510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K032458

B. Analyte:
Calibrator – estradiol, follicle stimulating hormone (FSH), leuteinizing hormone (LH), progesterone, prolactin, triiodothyronine (T3)

C. Type of Test:
Calibrator

D. Applicant:
Abbott Laboratories

E. Proprietary and Established Names:
Abbott ARCHITECT® Estradiol Calibrators
Abbott AxSYM® Estradiol Standard Calibrators
Abbott AxSYM® Estradiol Master Calibrators
Abbott ARCHITECT® FSH Calibrators
Abbott ARCHITECT® LH Calibrators
Abbott ARCHITECT® Progesterone Calibrators
Abbott ARCHITECT® Prolactin Calibrators
Abbott AxSYM® Total T3 Standard Calibrators
Abbott AxSYM® Total T3 Master Calibrators

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1150, Calibrator
2. Classification:
   Class II
3. Product Code:
   JIT, Secondary Calibrators
4. Panel:
   Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

Abbott ARCHITECT Estradiol Calibrators are devices intended for use in the ARCHITECT Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens.

Abbott AxSYM Estradiol Standard Calibrators and AxSYM Estradiol Master Calibrators are devices intended for use in the AxSYM Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens.

Abbott ARCHITECT FSH Calibrators are devices intended for use in the ARCHITECT FSH assay test system to establish points of reference that are used in the quantitative determination of follicle-stimulating hormone (FSH) in human specimens.

ARCHITECT LH Calibrators are devices intended for use in the ARCHITECT LH assay test system to establish points of reference that are used in the quantitative determination of luteinizing hormone (LH) in human specimens.

ARCHITECT Progesterone Calibrators are devices intended for use in the ARCHITECT Progesterone assay test system to establish points of reference that are used in the quantitative determination of progesterone in human specimens.

ARCHITECT Prolactin Calibrators are devices intended for use in the ARCHITECT Prolactin assay test system to establish points of reference that are used in the quantitative determination of prolactin in human specimens.

AxSYM Total T3 Standard Calibrators and AxSYM Total T3 Master Calibrators are devices intended for use in the AxSYM Total T3 assay test system to establish points of reference that are used in the quantitative determination of total T3 in human specimens.

2. Special condition for use statement(s):

   For professional use.

3. Special instrument Requirements:

   The ARCHITECT test system or the AxSYM test system is required.

H. Device Description:

Calibrator components and validation procedures are described below.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   IMx® Estradiol Calibrators
   Abbott FSH Calibrators
   AxSYM® LH Standard Calibrators
   AxSYM® Progesterone Standard Calibrators
   Abbott Prolactin Calibrators
   Ciba-Corning ACS:180 Prolactin Assay Calibrator
   AxSYM® Total T3 Standard and Master Calibrators

2. Predicate K number(s):
   K951629
   K890135

K935611
K955025
K896162
K934517

3. Comparison with predicate:
   All calibrators are identical to their predicate in intended use.

Similarities ARCHITECT® Estradiol Calibrators		
Item	**Device**	**Predicate**
matrix	Tris buffer based	Tris buffer based
traceability	Standardized to an internal reference standard – manufactured gravimetrically using a stock solution of estradiol (not less that 97% pure by HPLC) at each concentration level	Standardized to an internal reference standard – manufactured gravimetrically using a stock solution of estradiol (not less that 97% pure by HPLC) at each concentration level
Differences		
Item	**Device**	**Predicate**
number	2 levels (0 and 1600 pg/mL)	6 levels (0, 50, 250, 750, 1500, 3000 pg/mL

Similarities AxSYM® Estradiol Standard Calibrators and AxSYM® Estradiol Master Calibrators		
Item	**Device**	**Predicate**
matrix	Tris buffer based	Tris buffer based
Differences		
Item	**Device**	**Predicate**
traceability	Standardized to an internal reference standard for AxSYM Estradiol – standardized to correlate with GC/MS	Standardized to an internal reference standard – manufactured gravimetrically using a stock solution of estradiol (not less that 97% pure by HPLC) at each concentration level
concentration	6 levels (0, 50, 100, 200, 500, and 1000 pg/mL) (Master contains two of those – 0 and 200 pg/mL – to establish points of reference)	6 levels (0, 50, 250, 750, 1500, 3000 pg/mL

Similarities ARCHITECT® FSH Calibrators		
Item	**Device**	**Predicate**
matrix	Bovine serum	Bovine serum
traceability	Manufactured by addition of FSH to a target concentration – referenced against WHO FSH 2nd International Reference Preparation (IRP) 78/549	Manufactured by gravimetric addition of FSH to a target concentration – referenced against WHO FSH 2nd International Reference Preparation (IRP) 78/549
Differences		
Item	**Device**	**Predicate**
number	2 levels – 0, 100 mIU/mL	6 levels – 0, 1, 10, 25, 100, 250 mIU/mL

