March 24, 2026

Beckman Coulter, Inc.
Neha Desai
Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Dr.
Chaska, MN 55318

Re: K252169
Trade/Device Name: Access BNP II
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC
Dated: March 2, 2026
Received: March 3, 2026

Dear Neha Desai:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252169

Device Name
Access BNP II

Indications for Use *(Describe)*

The Access BNP II test is intended for use with the Beckman Coulter Access Family of Immunoassay Systems for the In Vitro quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used for the following indications:

· as an aid in the diagnosis of heart failure (HF) in patients presenting to the emergency department (ED) with clinical suspicion of new onset, acutely decompensated, or exacerbated heart failure

· for the risk stratification of patients with acute coronary syndromes

· for the risk stratification of patients with heart failure

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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I 510 (k) Summary
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number K252169

Submitted By:
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

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Device Name

Common Name: Access BNP
Trade Name: Access BNP II
Classification Name: B-Type Natriuretic Peptide Test System
Classification Regulation: [21 CFR 862.1117]

Predicate Device

Device Name: BNP Test
510(k) Numbers: K052789

Device Description

The Access BNP II assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of B-type natriuretic peptide (BNP) levels in human EDTA plasma using the Access Immunoassay Systems.

The Access BNP Calibrators are intended to calibrate the Access BNP and Access BNP II tests for the quantitative determination of BNP levels in human EDTA plasma using the Beckman Coulter Access Family of Immunoassay Systems.

The Access BNP II test is a two-site immunoenzymatic (“sandwich”) assay. A sample is added to a reaction vessel with mouse monoclonal anti-human BNP antibody-alkaline phosphatase conjugate and paramagnetic particles coated with mouse Omniclonal anti-human BNP antibody. BNP in human

plasma binds to the immobilized anti-BNP on the solid phase, while the mouse anti-BNP conjugate reacts specifically with bound BNP.

After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is inversely proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

Intended Use

The Access BNP II test is intended for use with the Beckman Coulter Access Family of Immunoassay Systems for the *In Vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used for the following indications:

- as an aid in the diagnosis of heart failure (HF) in patients presenting to the emergency department (ED) with clinical suspicion of new onset, acutely decompensated, or exacerbated heart failure
- for the risk stratification of patients with acute coronary syndromes
- for the risk stratification of patients with heart failure

Comparison of Technological Characteristics to the Predicate

Parameter	Access BNP Assay on Access 2 Immunoassay System (Predicate)	Access BNP II Assay on DxI 9000 Access Immunoassay System
Intended use	The Triage BNP test is intended for use with Beckman Coulter Immunoassay Systems (Access, Access 2, Synchron LXi 725 and UniCel DxI 800) for the *In Vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure). The test also is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.	The Access BNP test is intended for use with the Beckman Coulter Access Family of Immunoassay Systems for the In Vitro quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used for the following indications: • as an aid in the diagnosis of heart failure (HF) in patients presenting to the emergency department (ED) with clinical suspicion of new onset, acutely decompensated, or exacerbated heart failure • for the risk stratification of patients with acute coronary syndromes • for the risk stratification of patients with heart failure
Technology	Two-site immunoenzymatic assay	Same
Format	Chemiluminescent	Same

Parameter	Access BNP Assay on Access 2 Immunoassay System (Predicate)	Access BNP II Assay on DxI 9000 Access Immunoassay System
Calibration	Utilizes a stored calibration curve	Same
Sample Type	EDTA Plasma	Same
Measuring Range	1-5,000 pg/ml	5-5,000 pg/ml
Sample Volume	55 µL	13 µL
Instrument	Access Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos Pro Substrate

Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition

CLSI EP06-2nd Edition: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07- 3rd Edition: Interference Testing in Clinical Chemistry

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

CLSI EP24-A2: Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Draft Guideline-Second Edition

CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance

CLSI EP25-Ed2: Evaluation of Stability of In Vitro Medical Laboratory Test Reagents - 2nd Edition

CLSI EP28-A3c: Defining Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition

ISO 20916: In vitro diagnostic medical devices- Clinical Performance studies using specimens from human subjects- Good Study Practice

Summary of Non-Clinical Studies

Method Comparison:

A study based on CLSI EP09c, 3rd Edition using Weighted Deming regression and Pearson's correlation compared Access BNP II on the DxI 9000 Access Immunoassay Analyzer with Access BNP on the Access 2 Immunoassay System.

