

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

A. 510(k) Number:

k170232

B. Purpose for Submission:

New device

C. Measurand:

Thyroid stimulating hormone (TSH)

D. Type of Test:

Quantitative, immunofluorescent assay

E. Applicant:

Boditech Med Inc.

F. Proprietary and Established Names:

AFIAS TSH-SP

AFIAS TSH-VB

AFIAS-6/SP Analyzer

AFIAS-6/VB Analyzer

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JLW	Class II	21 CFR 862.1690 Thyroid stimulating hormone test system	Clinical Chemistry (75)
KHO	Class I	21 CFR 862.2560 Fluorometer for Clinical Use	

H. Intended Use:

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for use:

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 sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in serum or plasma samples.

AFIAS TSH-VB, for use in conjunction with AFIAS-6/VB Analyzer, is an immunofluorometric in vitro diagnostic 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) in sodium-heparinized or EDTA venous whole blood samples. The test system is intended for monitoring 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 sites in conjunction with various in vitro diagnostic AFIAS immunoassays for measuring the concentration of designated analytes in venous whole blood samples.

3. Special conditions for use statement(s):

For prescription use only.

For use in clinical laboratories and point-of-care settings.

4. Special instrument requirements:

AFIAS-6/SP analyzer

AFIAS-6/VB analyzer

I. Device Description:

The AFIAS TSH-SP and the AFIAS TSH-VB test cartridges consist of two closed chambers; one containing lyophilized detection buffer and the other containing diluent/reconstitution buffer. Lyophilized detection buffer contains the fluorochrome-labeled anti-human TSH murine antibodies (0.05 µg) and fluorochrome-labeled chicken immunoglobulin Y (0.01 µg). The nitrocellulose matrix of the test strip contains a test/capture line which is tagged with anti-human TSH murine antibodies (0.929 µg); and a control line which is tagged with anti-chicken immunoglobulin Y (0.465 µg).

The AFIAS TSH-SP and AFIAS TSH-VB ID chips are electronic memory devices fitted into a plastic flat rectangular device 24 mm x 20 mm x 3 mm. The AFIAS TSH-SP ID chip is intended for use with the AFIAS-6/SP analyzer for use with serum and plasma and the AFIAS-VB ID chip is intended for use with the AFIAS-6/VB analyzer for use with whole blood samples. The ID chip contains lot specific information. Relevant information derived from the ID chip (test name/item, lot number, expiration date and sample type) will be saved in the internal memory of AFIAS-6/SP or AFIAS 6/VB analyzer. The analyzers can save ID chip information of up to 100 ID chips.

AFIAS-6/SP and AFIAS-6/VB analyzers are identical except the AFIAS-6/SP analyzer will only accept the AFIAS-6/SP ID chip and is intended for use with serum and plasma samples and the AFIAS-6/VB analyzer will only accept the AFIAS-6/VB ID chip and is intended for use with venous whole blood samples. The 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/SP and AFIAS-6/VB are fluorescence-scanning analyzers to use in conjunction with various AFIAS tests which are based on antigen-antibody reaction and fluorescence technology. The analyzers use a semiconductor diode laser as the excitation light source for illuminating the sample loaded AFIAS test cartridges inserted in its cartridge holder; thereby triggering fluorescence from the fluorochrome-labeled complexes of analytes accumulated at the test line on the cartridge membrane. The on-board microprocessor computes concentration of the analyte in the test sample base on the pre-programmed calibration derived from the AFIAS ID chip inserted in the ID chip port.

The AFIAS TSH-SP cartridge is for use with the AFIAS-6/SP analyzer; this test system is intended for use with serum and plasma samples. The AFIAS TSH-VB cartridges are for use with the AFIAS-6/VB analyzer; this test system is for use with venous whole blood samples. The test systems are identical except for the intended uses and sample types.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Access Fast hTSH assay (modification to the Access HYPERsensitive hTSH)

Access 2 Immunoassay System

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

k042281

k922823

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device AFIAS-SP TSH Assay (k170232)	Predicate Device Access Fast hTSH (k042281)
Intended Use	For the quantitative measurement of thyroid stimulating hormone (TSH)	Same
Assay Methodology	Immunofluorometric sandwich immunoassay	Paramagnetic particle chemiluminescent immunoassay
Sample Matrices	Serum, K2-EDTA plasma, sodium heparin plasma	serum, heparinized plasma
Measuring range	0.07-80 µIU/mL	0.03-100 µIU/mL
Test time	18 minutes	20 minutes
Sample volume	200 µL	Minimum 300 µL

