

**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 ARCHITECTi 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 ARCHITECTi 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 ARCHITECTi 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 <sup>i</sup> 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