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

July 2, 2015

TOSOH BIOSCIENCE, INC.
ROBERT WICK
REGULATORY SPECIALIST
6000 SHORELINE COURT
SUITE 101
SOUTH SAN FRANCISCO CA 94080

Re: K143075
Trade/Device Name: ST AIA-PACK SHBG, ST AIA-PACK SHBG Calibrator Set
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone Test System
Regulatory Class: I, Reserved
Product Code: CDZ, JIT
Dated: June 22, 2015
Received: June 23, 2015

Dear Robert Wick:

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,

Katherine Serrano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143075

Device Name
ST AIA-PACK SHBG, ST AIA-PACK SHBG Calibrator Set

Indications for Use *(Describe)*
ST AIA-PACK SHBG is designed for In Vitro Diagnostic Use Only for the quantitative measurement of sex hormone binding globulin (SHBG) in human serum or Na heparinized plasma on Tosoh AIA System Analyzers. The ST AIA-PACK SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.

The ST AIA-PACK SHBG Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK SHBG assay.

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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510(k) Summary

510(k) Summary

K143075

ST AIA-PACK SHBG

Date: June 30, 2015

Submitter:
Tosoh Bioscience, Inc
3600 Gantz Road
Grove City, OH 43123

Contact Person:
Robert L. Wick
Regulatory Specialist
6000 Shoreline Ct., Ste. 101
South San Francisco, CA 94080
Phone: 650-636-8117
Fax: 650-636-8121
Email: Robert.Wick@tosoh.com

Device Name: ST AIA-PACK SHBG
Classification:
Class I, reserved
CDZ
Clinical Chemistry
21 CFR 862.1680

Device Name: ST AIA-PACK SHBG Calibrator Set
Classification
Class II
JIT
Clinical Chemistry
21 CFR 862.1150

Predicate Device: k060818
Abbott/ BIOKIT S.A.
ARCHITECT SHBG REAGENT KIT, ARCHITECT SHBG CALIBRATOR KIT

510(k) Summary

ST AIA-PACK SHBG

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Description:

The ST AIA-PACK SHBG is a two-site immunoenzymometric assay which is performed entirely in the ST AIA-PACK SHBG test cups. SHBG present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the test cups. The magnetic beads are washed to remove unbound enzyme-labeled antibody and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the SHBG concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

The following materials are required to perform SHBG analysis using the ST AIA-PACK SHBG (Cat. No. 025238) on the Tosoh AIA System Analyzer.

ST AIA-PACK SHBG Calibrator Set	025338
ST AIA-PACK SHBG Sample Diluting Solution	025538

Device Intended Use:

ST AIA-PACK SHBG is designed for In Vitro Diagnostic Use Only for the quantitative measurement of sex hormone binding globulin (SHBG) in human serum or Na heparinized plasma on Tosoh AIA System Analyzers. The ST AIA-PACK SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.

Calibrators:

The ST AIA-PACK SHBG Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK SHBG assay.

Substantial Equivalence:

Comparison between the Tosoh ST AIA-PACK SHBG and the Abbott Architect SHBG Immunoassay (k060818)

Similarities

Parameter	ST AIA-PACK SHBG	Abbott Architect SHBG Kit (k060818)
Intended use	For the quantitative measurement of SHBG in human serum and plasma.	For the quantitative measurement of SHBG in human serum and plasma.
Indications for Use	ST AIA-PACK SHBG is designed for In Vitro Diagnostic Use Only for the quantitative measurement of sex hormone binding globulin (SHBG) in human serum or Na heparinized plasma on Tosoh AIA System Analyzers. The ST AIA-PACK SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.	The ARCHITECT™ SHBG assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma on the ARCHITECT iSystem. The ARCHITECT SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.
Specimen type	Serum or sodium heparinized plasma	Human serum or plasma (Lithium Heparin, Sodium Heparin, Ammonium Heparin, Potassium EDTA)
Interference	No interference from: Hemoglobin Free bilirubin Conjugated bilirubin Lipemia, as indicated by triglyceride concentration Protein, as indicated by human albumin concentration HAMA	Non-significant interferences with: Hemoglobin Bilirubin Triglycerides Protein
Limit of detection	0.02 nmol/L	0.02 nmol/L
Specificity/Cross Reactivity	Non-cross reactive: Alpha-Fetoprotein (AFP) Estradiol Thyroxin-Binding Globulin Transferrin 11-Deoxycortisol 5alpha-Dihydroxytestosterone Cortisol Testosterone Thyroglobulin	Non-cross reactive: AFP Estradiol Thyroxin-Binding Globulin Transferrin 11-Deoxycortisol 5- dihydrotestosterone Cortisol Testosterone Thyroglobulin
Precision	Within-run: <10% CV from 15.5 -175.6 nmol/L	Within-run: <10% CV from 16.9 – 147.9 nmol/L

