

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

A. 510(k) Number:

k062957

B. Purpose for Submission:

New device

C. Measurand:

Controls for total PSA (tPSA)

D. Type of Test:

Assayed Quality Control material

E. Applicant:

Qualigen Incorporated

F. Proprietary and Established Names:

Qualigen™ FastPack® Total PSA Method Verification Kit

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
Class I, reserved
3. Product code:
JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
The FastPack® Total PSA Method Verification Kit consists of assayed quality control materials for verification of the calibration and reportable range of the FastPack® Total PSA Immunoassay to meet CLIA requirements.
2. Indication(s) for use:
Same as intended use.
3. Special conditions for use statement(s):
For prescription use only.
4. Special instrument requirements:
FastPack® analyzer

I. Device Description:

The FastPack® Total PSA Method Verification Kit consists of three assayed controls materials targeted at three PSA concentrations: Low Verifier (0 ng/mL), Mid Verifier (25 ng/mL) and high Verifier (50 ng/mL). The verifiers contain a specified quantity of human PSA (purified from human seminal fluid) in TRIS buffer supplemented with bovine serum albumin (BSA) and preservative (0.1% sodium azide).

J. Substantial Equivalence Information:

1. Predicate device name(s):
FastPack® PSA Controls
2. Predicate 510(k) number(s):
k003095

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Assayed quality control materials for verification of the calibration and reportable range of the FastPack® Total PSA Immunoassay to meet CLIA requirements	Assayed quality control materials for verification of the accuracy and precision of the FastPack® Analyzer system when used for the quantitative determination of PSA in human serum or plasma
Analytes	Total PSA	Same
Antigen source	Human seminal fluid	Same
Matrix	BSA in TRIS buffer	Same
Format	Liquid, ready-to-use	Same
Volume	5 mL	Same

Differences		
Item	Device	Predicate
Levels	Three levels (0, 25 and 50 ng/mL)	Two levels (2 and 10 ng/mL)

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

Guidance for Industry “Points to consider guidance document on assayed and unassayed quality control material”.

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):

The company provided a general document which outlines the protocols, materials, calculations and specifications for assigning values to controls and calibrators for FastPack assay. The following is a brief stepwise description of the value assignment process:

- Calibrate instruments with master calibrator lot and run released controls
- Run on-test Calibrator B as a sample and record raw RLU values
- Run on-test Calibrator A and controls as samples and record the recovered value.
- Runs should be evenly distributed among analyzers and test the

following samples:

Sample	#lots	Min # Analyzers	Min # runs/lots
Calibrator A	1	1	3
Calibrator B	Min of 2 (3 if available)	3	20
Low control	1	3	20
High control	1	3	20
Low verifier	3	3	20
Mid verifier	3	3	20
High verifier	3	3	20

- Use Excel to calculate the mean value of the samples by lot and analyzer. Results will be in concentration units except for Cal B which will be in normalized RLU/second
- Specifications – All released values must be within specified acceptable range and all mean values must be within specified acceptable limits

Assay	Cal A ng/mL	Cal B	Low control ng/mL	High Control ng/mL	Low Verifier Ng/mL	Mid Verifier ng/mL	High Verifier ng/mL
Total PSA	≤ 0.04	N/A	1-3	5-15	0-0.04	22-28	50-80

- Controls are run during master curve verification of subplot-2 prior to final value assignment. Compare those control values to the value assignment. If trends are noted, notify supervisor.
- For PSA, there should be no more than a 10%CV of the data used to generate the robust mean. If the CV >10%, compare the observed values to the assigned range. If all observed values fall within the range, proceed with the value assignment. If any observed value falls outside the range, determine if it is an outlier. If it is an outlier, remove the value and recalculate the results. If it is not determined to be an outlier, notify supervisor and document action taken by retesting sample and inspect pack.
- There should be no more than a 10% difference between the mean values (in concentration units) from each lot
- If all pass, proceed to value assignment; if any value fails, generate a non-conformance report and notify supervisor.
- Value assignment for method verifiers – use Excel to calculate the mean value (in concentration units) and the SD of the verifiers by combining all data.

The company claimed that the device is stable for 12 months when stored at 4°C. Shelf life determination was based on accelerated stability study at 25°C for 32 days, 30°C for 18 days and 37°C for 8 days. Real-time stability testing for closed and opened vials are ongoing.

- 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.