N	Concentration Range (pg/mL)*	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
144	7.5 – 4641	1.06	1.02 – 1.10	-6.8	-9.5 – -4.1	1.00

*Range is Access 2 values

Imprecision:

The assay was designed to have within-laboratory imprecision as listed below:

- SD ≤ 2.4 pg/mL for values < 30 pg/mL
- CV ≤ 8 % for values ≥ 30 pg/mL

A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Concentration (pg/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	**N**	**Mean pg/mL**	**SD pg/mL**	**%CV**	**SD pg/mL**	**%CV**	**SD pg/mL**	**%CV**	**SD pg/mL**	**%CV**
SAMPLE 1	80	5.1	0.5	10	0.0	0	0.4	7	0.6	12
SAMPLE 2	80	121	8.7	7	0.0	0	2.3	2	9.0	7
SAMPLE 3	80	226	11.4	5	8.4	4	5.0	2	15.0	7
SAMPLE 4	80	349	12.7	4	8.6	2	12.5	4	19.7	6
SAMPLE 5	80	1030	45.1	4	36.1	4	29.9	3	65.0	6
SAMPLE 6	80	1414	38.2	3	18.4	1	36.5	3	55.9	4
SAMPLE 7	80	3854	94.4	2	78.3	2	103.5	3	160.5	4

Linearity: A study based on CLSI EP06-Ed2 performed on the DxI 9000 Access Immunoassay Analyzer determined the assay demonstrated linearity across the measuring interval.

Hook Effect: A study was performed to verify the hook effect for the Access BNP II assay immunoassay on the DxI 9000 Access Immunoassay Analyzer. Access BNP II assay has no high dose hook effect observed up to 150,000 pg/mL.

Interfering Substances

EDTA plasma samples that contained BNP concentrations of approximately 100 and 500 pg/mL were spiked with the substances listed in the following table. The spiked samples were run on the DxI 9000 Access Immunoassay Analyzer. The values were calculated based upon CLSI EP07-A3 guidelines. The interference was determined by testing controls (with no interfering substance added) and matched test samples (with interfering substance added). None of the compounds tested were found to cause significant interference (as defined by a shift in dose > 10%) using the test concentrations provided in the following table.

Substance	Highest Concentration Added	Substance	Highest Concentration Added
Acetaminophen	20 mg/dL	Hydrochlorothiazide	20 µg/mL
Allopurinol	40 mg/dL	Ibuprofen	40 mg/dL
Ambroxol	40 mg/dL	Indomethacin	36 µg/mL
Amiodarone	4.2 mg/dL	Isosorbide dinitrate	0.593 mg/dL
Ampicillin	5 mg/dL	Lisinopril	16 µg/mL
Ascorbic acid	3 mg/dL	Lovastatin	0.021 mg/dL
Aspirin	50 mg/dL	Methyldopa	2.5 mg/dL
Atenolol	1 mg/dL	Nicotine	1.6 µg/mL
Conjugated Bilirubin	20 mg/dL	Nifedipine	6 mg/dL
Unconjugated Bilirubin	20 mg/dL	Nitrofurantoin	6.4 mg/dL
Biotin	3,510 ng/mL	Nystatin	0.7 mg/dL
Caffeine	10 mg/dL	Oxazepam	12 µg/mL
Captopril	1.25 mg/dL	Oxytetracycline	0.5 mg/dL
Chloramphenicol	7.8 mg/dL	Phenobarbital	69 mg/dL
Cinnarizine	40 mg/dL	Phenytoin	10 mg/dL
Clopidogrel bisulfate	30 µg/mL	Probenecid	600 µg/mL
Cyclosporine	40 µg/mL	Procainamide	4.8 mg/dL
Diclofenac	2 mg/dL	Propranolol	0.5 mg/dL
Digoxin	0.02 mg/dL	Protein (Human Serum Albumin)	6000 mg/dL
Dipyridamole	30 µg/mL	Quinidine Sulfate	5 mg/dL

Cross Reactivity

A study evaluated the potential for cross-reactivity of substances that are similar in structure to BNP. EDTA plasma samples that contained BNP concentrations of approximately 100 and 500 pg/mL were spiked with concentrations of the substances listed in the following table. The spiked samples were run on the DxI 9000 Access Immunoassay Analyzer. The values were calculated based upon CLSI EP07-A3, guidelines. Cross-reactivity was observed when the listed substances were tested at the indicated concentrations. The cross reactivity was determined by testing controls (with no substance added) and matched test samples (with substance added). No significant cross-reactivity (as defined by a shift in dose >10%) was observed when the listed substances were tested at the indicated concentrations.