	Total Precision <10% CV from 15.5 – 175.6 nmol/L	Total Precision: <10% CV from 16.9 – 147.9 nmol/L
Hook Effect	The "hook effect" phenomenon may occur only at SHBG concentrations > 10,000 nmol/L.	The "hook effect" phenomenon may occur only at SHBG concentrations > 10,000 nmol/L.

Differences

Parameter	**ST AIA-PACK SHBG**	**Abbott Architect SHBG Kit (k060818)**
Test Methodology	Fluorescence Immunosassay	Chemiluminescent Microparticle Immunoassay (CMIA)
Components	Unit dose test cups containing twelve lyophilized magnetic beads coated with anti-SHBG mouse monoclonal antibody and 100 µL of anti-SHBG mouse monoclonal antibody conjugated to bovine alkaline phosphatase with sodium azide as a preservative.	Microparticles 1 or 4 Bottle(s) (6.6 ml each) Anti-SHBG(mouse monoclonal) coated microparticles in TRIS buffer. Preservative: sodium azide
Specificity/Cross Reactivity	Non cross reactive: Plasminogen TSH Fibrinogen Human IgA Human IgG Corticosteroid Binding Globulin	Not specified
Expected Values	488 samples - 244 male and 244 female Male (21 to 49 years old) 10 – 68 nmol/L Male (≥50 years old)16–125 nmol/L Females (pre-menopausal) 18 – 260 nmol/L Females (post-menopausal) 15 – 185 nmol/L	319 samples - 152 male and 167 female Male 11.2 – 78.1 nmol/L Female 11.7 – 137.2 nmol/L
Interference	No interference from: Ascorbic acid Heparin	Not specified or tested
Linearity (measuring range)	0.2 to 250 nmol/L.	0.1 to 250 nmol/ L

Similarities

Calibrator Set

Parameter	**ST AIA-PACK SHBG Calibrator Set**	**Architect SHBG Calibrator Kit (k060818)**
Intended use	The ST AIA-PACK SHBG	The ARCHITECT"' SHBG

	Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK SHBG assay.	Calibrators are for the calibration of the ARCHITECT iSystem when used for the quantitative determination of SHBG in human serum and plasma.
Number of Calibrators	6	6

Differences

Calibrator Set

Parameter	AIA-PACK SHBG Calibrator Set	Architect SHBG Calibrator Kit (k060818)
Components	Bovine serum with assigned levels of sex hormone binding globulin (SHBG).	SHBG (human, purified) in phosphate buffered saline with protein (goat) stabilizer
Traceability/Standardization	Traceable to the 2nd International Standard for SHBG from the National Institute for Biological Standards and Control (NIBSC) code 08/266.	Traceable to the WHO Standard Material NIBSC CODE: 95/560.

PERFORMANCE CHARACTERISTICS

Precision

The precision study was developed with reference to the CLSI protocol entitled: Evaluation of Precision Performance of Quantitative Measurement Methods (EP5-A2).

The precision study for the ST AIA-PACK SHBG assay was evaluated utilizing three AIA-2000 analyzers and three different lots of reagents. Precision was assessed by assaying three levels of serum and heparinized plasma specimens. Estimates of total and within run precision were obtained from measurements of 2 replicates in a single run, 2 times a day for 20 non-consecutive days. The mean of each duplicate was used to obtain the pooled standard deviation (SD), which was then used to calculate the coefficient of variation (CV). In addition, all of the data were combined to assess the within run, between run, between day, between lot and total precision.

