510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k112603

B. Purpose for Submission:
New device

C. Measurand:
p2PSA tri-level controls

D. Type of Test:
Quantitative, chemiluminescent immunoassay

E. Applicant:
Beckman Coulter, Inc.

F. Proprietary and Established Names:
Access Hybritech p2PSA QC

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:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The Access Hybritech p2PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]proPSA isoform of Prostate Specific antigen (PSA) using the Access Immunoassay Systems.

2. Indication(s) for use:
   Same as intended use

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

4. Special instrument requirements:
   Access Immunoassay Systems (Access 2, UniCel DxI 800 and UniCel DxI 600) and integrated workstations (DxC 600i, 880i, 860i, 660i and 680i)

I. Device Description:

The Access Hybritech p2PSA QC kit contains three 5.0 mL vials, one for each of the three control levels (QC 1-3). For QC 1, the [-2]proPSA concentration 1 is ~20 pg/mL, 175 pg/mL for QC 2 and 1000 pg/mL for QC 3. The control base matrix is a buffered bovine serum albumin with <0.1% sodium azide and 0.25% ProClin® 300. A lot specific QC information card containing the lot number, the value assigned mean and the value for one standard deviation is included.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):
   Access Hybritech free PSA QC (k993210)

2. Comparison with predicate:

Similarities		
Item	New The Access Hybritech p2PSA QC	Predicate The Access Hybritech free PSA QC
Intended Use	Verify assay performance	Same.
Instrumentation	Access Immunoassay Systems	Same
Technology	Chemiluminescent sandwich immunoassay	Same
Matrix	Buffered bovine serum albumin with preservatives	Same
Form	Ready to use	Same
Shelf life	12 months	Same
Storage temperature (unopened)	-20°C or colder	Same
Storage temperature and shelf life after opening	2-10°C for 60 days	Same

Differences		
Item	Device The Access Hybritech p2PSA QC	Predicate The Access Hybritech free PSA QC
Analyte	[-2]proPSA	Free PSA
Antigen source	Recombinant mammalian cell line	Seminal fluid
Kit configuration	Three 5.0 mL vials, 1 vial per level	Two 5.0 mL vials, 1 vial per level
Analyte concentrations	Tri-level	Bi-level

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

Guidance for Industry and FDA staff – Assayed and Unassayed Quality Control Material.

L. Test Principle:

The Access Hybritech p2PSA QC reagents are used to verify the performance of the Access Hybritech p2PSA assay which is a two-site immunoenzymatic "sandwich" chemiluminescent assay. A sample is added to a reaction vessel with mouse monoclonal anti-PSA-alkaline phosphatase conjugate, paramagnetic particles coated with a mouse monoclonal anti-[-2]proPSA antibody, and a blocking reagent. The [-2]proPSA in the sample binds to the immobilized monoclonal anti-[-2]proPSA on the solid phase while, at the same time, the monoclonal anti-PSA-alkaline phosphatase conjugate reacts with different antigenic sites on the [-2]proPSA molecule. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos® 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of [-2]proPSA in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

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:
   The [-2]proPSA antigen is purified from a recombinant mammalian cell line

from cell culture supernatant (VAV12-PSA008.6-CCS) and is traceable to an internal reference preparation.

Value assignment:
For each new lot of the Access Hybritech p2PSA QC, samples from vials from the beginning, middle and end of the fill process are tested in five Access Hybritech p2PSA assays on 3 instruments with two lots of reagents. The assays were calibrated using the reference calibrators. Each test control sample was run in replicates of 5 resulting in a total of 75 replicates per control level. The individual replicates were used to calculate the overall mean concentration, standard deviation and %CV for each test level. The observed mean concentration for each control level should be within 3% of the actual mean.

Stability**:**
Shelf Life Stability: To verify the stability at the recommended unopened storage condition at -20°C, the Access Hybritech p2PSA QC and three commercial controls were assayed at multiple time points (0, 3, 6, 9, 12 and 13 months). Each sample was tested in duplicate using multiple lots of reagents and calibrators and one calibration curve per time point on two Access Immunoassay Systems. The %difference from the time zero (baseline) was calculated. The acceptance criterion was the overall mean %difference from baseline for each time point must be within ±10%. Data showed the overall %difference from baseline at 12 months for 3 lots met the specification. Stability studies are on-going and the claimed shelf life is 12 months at -20°C.

Open Vial Stability: To verify the stability of the Access Hybritech p2PSA QC at the recommended opened storage conditions at 2-10°C, two lots of the p2PSA QC and three commercial controls ([-2]proPSA concentrations of 2.26, 19.159 and 89.543 pg/mL) were assayed in replicates of 5 using one lot of Access Hybritech p2PSA reagents and calibrators on the Access Immunoassay Systems at multiple time points (0, 8, 14, 30, 60, 90 and 120 days) at an internal site. The QC dose values were converted to %of dose at time zero (baseline). A linear regression line was fitted through the data and a 95% confidence interval was determined. The acceptance criterion was ≤10% overall change in control dose. Results showed %change at 60 days was -4.9% (95%CI: -6.4%,-3.4%). The claimed open vial stability is 60 days when stored at 2-10°C.

Shipping Stability: The Access Hybritech p2PSA QC shipping stability was tested at an internal site on one lot of QC using the Access 2 analyzer. Stability was assessed at multiple time points following simulated summer and winter shipping cycles. QC reagents were kitted and packaged according to general shipping operation procedures. Packaged QC kits were subjected to simulated summer conditions and simulated winter conditions. A non-cycled

control group of packaged QC kits were stored at the recommended storage condition of 2-10°C. Summer cycled and winter cycled QC kits were stored at 2-10°C following shipping simulation. QC kits subjected to summer conditions, winter conditions, and the non-cycled reagents were tested at day 0 (baseline), day 30 and day 60. The differences between the cycled and non-cycled QC materials using non-cycled Access Hybritech p2PSA reagent packs and calibrators were analyzed by calculating

1. the mean dose responses for each QC level,
2. the percent difference of the QC dose obtained on the summer and winter cycled QC vs. the non-cycled QC for each level,
3. an overall dose average percent for both summer and winter cycled QC from the non-cycled controls.

The acceptance criterion was the grand mean recovery for the cycled QC must be within ±10%. The grand mean recoveries at baseline, 30 days and 60 days met the acceptance criterion indicating that the Access Hybritech p2PSA QC is stable following shipping.

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.