS TSH-VB (with AFIAS-6/VB analyzer) test systems are substantially equivalent to the predicate device Acces Fast hTSH (with Access 2 System).