Within run precision

Sample	Mean (nmol/L)	Pooled SD (nmol/L)	CV (%)
Serum 1L	17.3	0.454	2.6
Serum 1M	52.7	1.48	2.8
Serum 1H	154.9	4.96	3.2
Serum 2L	18.0	0.39	2.1
Serum 2M	54.8	1.29	2.3
Serum 2H	158.9	4.07	2.6
Serum 3L	18.8	0.56	2.9

Serum 3M	58.4	1.40	2.4
Serum 3H	175.6	5.26	3.0
Heparinized Plasma 1L	15.5	0.48	3.1
Heparinized Plasma 1M	62.9	1.70	2.7
Heparinized Plasma 1H	139.6	3.92	2.8
Heparinized Plasma 2L	16.1	0.39	2.4
Heparinized Plasma 2M	65.2	1.03	1.6
Heparinized Plasma 2H	142.2	3.70	2.6
Heparinized Plasma 3L	17.2	0.43	2.5
Heparinized Plasma 3M	70.7	1.59	2.3
Heparinized Plasma 3H	159.3	4.90	3.1

Total Precision

Sample	Mean (nmol/L)	Pooled SD (nmol/L)	CV (%)
Serum 1L	17.3	0.485	2.8
Serum 1M	52.7	1.62	3.1
Serum 1H	154.9	5.13	3.3
Serum 2L	18.0	0.54	3.0
Serum 2M	54.8	1.75	3.2
Serum 2H	158.9	4.80	3.0
Serum 3L	18.8	0.61	3.2
Serum 3M	58.4	1.51	2.6
Serum 3H	175.6	6.43	3.7
Heparinized Plasma 1L	15.5	0.54	3.5
Heparinized Plasma 1M	62.9	2.03	3.2
Heparinized Plasma 1H	139.6	5.13	3.7
Heparinized Plasma 2L	16.1	0.52	3.2
Heparinized Plasma 2M	65.2	1.55	2.4
Heparinized Plasma 2H	142.2	4.39	3.1
Heparinized Plasma 3L	17.2	0.52	3.0
Heparinized Plasma 3M	70.7	1.98	2.8
Heparinized Plasma 3H	159.3	5.42	3.4

Between run precision

Sample	Mean (nmol/L)	Pooled SD (nmol/L)	CV (%)
Serum 1L	17.3	0.33	1.9
Serum 1M	52.7	1.17	2.2
Serum 1H	154.9	3.75	2.4
Serum 2L	18.0	0.37	2.0
Serum 2M	54.8	1.32	2.4
Serum 2H	158.9	3.39	2.1
Serum 3L	18.8	0.43	2.3
Serum 3M	58.4	1.14	2.0
Serum 3H	175.6	4.99	2.8
Heparinized Plasma 1L	15.5	0.42	2.7
Heparinized Plasma 1M	62.9	1.63	2.6
Heparinized Plasma 1H	139.6	4.29	3.1
Heparinized Plasma 2L	16.1	0.41	2.5
Heparinized Plasma 2M	65.2	0.95	1.5
Heparinized Plasma 2H	142.2	2.88	2.0
Heparinized Plasma 3L	17.2	0.42	2.4
Heparinized Plasma 3M	70.7	1.40	2.0
Heparinized Plasma 3H	159.3	4.16	2.6

Between day precision

Sample	Mean (nmol/L)	Pooled SD (nmol/L)	CV (%)
Serum 1L	17.3	0.28	1.6
Serum 1M	52.7	0.91	1.7
Serum 1H	154.9	2.59	1.7
Serum 2L	18	0.39	2.1
Serum 2M	54.8	1.29	2.3
Serum 2H	158.9	4.07	2.6
Serum 3L	18.8	0.56	2.9
Serum 3M	58.4	1.4	2.4
Serum 3H	175.6	5.26	3.0
Heparinized Plasma 1L	15.5	0.48	3.1
Heparinized Plasma 1M	62.9	1.7	2.7
Heparinized Plasma 1H	139.6	3.92	2.8
Heparinized Plasma 2L	16.1	0.39	2.4
Heparinized Plasma 2M	65.2	1.03	1.6
Heparinized Plasma 2H	142.2	3.7	2.6
Heparinized Plasma 3L	17.2	0.43	2.5

Heparinized Plasma 3M	70.7	1.59	2.3
Heparinized Plasma 3H	159.3	4.9	3.1

Representative Lot-to-Lot Precision

Sample	Mean (n=80) nmol/L	Within-Run		Between-Run		Total	
		SD	%CV	SD	%CV	SD	%CV
Serum Low	18.0	0.39	2.1	0.37	2.0	0.53	3.0
Serum medium	54.8	1.29	2.3	1.32	2.4	1.8	3.3
Serum High	158.9	4.07	2.6	3.39	2.1	4.93	3.1
Hep Plasma Low	16.1	0.4	2.4	0.4	2.5	0.6	3.4
Hep Plasma Medium	65.2	1.0	1.6	1.0	1.5	1.5	2.3
Hep Plasma High	142.2	3.7	2.6	2.9	2.0	4.4	3.1