Substance	High Concentration
Adrenomedullin	1000 pg/mL
Aldosterone	600 pg/mL
α Atrial Natriuretic polypeptide 1-28	1000 pg/mL
Angiotensin I	600 pg/mL
Angiotensin II	600 pg/mL
Angiotensin III	1000 pg/mL
Arg Vasopressin	1000 pg/mL
C type Natriuretic Peptide 53	1000 pg/mL
Endothelin I	20 pg/mL
Prepro ANF 104-123	1000 pg/mL
Prepro ANF 26-55	1000 pg/mL
Prepro ANF 56-92	1000 pg/mL
Prepro BNP 1-21	1000 pg/mL
Prepro BNP 22-46	1000 pg/mL
Renin	50 ng/mL
Urodilatin 95-126	1000 pg/mL

Detection Capability:

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on the DxI 9000 Access Immunoassay Analyzer following CLSI guideline EP17-A2. The LoB study included multiple reagent lots and 3 instruments over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and 3 instruments over a minimum of 5 days.

	Maximum Observed Result	Design Criteria
	pg/mL	pg/mL
Limit of Blank (LoB)	0.3	≤ 1
Limit of Detection (LoD)	1	≤ 3
Limit of Quantitation (LoQ)	2	≤ 5

CLINICAL PERFORMANCE EVALUATION

A multicenter prospective study was conducted in the intended use population to validate the recommended cutoff. BNP concentrations were determined in samples from 1323 adult patients ≥22 years old presenting to the Emergency Department with clinical suspicion of new onset heart failure or worsening symptoms suggestive of decompensated or exacerbated heart failure. Heart failure diagnosis collected by the clinical site was used to evaluate clinical performance of the Access BNP II assay. The HF incidence was 34% (449/1323). Descriptive statistics for the enrolled population without and with a HF diagnosis are presented in Tables 1.0 and 2.0. Clinical data demonstrated the recommended age-independent cutoff of 100 pg/mL to be an appropriate decision threshold.

Note: The Access BNP II assay is not intended to be used in isolation; results should be interpreted in conjunction with other diagnostic tests and clinical information. BNP results less than or equal to 100 pg/mL are representative of normal values in patients without HF. BNP results greater than 100 pg/mL are considered abnormal and suggestive of patients with HF.

Table 1.0: Descriptive Statistics for Non-HF Population by Age and Sex

Statistics	All Ages	Age < 45	Age 45-54	Age 55-64	Age 65-74	Age 75 +
All Subjects						
N	874	141	145	232	203	153
Mean (pg/mL)	162	97	100	161	179	262
SD (pg/mL)	323.3	236.4	186.5	363.5	274.3	444.0
Median (pg/mL)	52	20	25	40	75	126
IQR: 25th – 75th percentile (pg/mL)	17 - 159	10 - 51	11 - 91	14 - 135	31 - 219	59 - 304
Min (pg/mL)	< 5	< 5	< 5	< 5	5	8
Max (pg/mL)	4294	1363	1100	2879	1835	4294
Male						
N	469	71	81	132	107	78
Mean (pg/mL)	168	100	88	201	157	270
SD (pg/mL)	361.8	273.7	194.8	449.7	205.7	511.7
Median (pg/mL)	46	13	21	39	69	126
IQR: 25th – 75th percentile (pg/mL)	15 - 155	5 - 29	9 - 63	14 - 170	35 - 201	67 - 304
Min (pg/mL)	< 5	< 5	< 5	< 5	6	8
Max (pg/mL)	4294	1363	1100	2879	1095	4294
Female						
N	405	70	64	100	96	75
Mean (pg/mL)	156	95	116	108	203	253

SD (pg/mL)	272.4	193.4	175.6	188.7	334.0	363.9
Median (pg/mL)	56	25	43	43	86	128
IQR: 25th – 75th percentile (pg/mL)	20 - 176	13 - 60	12 - 134	16 - 97	29 - 233	56 - 318
Min (pg/mL)	< 5	< 5	< 5	< 5	5	12
Max (pg/mL)	2317	932	840	1182	1835	2317

Table 2.0: Descriptive Statistics for HF Population by Age and Sex

Statistics	All Ages	Age < 45	Age 45-54	Age 55-64	Age 65-74	Age 75 +
All Subjects						
N	445	40	72	109	114	110
Mean (pg/mL)	1046	1163	1010	1123	1096	899
SD (pg/mL)	1080.0	1049.3	1042.8	1217.6	1130.5	904.9
Median (pg/mL)	729	919	660	800	831	626
IQR: 25th – 75th percentile (pg/mL)	318 - 1419	336 - 1578	304 - 1363	354 - 1450	326 - 1492	318 - 1105
Min (pg/mL)	10	54	20	10	30	13
Max (pg/mL)	> 5000	4457	> 5000	> 5000	> 5000	4618
Male*						
N	278	25	48	77	69	59
Mean (pg/mL)	1149	1393	1113	1145	1248	964
SD (pg/mL)	1118.3	1119.7	1107.5	1046.1	1292.9	996.6
Median (pg/mL)	819	982	772	857	864	630
IQR: 25th – 75th percentile (pg/mL)	387 - 1515	718 - 1596	374 - 1426	394 - 1450	360 - 1719	360 - 1078
Min (pg/mL)	10	94	32	10	30	13
Max (pg/mL)	> 5000	4457	> 5000	> 5000	> 5000	4618
Female						
N	167	15	24	32	45	51
Mean (pg/mL)	875	780	803	1070	863	824
SD (pg/mL)	992.7	816.4	885.1	1574.1	779.2	788.8
Median (pg/mL)	615	356	390	659	680	580
IQR: 25th – 75th percentile (pg/mL)	253 - 1151	191 - 1440	265 - 1149	152 - 1315	276 - 1237	279 - 1118
Min (pg/mL)	20	54	20	56	47	48
Max (pg/mL)	> 5000	2778	3325	> 5000	3471	3858