Similarities ARCHITECT® LH Calibrators		
Item	**Device**	**Predicate**
matrix	calf serum	calf serum
traceability	Manufactured gravimetrically– referenced to WHO LH Human, Pituitary 2nd International Standard 80/552 at each concentration	Manufactured gravimetrically– referenced to WHO LH Human, Pituitary 2nd International Standard 80/552 at each concentration
Differences		
Item	**Device**	**Predicate**
number	2 levels – 2, 100 mIU/mL	6 levels – 0, 2, 10, 25, 100, 250 mIU/mL

Similarities ARCHITECT® Progesterone Calibrators		
Item	**Device**	**Predicate**
Same intended use		
Differences		
Item	**Device**	**Predicate**
number	2 levels – 0.7, 40 ng/mL	6 levels – 0, 0.7, 2, 7, 20, 40 ng/mL
matrix	Human serum	Serum for level 0 and Tris buffer based for the remaining levels

Similarities ARCHITECT® Prolactin Calibrators		
Item	**Device**	**Predicate**
traceability	Referenced to WHO 3rd International Standard 84/500 for Prolactin	Referenced to WHO 3rd International Standard 84/500 for Prolactin
matrix	Tris buffer based	Tris buffer based
Differences		
Item	**Device**	**Predicate**
number	2 levels – 5, 30 ng/mL	6 levels – 0, 5, 10, 30, 80, 200 ng/mL

Similarities AxSYM® Total T3 Standard and Master Calibrators		
Item	**Device**	**Predicate**
matrix	Bovine serum	Bovine serum
number	6 levels – 0, 0.5, 1, 2, 4, 8 ng/mL (only 0 and 1 ng/mL for Master)	6 levels – 0, 0.5, 1, 2, 4, 8 ng/mL (only 0 and 1 ng/mL for Master)
Differences		
Item	**Device**	**Predicate**
traceability	Manufactured using USP Grade L-triiodothyronine, sodium salt and signal matched to internal reference standards which are traceable to the USP Reference Standard L-triiodothyronine (free acid) at each concentration level. The stock solution concentration is determined by HPLC	Internal reference standards are manufactured using L-triiodothyronine Sodium (HPLC purity 95.0 – 101.0%). Primary and secondary standards are manufactured gravimetrically using this reference standard. All list material is tested against these primary and secondary calibrators.

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

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

K. Test Principle:

Not applicable as this submission is for calibrators (for two different test systems).

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
      Not applicable. See traceability below.
    - *b. Linearity/assay reportable range:*
      Not applicable.

c. Traceability (controls, calibrators, or method):

Calibrator validation and stability studies are summarized for each of the calibrators. The sponsor specifies the concentrations of materials evaluated in the studies, the frequency of testing, the method for testing the materials, environmental conditions of storage, and acceptance criteria for the study. Real time studies are being performed to support the stability claims in the labeling.

Abbott ARCHITECT® Estradiol Calibrators are standardized to an internal reference standard and manufactured gravimetrically using a stock solution of estradiol (not less that 97% pure by HPLC) at each concentration level.

Abbott AxSYM® Estradiol Standard Calibrators and Abbott AxSYM® Estradiol Master Calibrators are standardized to an internal reference standard for AxSYM Estradiol which correlates with GC/MS.

Abbott ARCHITECT® FSH Calibrators are manufactured by addition of follicle stimulating hormone to a target concentration and referenced against WHO FSH 2nd International Reference Preparation (IRP) 78/549.

Abbott ARCHITECT® LH Calibrators are manufactured gravimetrically and referenced to WHO Leuteinizing Hormone Human, Pituitary 2nd International Standard 80/552 at each concentration.

Abbott ARCHITECT® Progesterone Calibrators are manufactured by spiking stripped normal male human serum with calculated amounts of a progesterone stock solution. This stock solution is manufactured by adding Progesterone USP gravimetrically to a target concentration which is then assigned to the stock solution. The levels are tested by RLU matching to Progesterone Reference Calibrators. The concentration is adjusted, if necessary, by adding stripped normal male human serum or progesterone stock solution.

Abbott ARCHITECT® Prolactin Calibrators are referenced to WHO 3rd International Standard 84/500 for Prolactin.

Abbott AxSYM® Total T3 Standard Calibrators and Abbott AxSYM® Total T3 Master Calibrators are manufactured using USP Grade L-triiodothyronine, sodium salt and signal matched to internal reference standards which are traceable to the USP Reference Standard L-triiodothyronine (free acid) at each concentration level. The stock solution concentration is determined by HPLC.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable.
   b. Matrix comparison:
   Not applicable. The sponsor summarizes the methods used for analysis and validation of the calibrator material and matrix.

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:
   Not applicable.

M. Conclusion:

I recommend that the Abbott ARCHITECT® Estradiol Calibrators, Abbott AxSYM® Estradiol Standard Calibrators, Abbott AxSYM® Estradiol Master Calibrators, Abbott ARCHITECT® FSH Calibrators, Abbott ARCHITECT® LH Calibrators, Abbott ARCHITECT® Progesterone Calibrators, Abbott ARCHITECT® Prolactin Calibrators, Abbott AxSYM® Total T3 Standard Calibrators, and Abbott AxSYM® Total T3 Master Calibrators are substantially equivalent to the legally marketed predicate devices.