Combined Summary Table

Sample		**Serum-1**	**Serum-2**	**Serum-3**	**Hep Plasma-1**	**Hep Plasma-2**	**Hep Plasma-3**
Mean Conc. (nmol/L)		18.1	55.3	163.1	16.3	66.3	147.0
Within Run	**SD**	0.47	1.39	4.79	0.43	1.47	4.21
	%CV	2.6	2.5	2.9	2.7	2.2	2.9
Between Run	**SD**	0.38	1.21	4.10	0.42	1.36	3.83
	%CV	2.1	2.2	2.5	2.6	2.0	2.6
Between Day	**SD**	0.72	2.57	9.59	0.74	3.47	9.19
	%CV	4.0	4.6	5.9	4.6	5.2	6.3
Between Lot	**SD**	0.77	1.54	2.77	0.84	1.59	1.79
	%CV	4.3	2.8	1.7	5.1	2.4	1.2
Total	**SD**	0.84	2.88	9.42	0.85	3.75	10.04
	%CV	4.6	5.2	5.8	5.3	5.7	6.8

Linearity:

Linearity: The linearity for ST AIA-PACK SHBG was determined, based on guidance from CLSI Protocol EP6-A entitled: Evaluation of the Linearity of Quantitative Measurement Procedures: a Statistical Approach: Approved Guideline. The linearity was measured on the AIA-2000 instrument and has been demonstrated to be linear from 0.2 to 250 nmol/L.

Correlation

The methods comparison study was based on guidance from EP9-A2.

Method Comparison

A total of 126 serum specimens were assayed in singleton utilizing the ST AIA-PACK SHBG assay on the AIA-2000 analyzer and the predicate SHBG.

	Deming	**Regular**
Slope:	0.949 (0.926 to 0.972)	0.940 (0.917 to 0.964)
Intercept:	-0.64 (-2.61 to 1.34)	-0.09 (-2.06 to 1.89)
Corr Coef (R):	0.991	
Result Ranges:	Tosoh ST AIA-PACK SHBG 0.6 to 241.0 nmol/L Predicate SHBG 0.5 to 221.6 nmol/L	

*95% Confidence Intervals are shown in parentheses

Matrix Comparison

The correlation between serum (x) and Na heparinized plasma (y) on ST AIA-PACK SHBG was carried out using 116 patient specimens. Five specimens were diluted to obtain the low end of the measuring range.

	Deming	**Regular**
Slope:	0.977 (0.964 to 0.991)	0.975 (0.961 to 0.988)
Intercept:	0.269 (-0.629 to 1.168)	0.415 (-0.483 to 1.313)
Corr Coef (R):	0.997	
Result Ranges	Serum: 0.2 to 219.1 nmol/L Na heparinized plasma: 0.2 to 219.9 nmol/L	

*95% Confidence Intervals are shown in parentheses

Specificity

The following substances were tested for cross-reactivity. Cross-reactivity is the percentage of the compound which will be identified as SHBG.

Substance	Concentration added	Cross-reactivity (%)
Alpha-Fetoprotein (AFP)	48.4 µg/dL	N.D.
Cortisol	100 µg/mL	0.003
11-Deoxycortisol	4 µg/mL	0.114
5alpha-Dihydroxytestosterone	20 µg/mL	0.007
Estradiol	3600 pg/mL	N.D.
Testosterone	20 µg/mL	0.019
Thyroglobulin	300 µg/mL	2.544
Thyroxin-Binding Globulin	200 µg/mL	N.D.
Transferrin	4 mg/mL	N.D.
Fibrinogen	4.5 g/L	0.120
Plasminogen	250 mg/L	N.D.
Human IgA	367 mg/dL	0.072
Human IgG	335 mg/dL	0.218
CBG	35 mg/dL	0.012
TSH	180 mIU/L	N.D.

(N.D.: not detectable)

Reference Ranges

The reference range study was conducted with reference to the CLSI protocol entitled: How to Define and Determine Reference Intervals in the Clinical Laboratory (C28-A3) entitled: Defining, Establishing, and verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition.

