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

A. 510(k) Number:

k111023

B. Purpose for Submission:

New device

C. Measurand:

Calibrator materials for luteinizing hormone (LH)

D. Type of Test:

Not applicable

E. Applicant:

Abbott Laboratories

F. Proprietary and Established Names:

ARCHITECT LH Calibrators

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT	Class II	21 CFR § 862.1150, Calibrator	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   The ARCHITECT LH Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.

3. Special conditions for use statement(s):
   For prescription use only.

4. Special instrument requirements:
   ARCHITECT *i*2000SR analyzer

I. Device Description:

The ARCHITECT LH calibrators consists of six bottles of calibrators (Cal A through F), with 4.0 mL of different concentrations of human luteinizing hormone (LH) in each bottle (0, 1.0, 3.5, 15, 50, and 250 mIU/mL). The calibrators are supplied as a ready to use liquid, requiring no reconstitution or dilution. They contain phosphate buffer with protein stabilizers, luteinizing hormone (LH), and preservatives (ProClin 300 and ProClin 950).

All human source materials has been tested using FDA cleared or approved methods and found to be nonreactive for HbsAg, HIV-Ag or HIV-RNA, anti-HIV-1/2, and anti-HCV.

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
Architect LH calibrators	k032458

Comparison with predicate:

Similarities and Differences		
Item	New Device	Predicate Device (k032458)
Indications for Use	Same	For the calibration of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.
Analyte	Same	luteinizing hormone (LH)
Number of Levels	6 levels (A to F) Note: Matching of calibrators with reagents and controls is not required.	2 levels (level 1 and 2) Note: Calibrators must be used with matched reagents and controls per labeling.
Standardization	The calibrators are referenced to the World Health Organization (WHO) Luteinizing Hormone (LH) Human, Pituitary 2nd International Standard 80/552. Note: Calibrators B-F are manufactured by dilution.	The calibrators are manufactured by dilution and referenced to the World Health Organization (W.H.O.) Luteinizing Hormone (LH) Human, Pituitary 2nd International Standard 80/552 at each Concentration.
Composition	Calibrators B-F: Luteinizing	Calibrators 1-2: Luteinizing

	hormone (from human pituitary) - changed vendor code Calibrators A-F: Diluent: Phosphate buffer with protein stabilizers (bovine) Calibrators A-F: Preservatives: ProClin 300 and ProClin 950	hormone (from human pituitary) Calibrators 1-2: Diluent: Calf serum Calibrators A-F: Preservatives: Sodium azide

K. Standard/Guidance Document Referenced (if applicable):
None were referenced.

L. Test Principle:
Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Not applicable

b. Linearity/assay reportable range:
Not applicable

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

Traceability
ARCHITECT LH calibrators are prepared gravimetrically using human luteinizing hormone (LH) and are traceable to the WHO International Standard 80/552.

Value Assignment
ARCHITECT LH calibrators are manufactured using human luteinizing hormone (LH) and the concentration values are assigned against internal reference standards. The internal reference standards are assigned against the WHO International standard 80/552. The concentration values of the working calibrators were assigned by testing multiple times on one Architect *i*2000SR analyzer using one lot of reagent. The sponsor's protocol and acceptance criteria was reviewed and found to be acceptable.

Stability:
Stability of the calibrators is determined by accelerated stability study using the Architect *i* instrument. Real-time stability study is still on-going. Based on the real-time stability study the sponsor determined that the calibrators have a

shelf-life stability of 12 months when stored at 2-8°C and an open-vial stability of 4 months when stored at 2-8°C. The sponsor's protocol and acceptance criteria was reviewed and found to be acceptable.

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

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

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.