Similarities and Differences		
Item	Candidate Device AFIAS-VB TSH Assay (k170232)	Predicate Device Access Fast hTSH (k042281)
Intended Use	For the quantitative measurement of thyroid stimulating hormone (TSH)	Same
Assay Methodology	Immunofluorometric sandwich immunoassay	Paramagnetic particle chemiluminescent immunoassay
Sample Matrices	Venous K2-EDTA whole blood and venous Na-heparin whole blood	Venous serum, venous heparinized plasma
Measuring range	0.3 -80 µIU/mL	0.03-100 µIU/mL
Test time	18 minutes	20 minutes
Sample volume	150 µL	Minimum 300 µL

Similarities and Differences		
Item	Candidate Device AFIAS-6/SP Analyzer (k170232)	Predicate Device Access 2 Immunoassay System (k922823)
Intended Use	Analyzer for the measurement of immunoassay analytes	Same
Intended Use Sites	Clinical laboratories and Point-of-Care	Clinical laboratories
Sample type	Serum, K2-EDTA and Na-heparin plasma	Same
Sample capacity	Up to 6 samples at a time	Up to 60 samples at one time
Reagent format	Unitized test cassettes	Reagent packs
Analyzer Format	Bench-top	Same

Similarities and Differences		
Item	Candidate Device AFIAS-6/VB Analyzer (k170232)	Predicate Device Access 2 Immunoassay System (k922823)
Intended Use	Analyzer for the measurement of immunoassay analytes	Same
Intended Use Sites	Clinical laboratories and Point-of-Care	Clinical laboratories
Sample type	Venous K2-EDTA and Na-heparin whole blood	Serum and plasma
Sample capacity	Up to 6 samples at a time	Up to 60 samples at one time
Reagent format	Unitized test cassettes	Reagent packs
Analyzer Format	Bench-top	Same

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

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 EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition.

CLSI EP14-A3: Evaluation of Commutability of Processed Samples; Approved Guideline; Third Edition

CLSI EP 17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline.

CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline; Third Edition.

L. Test Principle:

Fluorochrome-labeled anti-human TSH murine antibodies (detector antibody) present in the reconstituted detection buffer bind with thyroid stimulating hormone present in the sample. The test mixture migrates through the nitrocellulose matrix of the test strip which contains a test capture line and a control line. The test line is tagged with anti-human TSH murine antibodies and the control line is tagged with anti-chicken immunoglobulin Y. As the test sample migrates through the test strip, anti-human TSH murine antibodies at the test line capture the detector antibody-TSH complexes. Similarly, complexes of fluorochrome-labeled chicken immunoglobulin Y-capture antibodies accumulate at the control line. At the end of the 15 minute incubation time, a laser light source illuminates the cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test and control lines. The intensity of the fluorescence is scanned and converted into an electric signal which correlates to the concentration of human TSH in the test sample. An on-board microprocessor calculates the TSH concentration in the sample utilizing a pre-programmed, lot-specific and sample-specific master calibration curve stored in the AFIAS TSH ID chip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

In-house precision studies were performed by testing four spiked serum samples and seven spiked sodium-heparinized venous whole blood samples. The serum samples were tested once a day for 21 consecutive days. The venous whole blood samples were tested once per day for 6 consecutive days. All the studies were performed by 3 in-house laboratory technicians using 3 lots of cartridges, one lot per three

analyzers. The results of the in-house precision studies are summarized in the tables below:

Serum analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:

Sample	n	Mean (μ IU/mL)	Between lot		Between day		Total	
			SD	%CV	SD	%CV	SD	%CV
1	63	0.49	0.005	1.0	0.012	2.5	0.020	4.0
2	63	4.99	0.058	1.2	0.151	3.0	0.275	5.5
3	63	14.97	0.244	1.6	0.451	3.0	0.826	5.5
4	63	53.31	0.295	0.6	2.844	5.3	3.044	5.7

Venous Na-heparin whole blood analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:

Sample	n	Mean (μ IU/mL)	Between lot		Between day		Total	
			SD	%CV	SD	%CV	SD	%CV
1	18	0.49	0.006	1.3	0.029	6.0	0.030	6.1
2	18	1.18	0.001	0.1	0.075	6.4	0.085	7.2
3	18	2.66	0.058	2.2	0.157	5.9	0.201	7.6
4	18	3.95	0.034	0.9	0.289	7.3	0.298	7.5
5	18	4.89	0.065	1.3	0.328	6.7	0.327	6.7
6	18	14.39	0.126	0.9	1.026	7.1	0.986	6.8
7	18	54.53	0.227	0.4	3.980	7.3	3.762	6.9

External precision studies were performed at three point-of-care (POC) sites. The following sample types were tested: 2 native serum samples, 2 native Na-heparin venous whole blood samples, and 2 spiked Na-heparin venous whole blood samples. At each of the 3 sites, 3 lots of test cartridges and 3 analyzers were used (one lot per analyzer). At each of the 3 test sites, 3 operators tested each sample one time a day for 5 consecutive days for a total of 45 results per sample. The results are summarized in the tables below:

Serum analysis for the AFIAS TSH-SP on the AFIAS-6/SP Analyzer:

Sample	Site	n	Mean (μ IU/mL)	Between lot		Between day		Total	
				SD	%CV	SD	%CV	SD	%CV
1	1	15	0.49	0.003	0.7	0.006	1.3	0.020	4.2
	2	15	0.49	0.003	0.7	0.009	1.8	0.018	3.7
	3	15	0.50	0.009	1.8	0.011	2.2	0.021	4.2
2	1	15	4.91	0.034	0.7	0.187	3.8	0.288	5.9
	2	15	4.96	0.057	1.1	0.154	3.1	0.318	6.4
	3	15	5.03	0.029	0.6	0.145	2.9	0.233	4.6
3	1	15	14.96	0.423	2.8	0.658	4.4	1.008	6.7
	2	15	14.93	0.240	1.6	0.280	1.9	0.749	5.0
	3	15	15.26	0.423	2.8	0.277	1.8	0.603	4.0
4	1	15	54.26	0.496	0.9	1.385	2.6	3.003	5.5
	2	15	54.35	2.136	3.9	1.381	2.5	3.141	5.8
	3	15	53.53	0.596	1.1	2.306	4.3	2.883	5.4

Serum (combined sites) analysis for the AFIAS TSH-SP on the AFIAS-6/SP Analyzer:

Sample	n	Mean (μ IU/mL)	Between lot		Between day		Total	
			SD	%CV	SD	%CV	SD	%CV
1	45	0.49	0.005	1.0	0.007	1.5	0.020	4.0
2	45	4.97	0.028	0.6	0.072	1.5	0.280	5.6
3	45	15.05	0.297	2.0	0.244	1.6	0.801	5.3
4	45	54.05	0.468	0.9	0.531	1.0	2.965	5.5

Venous Na-heparin whole blood analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:

Sample	Site	n	Mean (μ IU/mL)	Between lot		Between day		Total	
				SD	%CV	SD	%CV	SD	%CV
1	1	15	0.45	0.008	1.7	0.015	3.4	0.029	6.3
	2	15	0.44	0.005	1.2	0.013	2.8	0.031	7.0
	3	15	0.46	0.004	0.9	0.024	5.3	0.029	6.4
2	1	15	4.88	0.116	2.4	0.273	5.6	0.321	6.6
	2	15	5.00	0.105	2.1	0.183	3.7	0.350	7.0
	3	15	5.01	0.186	3.7	0.200	4.0	0.403	8.1
3	1	15	15.97	0.532	3.3	0.581	3.6	1.161	7.3
	2	15	15.31	0.425	2.8	0.563	3.7	1.156	7.5
	3	15	16.10	0.344	2.1	0.712	4.4	0.995	6.2
4	1	15	55.77	0.906	1.6	0.944	1.7	2.853	5.1
	2	15	56.57	0.450	0.8	1.326	2.3	2.977	5.3
	3	15	55.71	1.791	3.2	2.349	4.2	3.300	5.9

Venous Na-heparin whole blood (combined sites) analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:

Sample	n	Mean (μ IU/mL)	Between lot		Between day		Total	
			SD	%CV	SD	%CV	SD	%CV
1	45	0.45	0.005	1.0	0.012	2.6	0.029	6.5
2	45	4.96	0.125	2.5	0.103	2.1	0.356	7.2
3	45	15.79	0.206	1.3	0.362	2.3	1.136	7.2
4	45	56.02	0.199	0.4	0.750	1.3	3.005	5.4

b. Linearity/assay reportable range:

A linearity study was performed on serum and Na-heparinized whole blood samples. A serum sample with a high TSH concentration was serially diluted using a serum sample with a low concentration of TSH to produce 22 equally spaced, TSH concentrations. The serum linearity samples had the following mean TSH concentrations: 0.0, 0.03, 0.49, 0.99, 1.98, 2.99, 3.98, 4.99, 5.94, 6.99, 7.96, 9.00, 10.03, 20.16, 29.99, 40.77, 50.25, 61.63, 68.00, 79.01, 90.56, and 102.91 μ IU/mL. Likewise, a Na-heparinized whole blood sample with a high TSH concentration was serially diluted with a Na-heparinized whole blood sample with a low TSH concentration to produce 22 equally spaced TSH concentrations. The Na-heparinized whole blood linearity samples had the following mean TSH concentrations: 0.00, 0.14, 0.49, 0.97, 1.92, 2.92, 3.91, 4.92, 5.94, 6.93, 7.86, 8.82, 9.81, 19.39, 30.50, 39.38, 48.77, 57.69, 70.40, 77.66, 88.69, and 98.36 μ IU/mL. The samples were run in replicates of three. The following linear regression equations were obtained:

Serum analysis for the AFIAS TSH-SP on the AFIAS-6/SP Analyzer:
 $y=1.0081 x - 0.0785$, $R^2= 0.9993$

Na-heparinized whole blood analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:
 $y= 0.9824 x + 0.0216$, $R^2= 0.9997$

The claimed measuring range of the AFIAS TSH-SP on the AFIAS TSH/SP Analyzer for serum TSH is 0.07 to 80 μ IU/mL.

The claimed measuring range of the AFIAS TSH-VB on the AFIAS TSH/VB Analyzer for venous whole blood TSH is 0.3 to 80 μ IU/mL.

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

Traceability: AFIAS TSH Controls are prepared gravimetrically and are traceable to the WHO International Standard Human Thyroid Stimulating Hormone for Immunoassay (3rd IRP, NIBSC Code 81/565).

d. Detection limit:

Detection limit studies were performed on both serum and Na-heparinized whole blood samples to determine the limit of blank, limit of detection, and limit of quantitation for both matrix types.

Limit of Blank (LoB): Five TSH-depleted human serum and whole blood samples were each tested in replicates of 5 using 3 cartridge lots and 3 analyzers for 3 days for a total of 75 test results per lot. The LoB was calculated by non-parametric analysis of the study data. The sponsor used the highest LoB from the three lots as the claimed LoB. The LoB for the serum matrix was determined to be 0.03 µIU/mL for use with the AFIAS TSH-SP on the AFIAS-6/SP Analyzer. The LoB for the whole blood matrix was determined to be 0.13 µIU/mL for use with the AFIAS TSH-VB on the AFIAS-6/VB Analyzer.

Limit of Detection (LoD): Five low level TSH spiked human serum samples were prepared to have approximate TSH concentrations of 0.04, 0.06, 0.08, 0.10, and 0.12 µIU/mL. Five low level TSH spiked venous whole blood samples were prepared to have approximate TSH concentrations of 0.2, 0.3, 0.4, 0.5, and 0.6 µIU/mL. The samples were tested in replicates of 5 using 3 cartridge lots and 3 analyzers for 3 days for a total of 75 tests per lot. The following equation was used to calculate the LoD: LoD= LoB + Cp x SD_L. The sponsor used the highest LoD from the three lots as the claimed LoD. The LoD for the serum matrix was determined to be 0.05 µIU/mL for use with the AFIAS TSH-SP on the AFIAS-6/SP Analyzer. The LoD for the whole blood matrix was determined to be 0.2 µIU/mL for use with the AFIAS TSH-VB on the AFIAS-6/VB Analyzer.