The interval given here was determined in serum samples from 488 apparently healthy American and European individuals.

	n	Range (nmol/L)
Male (21 to 49 years old)	121	10 - 68
Male (≥50 years old)	123	16 – 125
Females (pre-menopausal ≥ 21 years if age)	122	18 – 260
Females (post-menopausal)	122	15 – 185

Interference

Interference is defined, for the purposes of this study, with recovery outside of 10 % of the known concentration of the specimen after the following substances are added to human specimens.

- Hemoglobin (up to 446 mg/dL), free bilirubin (up to 17.6 mg/dL), and conjugated bilirubin (up to 18.5 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by triglyceride concentration (up to 1,667 mg/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) does not interfere with the assay.
- Protein, as indicated by human albumin concentration (up to 5.00 g/dL added to samples from apparently healthy subjects), does not interfere with the assay.
- Na Heparin (up to 100.0 U/mL) does not interfere with the assay.
- Rheumatoid factor (up to 550 IU/mL) does not interfere with the assay.
- HAMA (up to 24,269 ng/mL) does not interfere with the assay.

Limit of Detection (LoD) and Limit of Quantitation (LoQ):

The LoD and LoQ for ST AIA-PACK SHBG was determined, according to CLSI guideline EP17-A entitled: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

The LoB was determined by 60 measurements of 4 different blank specimens. The LoB was the value at the 95^{th} percentile. In this case LoB was determined to be 0.017 nmol/L.

The LoD was determined by 12 measurements of 10 low level samples. The sample range was chosen to be between LoB and 5XLoB. The LoD was determined to be 0.063 nmol/L.

The Limit of Quantification (LoQ) 12 measurements of 5 samples for ST AIA-PACK SHBG. The test results from the LoD study were used to calculate the %TE at that level. The LoQ was determined to be 0.2 nmol/L based on a % total error of 12%.

Calibrator Stability

Real Time Testing

ST AIA-PACK SHBG Calibrator Set were stored at refrigerated temperatures and assayed at 3, 6, 9, 12 and 13 months after the day of the first assay.

The acceptance criteria for recovery was within 100 +/- 10%.

The criterion for reproducibility (CV %) was </= 10%.

Current real time studies support a 12 month shelf life at refrigerated temperatures from the date of manufacturing.

Open Vial Stability

Open vial stability of the ST AIA-PACK SHBG Calibrator Set was assessed by reconstituting the material according to the package insert. Samples were reconstituted and stored at refrigerated temperatures for 2 days and tested for SHBG.

The criterion for recovery was within 100 +/-10%.

The criterion for reproducibility (CV %) was </= 10%.

Current open vial studies support an in-use claim of 1 day when refrigerated.

Summary of Calibrator Value Assignment

The value assignment of the ST AIA-PACK SHBG Calibrator Set is determined on a lot-by-lot basis and is designed to provide an assay calibration range of 0.005 to 12.5 nmol/L of SHBG. The calibrators in this set are referenced to the 2nd International Standard for SHBG from the National Institute for Biological Standards and Control (NIBSC) code 08/266.

The primary reference material was prepared by diluting the SHBG with the calibrator base. The value of SHBG was assigned based on WHO 2nd IS SHBG using ST AIA-PACK SHBG

The value of the secondary reference material was assigned using the AIA instruments with the primary reference material as calibrator. The value was verified by comparing measured results with those obtained with the previous lot for patient samples.

Note: As each manufactured calibrator concentration corresponds to a unique rate generated by the reaction detected by the instrument, the rate generated by the patient sample (which is diluted 1:20) would correspond to a rate on the curve generated by the manufactured calibrator. The value would then be multiplied automatically by the factor of 20 to generate the actual concentration of SHBG in the sample.

Standards:

Number	FDA Recognition Number	Revision Date	Title
EP5-A2	7-110	10/31/2005	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition
EP6-A	7-193	03/18/2009	Evaluation of the Linearity of Quantitative Measurement Procedures: a Statistical Approach: Approved Guideline

EP28-A3c	7-224	10/1/2010	Defining, Establishing, and verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
EP07-A2	7-127	05/21/2007	Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition
EP9-A2	7-92	07/01/2010	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition

Conclusion:

The Tosoh Bioscience, Inc. ST AIA-PACK SHBG is substantially equivalent to the Abbott Architect SHBG (k)060818 for In Vitro Diagnostic Use Only for the quantitative measurement of SHBG in human serum or Na heparinized plasma on Tosoh AIA System Analyzers. The ST AIA-PACK SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.