

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k042335

B. Purpose for Submission:

New device

C. Analyte:

Total PSA and Free PSA

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Architect Total PSA MasterCheck

Architect Free PSA MasterCheck

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660, Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product Code:
JJY, Multi-analyte controls all kinds (assayed and unassayed)
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
Total PSA MasterCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Total PSA assay on the Abbott ARCHITECT_i System.
Free PSA MasterCheck is intended for use in the verification of sensitivity, calibration linearity and reportable range of the Free PSA assay on the Abbott ARCHITECT_i System.
2. Indication(s) for use:
Same as Intended use(s)
3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
Abbott ARCHITECT_i System.

I. Device Description:

The Architect Total PSA MasterCheck consists of 4 bottles of controls. Level 0 contains HEPES buffer with bovine stabilizer. Levels 1, 2 3 and 4 contain different concentrations of total PSA (human) in HEPES buffer with bovine stabilizer and preservatives. The Architect Free PSA MasterCheck consists of 3 bottles of controls. Level 0 contains HEPES buffer with bovine stabilizer.

Levels 1, 2 and 3 contain different concentrations of free PSA (human) in HEPES buffer with bovine stabilizer and preservatives. Each kit is supplied with a package insert that contains instruction for use, information on storage conditions and shelf life and a data sheet. The data sheet has the assigned values for each level of controls.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Abbott ARCHITECT Progesterone MasterCheck
2. Predicate K number(s):
k990393
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Intended for use in the verification of sensitivity, calibration, linearity and reportable range of the assay on the Abbott ARCHITECT ⁱ System	Same
Form	Liquid	Same
Open Vial Stability	3 days at 2 °C to 8°C	Same
Unopened Stability	2 °C to 8°C until expiration date	Same
Differences		
Item	Device	Predicate
Analyte	Free PSA or Total PSA	Progesterone
Matrix	HEPES buffer with bovine	Human serum

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

None 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 (controls, calibrators, or method):*
The controls are not traceable to any recognized reference material. Value assignments were performed according to Abbott's testing protocols for MasterCheck control products.
 - 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. Conclusion:

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