Limit of Quantitation (LoQ): Five low level TSH spiked human serum samples were prepared to have approximate mean TSH concentrations of 0.05, 0.06, 0.07, 0.08, and 0.09 µIU/mL. Four low level TSH spiked Na-heparin whole blood samples were prepared to have approximate mean TSH concentrations of 0.2, 0.3, 0.4, and 0.5 µIU/mL. The samples were tested and the SD and %CVs were calculated from the data. The sponsor defines LoQ as the lowest TSH concentration with an imprecision of less than or equal to 20%. The sponsor used the highest LoQ from the three lots as the claimed LoQ. The LoQ for the serum matrix was determined to be 0.07 µIU/mL for use with the AFIAS TSH-SP on the AFIAS-6/SP Analyzer. The LoQ for the whole blood matrix was determined to be 0.3 µIU/mL for use with the AFIAS TSH-VB on the AFIAS-6/VB Analyzer.

	Serum (μ IU/mL) for use with the AFIAS TSH-SP on the AFIAS-6/SP Analyzer	Whole Blood (μ IU/mL) for use with the AFIAS TSH-VB on the AFIAS-6/VB Analyzer
Limit of Blank	0.03	0.13
Limit of Detection	0.05	0.20
Limit of Quantitation	0.07	0.30

The claimed measuring range of the AFIAS TSH-SP on the AFIAS TSH/SP Analyzer for serum TSH is 0.07 to 80 μ IU/mL.

The claimed measuring range of the AFIAS TSH-VB on the AFIAS TSH/VB Analyzer for venous whole blood TSH is 0.3 to 80 μ IU/mL.

e. *Analytical specificity:*

Interference study:

The sponsor performed an interference study to evaluate the susceptibility of the AFIAS TSH test systems to interference from several endogenous substances and common thyroid medications. Two serum samples and two Na-heparin venous whole blood samples with TSH concentrations of 0.5 and 5.0 μ IU/mL were spiked with endogenous substances and medications. The samples were run in triplicate and the results were compared to control sample results which were not spiked with potential interfering substances. The sponsor defines significant interference as $\pm 10\%$ bias as compared to the control results. The results of the interference study are summarized in the table below and are applicable to the AFIAS TSH-SP and AFIAS TSH-VB assays:

Substance	Highest concentration of substance tested that did not demonstrate significant interference
Albumin	6 g/dL
Conjugated bilirubin	20 mg/dL
Unconjugated bilirubin	20 mg/dL
Biotin	56 ng/mL
HAMA	138 ng/mL
Hemoglobin	500 mg/dL
Rheumatoid factor	1500 IU/mL
Triglycerides	3000 mg/dL
Levothyroxine	75 μ g/L
Methimazole	36 mg/L
Metoprolol	4.99 mg/L

Cross-Reactivity Study

Cross-reactivity studies were performed to evaluate the susceptibility of the AFIAS TSH test systems to cross-reactivity with the following endogenous structural analogs of human TSH: human follicle stimulating hormone (hFSH), human luteinizing hormone (hLH), and human chorionic gonadotropin (hCG). Two serum samples and two Na-heparin venous whole blood samples with TSH levels of 0.5 μ IU/mL and 5.0 μ IU/mL were spiked with 1,200 mIU/mL of each of the potential cross-reactants and measured in triplicate. The sponsor defines significant cross reactivity as less than a 10% bias in expected results.

The following equation was used to calculate the % cross reactivity:

$$\frac{\text{Mean concentration of spiked sample} - \text{mean concentration of unspiked sample}}{\text{Spiked concentration of the cross-reactant}} \times 100$$

The cross-reactivity study results are summarized in the table below and are applicable to the AFIAS TSH-SP and AFIAS TSH-VB assays:

Substance	Highest concentration of substance tested that did not demonstrate significant cross-reactivity
hFSH	1,200 mIU/mL
hLH	1,200 mIU/mL
hCG	1,200 mIU/mL

High Dose Hook Effect study

A hook effect study was performed by spiking a serum sample with the following TSH concentrations: 25, 50, 75, 100, 150, 200, 500, 1000, 1500, 2000, 2500, and 3,000 μ IU/mL. The samples were run in triplicate using the AFIAS TSH test system. The study showed that the samples with a TSH concentration of greater than 80 μ IU/mL of TSH displayed results of “>80 μ IU/mL” on the AFIAS-6 analyzer. The sponsor concludes that the AFIAS TSH test system did not show hook effect for TSH concentrations up to 3000 μ IU/mL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed at 3 point-of-care (POC) sites to evaluate the accuracy of the AFIAS TSH test system against the comparator method, the Access Fast hTSH test. Matching sets of serum and Na-heparinized venous whole blood were tested by the candidate devices. Serum was measured by the comparator

method at an in-house laboratory. The method comparison study included 183 serum samples and 157 Na-heparinized venous whole blood samples. Less than 15% of the samples were contrived. The method comparison study was performed by 3 POC operators at each of the 3 POC sites for a total of 9 POC operators (nurses, nursing assistants, medical assistants, office assistants, etc.). One lot of AFIAS test cartridges and 3 analyzers were used in the study. The results of the method comparison study are summarized below for each sample type:

Serum analysis for the AFIAS TSH-SP on the AFIAS-6/SP Analyzer:
 $y = 0.976x + 0.003$, $R^2 = 0.9994$ (n=183), test range: 0.07-79.9 $\mu\text{IU}/\text{mL}$

Na-heparinized venous whole blood analysis for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer:

Serum results on the predicate were compared to Na-heparinized venous whole blood on the candidate device.

$y = 0.909x + 0.012$, $R^2 = 0.999$ (n=157), test range: 0.31-76.26 $\mu\text{IU}/\text{mL}$

Analysis of individual sample results was performed to assess the classification as hypothyroid or normal using the reference range for each. The classification into hypothyroid or normal by the candidate was the same as the predicate for all samples. The difference in results are due matrix differences between serum and whole blood. Serum and whole blood results are not interchangeable and must be interpreted with the corresponding reference range only. See M.5. below.

b. Matrix comparison:

A matrix comparison study was performed by testing matched sample sets of the claimed sample types: serum, sodium heparin venous whole blood and plasma, EDTA venous whole blood and plasma. The results are summarized in the following table:

Compared matrices	n	Linear Regression	R^2	Range tested ($\mu\text{IU}/\text{mL}$)
Serum vs Na-heparin plasma	81	$y = 0.956x + 0.04$	0.9998	0.09-77.52
Serum vs K2-EDTA plasma	79	$y = 0.9654x + 0.0131$	0.9997	0.09-77.52
Venous Na-heparin whole blood vs K2-EDTA whole blood	63	$y = 0.993x - 0.0325$	0.9998	0.40-71.74

The results of the matrix comparison study support the manufacturer's claim that serum, K2-EDTA plasma and Na-heparin plasma are acceptable sample types to use with the AFIAS TSH-SP test system and that venous K2-EDTA and venous Na-heparin whole blood are acceptable sample types to use with the AFIAS TSH-VB test systems.

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:

A reference range study was performed to establish TSH reference intervals for serum, and venous Na-heparin whole blood for the candidate assay. The study included analyses of 128 serum samples (65 males and 63 females), and 133 venous sodium-heparinized whole blood samples (69 males and 64 females). All subjects were between the ages of 21 and 70 years of age. The central 95% distribution of the results are shown below:

Serum reference range for the AFIAS TSH-SP on the AFIAS-6/SP Analyzer: 0.45 to 4.49 µIU/mL

Venous heparinized whole blood reference range for the AFIAS TSH-VB on the AFIAS-6/VB Analyzer: 0.41 to 4.06 µIU/mL

The manufacturer claims 0.45 to 4.50 µIU/mL as the adult reference for serum/plasma samples analyzed on the AFIAS-6/SP test system and 0.40 to 4.0 µIU/mL for venous whole blood samples analyzed on the AFIAS-6/VB test system.

N. Instrument Name:

AFIAS-6/SP Analyzer

AFIAS-6/VB Analyzer

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes X or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No X

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:

On-screen keypad or USB keyboard patient ID entry.

4. Specimen Sampling and Handling:

The test sample is manually pipetted into test cartridge prior to placing the cartridge on the analyzer.

5. Calibration:

The AFIAS TSH test system uses a lot-specific calibration factor, stored on the AFIAS ID-Chip which is inserted into the AFIAS-6 analyzer prior to testing with a new lot of AFIAS TSH test cartridges.

Periodic user-level calibration using the two-level AFIAS TSH Calibrators adjusts the two sample type specific master calibration curves (derived from each lot-specific AFIAS TSH ID chip) stored in the internal memory of the AFIAS-6.

6. Quality Control:

AFIAS TSH Controls, Level 1 and Level 2, are sold by the manufacturer and are the recommended quality control material.

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

Not applicable.

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.