*Four (4) male subjects with adjudicated diagnosis of Acute HF are excluded due to undetermined Access BNP II numerical values for descriptive statistics reporting.

The clinical sensitivity and specificity of the Access BNP II test using a cutoff of 100 pg/mL and the clinical site diagnosis across age groups and by sex is described in Table 3.0.

Table 3.0: Diagnostic Accuracy of the Established Access BNP II Cutoff (100 pg/mL) by Age and Sex

Statistics		All Ages	Age < 50	Age 50-75	Age > 75
All Subjects					
Sensitivity	Estimate	93.1% (418/449)	93.7% (74/79)	91.8% (246/268)	96.1% (98/102)
	95% Confidence Interval	(90.4-95.1%)	(86.0-97.3%)	(87.9-94.5%)	(90.3-98.5%)
Specificity	Estimate	65.6% (573/874)	82.0% (168/205)	66.4% (352/530)	38.1% (53/139)
	95% Confidence Interval	(62.3-68.6%)	(76.1-86.6%)	(62.3-70.3%)	(30.5-46.4%)
NPV	Estimate	94.9% (573/604)	97.1% (168/173)	94.1% (352/374)	93.0% (53/57)
	95% Confidence Interval	(92.8-96.4%)	(93.4-98.8%)	(91.3-96.1%)	(83.3-97.2%)
PPV	Estimate	58.1% (418/719)	66.7% (74/111)	58.0% (246/424)	53.3% (98/184)
	95% Confidence Interval	(54.5-61.7%)	(57.5-74.7%)	(53.3-62.6%)	(46.1-60.3%)
Male					
Sensitivity	Estimate	94.3% (266/282)	98.0% (49/50)	93.2% (165/177)	94.5% (52/55)
	95% Confidence Interval	(91.0-96.5%)	(89.5-99.6%)	(88.5-96.1%)	(85.1-98.1%)
Specificity	Estimate	65.7% (308/469)	85.6% (89/104)	65.8% (194/295)	35.7% (25/70)
	95% Confidence Interval	(61.3-69.8%)	(77.6-91.1%)	(60.2-70.9%)	(25.5-47.4%)
NPV	Estimate	95.1% (308/324)	98.9% (89/90)	94.2% (194/206)	89.3% (25/28)
	95% Confidence Interval	(92.1-96.9%)	(94.0-99.8%)	(90.1-96.6%)	(72.8-96.3%)
PPV	Estimate	62.3% (266/427)	76.6% (49/64)	62.0% (165/266)	53.6% (52/97)
	95% Confidence Interval	(57.6-66.8%)	(64.9-85.3%)	(56.1-67.7%)	(43.7-63.2%)
Female					
Sensitivity	Estimate	91.0% (152/167)	86.2% (25/29)	89.0% (81/91)	97.9% (46/47)

Statistics		All Ages	Age < 50	Age 50-75	Age > 75
	95% Confidence Interval	(85.7-94.5%)	(69.4-94.5%)	(80.9-93.9%)	(88.9-99.6%)
Specificity	Estimate	65.4% (265/405)	78.2% (79/101)	67.2% (158/235)	40.6% (28/69)
	95% Confidence Interval	(60.7-69.9%)	(69.2-85.2%)	(61.0-72.9%)	(29.8-52.4%)
NPV	Estimate	94.6% (265/280)	95.2% (79/83)	94.0% (158/168)	96.6% (28/29)
	95% Confidence Interval	(91.4-96.7%)	(88.3-98.1%)	(89.4-96.7%)	(82.8-99.4%)
PPV	Estimate	52.1% (152/292)	53.2% (25/47)	51.3% (81/158)	52.9% (46/87)
	95% Confidence Interval	(46.3-57.7%)	(39.2-66.7%)	(43.5-58.9%)	(42.5-63.0%)

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access BNP II Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access BNP Assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.