

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k152185

B. Purpose for Submission:

Adding Testosterone and free testosterone index (FTI) reference ranges in the labeling.

C. Measurand:

Sex-Hormone Binding Globulin (SHBG)

D. Type of Test:

Quantitative, Chemiluminescence assay

E. Applicant:

Biokit, S.A.

F. Proprietary and Established Names:

ARCHITECT SHBG

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1680

2. Classification:

Class I, reserved

3. Product code:

CDZ

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The ARCHITECT SHBG assay is a chemiluminescent micro-particle immunoassay (CMIA) for the quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma on the ARCHITECT i System. The ARCHITECT SHBG assay is used as an aid in the diagnosis of androgen disorders.

3. Special conditions for use statement(s):

Prescription use only.

4. Special instrument requirements:

ARCHITECT i System.

I. Device Description:

Each ARCHITECT SHBG Reagent Kit contains the following: Microparticles, Conjugate, Assay Diluent, and Multi-Assay Manual Diluent

- Microparticles (1 or 4 bottles) contain 6.6 mL Anti-SHBG (mouse, monoclonal) coated microparticles in Tris buffer and Sodium Azide as preservative.
- Conjugate (1 or 4 bottles) contains 5.9 mL Anti-SHBG (mouse, monoclonal) acridinium-labeled conjugate in phosphate buffer with protein (mouse, bovine) stabilizer and Sodium Azide as preservative.
- Assay Diluent (1 or 4 bottles) contains 8.0 mL SHBG Assay Diluent containing phosphate buffer with protein (mouse, bovine) stabilizer and Sodium Azide as preservative.
- Multi-Assay Manual Diluent (1 bottle) contains 100 mL ARCHITECT Multi-Assay Manual Diluent, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

The SHBG reagents are identified to the reagents cleared in k06818; there are no changes to the reagents.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ARCHITECT SHBG assay

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

k060818

3. Comparison with predicate:

Similarities		
Item	Candidate Device Abbott Architect SHBG assay (k152185)	Predicate device Abbott Architect SHBG assay (k060818)
Intended use	Immunoassay for the in vitro quantitative determination of sex hormone binding globulin (SHBG) in human serum and plasma	Same
Platform	ARCHITECT i System (immunoassay analyzer)	Same
Methodology	chemiluminescent microparticle immunoassay (CMIA)	Same
Specimen type	Human serum and plasma	Same
Measuring range	0.1-250 nmol/L	Same
Calibrator levels	6 levels Cal A 0.0 nmol/L Cal B 2.0 nmol/L Cal C 6.0 nmol/L Cal D 25.0 nmol/L Cal E 125.0 nmol/L Cal F 250.0 nmol/L	Same

Differences		
Item	Candidate Device Abbott Architect SHBG assay (k152185)	Predicate device Abbott Architect SHBG assay (k060818)
Expected values listed in the labeling	SHBG, Testosterone, and Free testosterone Index (FTI) or Free Androgen Index (FAI)	SHBG

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

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

L. Test Principle:

The ARCHITECT SHBG assay is a two-step immunoassay to determine the presence of SHBG in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex. In the first step, sample, assay diluent, and anti-SHBG coated paramagnetic micro-particles are combined. SHBG present in the sample binds to anti-SHBG coated micro-particles. After washing, the SHBG binds to the anti-SHBG acridinium-labeled conjugate that is added in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of SHBG in the sample and the RLUs detected by the ARCHITECT i System optics. The concentration of SHBG in the sample is determined by comparing the chemiluminescent signal in the reaction to the ARCHITECT SHBG calibration.

In order to obtain the Free testosterone index (FTI) or Free Androgen index (FAI) result, the ARCHITECT 2nd Generation Testosterone assay and the Abbott ARCHITECT SHBG assays are utilized and are measured at the same time when the sample is tested on the analyzer. The free testosterone index (%FTI) or free androgen index (%FAI) was obtained using the following equation:

$$\text{FTI or FAI (\%)} = \frac{\text{ARCHITECT 2}^{\text{nd}} \text{ Generation Testosterone Value (nmol/L)} \times 100}{\text{ARCHITECT SHBG (nmol/L)}}$$

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Previously established in k060818

b. Linearity/assay reportable range:

Previously established in k060818

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

Previously established in k060818

d. Detection limit:

Previously established in k060818

e. Analytical specificity:

Previously established in k060818

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Previously established in k060818

b. Matrix comparison:

Previously established in k060818

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:

Reference ranges are assay dependent for total testosterone, sex hormone-binding globulin (SHBG) and the free testosterone index (FTI). FTI is calculated from the total testosterone and SHBG results. The new FTI/FAI expected values study was performed on a minimum of 120 samples from individuals in the following categories: normal males 21-49 years of age, normal males ≥ 50 years of age, premenopausal normal females 21-49 years of age, and postmenopausal normal females ≥ 50 years of age not on hormone replacement therapy. The following inclusion/exclusion criteria apply to the study: Samples that were within the expected values of the ARCHITECT 2nd Generation Testosterone (LN 2P13) reagent insert and the ARCHITECT SHBG (LN 8K26) reagent insert were included in the study. The free testosterone index (%FTI) or free androgen index (%FAI) was obtained using the following equation:

$$\text{FTI or FAI (\%)} = \frac{\text{ARCHITECT 2nd Generation Testosterone Value (nmol/L)} \times 100}{\text{ARCHITECT SHBG (nmol/L)}}$$

The expected values for total testosterone, SHBG, and FTI are presented in the tables below:

Total Testosterone (nmol/L and ng/dL)				
Category	n	median	2.5 th Percentile	97.5 th Percentile
Males (21-49 years of age)	163	15.33 nmol/L 442.07 ng/dL	8.76 nmol/L 252.73 ng/dL	27.85 nmol/L 803.24 ng/dL
Males (≥ 50 years of age)	144	14.42 nmol/L 415.85 ng/dL	8.58 nmol/L 247.50 ng/dL	23.37 nmol/L 674.13 ng/dL
Females (Premenopausal, 21-49 years of age)	174	1.05 nmol/L 30.43 ng/dL	0.52 nmol/L 14.92 ng/dL	1.72 nmol/L 49.56 ng/dL
Females (Postmenopausal, ≥ 50 years of age)	175	0.76 nmol/L 21.83 ng/dL	0.46 nmol/L 13.34 ng/dL	1.18 nmol/L 33.90 ng/dL

SHBG nmol/L				
Category	n	median	2.5 th Percentile	97.5 th Percentile
Males (21-49 years of age)	163	31.1	16.2	68.5
Males (≥50 years of age)	144	35.3	13.7	69.9
Females (Premenopausal, 21-49 years of age)	174	48.6	14.7	122.5
Females (Postmenopausal, ≥50 years of age)	175	49.9	16.7	124.4

Free Testosterone Index (FTI)/Free Androgen Index (FAI) (%)				
Category	n	median	2.5 th Percentile	97.5 th Percentile
Males (21-49 years of age)	163	46.6	24.5	113.3
Males (≥50 years of age)	144	40.7	19.3	118.4
Females (Premenopausal, 21-49 years of age)	174	2.0	0.7	8.7
Females (Postmenopausal, ≥50 years of age)	175	1.5	0.5	4.7

The sponsor recommended that each laboratory establish its own reference range that is appropriate for the laboratory patient population (i.e., a normal range that depends on the geographical, dietary, or environmental factors reflects the type of specimen and demographic variables such as age and sex, as applicable).

N. Proposed Labeling:

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

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.