June 12, 2018

Beckman Coulter, Inc.
Kerrie Oetter
Staff Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: K172783
Trade/Device Name: Access hsTnI
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: May 3, 2018
Received: May 4, 2018

Dear Kerrie Oetter:

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 (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. 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.

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

803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172783

Device Name
Access hsTnI

Indications for Use *(Describe)*
Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay Systems to aid in the diagnosis of myocardial infarction (MI).

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**Immunodiagnostic Development Center**
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a)(1).

The assigned 510(k) number is K172783

**Submitted By:**

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**Date Prepared:**

June 7, 2018

**Device Name:**

Proprietary / Trade Name: Access hsTnI
Common Name: Troponin I Enzyme Immunoassay
Classification Name: Immunoassay, Troponin Subunits
Classification Regulation: 21 CFR 862.1215
Classification Product Code: MMI

**Predicate Devices:**

The Access hsTnI claims substantial equivalence to the Access AccuTnI+3 Reagent, FDA 510(k) Number K121214, cleared June 14, 2013.

**Device Description:**

The Access hsTnI and Access UniCel DxI 800 Immunoassay System comprise the Access Immunoassay System for the quantitative determination of cardiac troponin I (cTnI) in human serum and plasma.

The Access hsTnI reagent packs contain specific reagents for the *in vitro* diagnostic measurement of cTnI including:

- R1a: Dynabeads* paramagnetic particles coated with mouse monoclonal anti-human cTnI antibody suspended in TRIS buffered saline, with surfactant, bovine serum albumin (BSA), < 0.1% sodium azide, and 0.1% ProClin** 300.
- R1b: 0.1 N NaOH
- R1c: TRIS buffered saline, surfactant, protein (mouse), < 0.1% sodium azide, and 0.1% ProClin 300.
- R1d: Sheep monoclonal anti-human cTnI alkaline phosphatase conjugate diluted in ACES buffered saline, with surfactant, BSA matrix, protein (bovine, sheep, mouse), < 0.1% sodium azide, and 0.25% ProClin 300.

*Dynabead® is a registered trademark of Dynal A.S., Osio, Norway
**ProClin™ is a trademark of The Dow Chemical Company ("Dow") or an affiliate company of Dow.

**Intended Use:**

Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay System to aid in the diagnosis of myocardial infarction (MI).

**Comparison to the Predicates:**

The Access hsTnI and the predicate device, Access AccuTnI+3 Reagent, were compared. The information for the predicate device was derived from the predicate device 510(k) Summary and product labeling.

**Comparison of Technological Characteristics to the Predicate (Assay)**

| Characteristic | Predicate Device<br>Access AccuTnI+3 for Access 2 Immunoassay Systems – k121214 | New Device<br>Access hsTnI on UniCel DxI 800 Access Immunoassay System |
|---|---|---|
| Intended Use/ Indications for Use | The Access AccuTnI+3 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay System to aid in the diagnosis of myocardial infarction. | Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay System to aid in the diagnosis of myocardial infarction (MI). |
| Assay Principle | Chemiluminescent sandwich immunoassay | Same |
| Test System | Automated immunoassay instrument | Same |
| Sample Type | Serum and heparinized plasma | Same |
| Reagent Pack configuration | Reagents ready to use and separated in a single reagent pack | Same |
| Primary Reagent Materials | Solid phase magnetic particles, anti- cTnI antibodies | Dynabeads* paramagnetic particles coated with mouse monoclonal anti-human cTnI antibody |
| Sample Volume | 55µl | same |
| Specific Reagent Materials | Mouse monoclonal anti-human cTnI alkaline phosphatase conjugate, magnetic particles coated with mouse monoclonal anti-human cTnI | Sheep monoclonal anti - human cTnI alkaline phosphatase conjugate diluted in ACES buffered saline, with surfactant, BSA matrix, protein (bovine, sheep, mouse) |
| Immunoassay Instrument | Access 2 Immunoassay System | UniCel DxI 800 Access Immunoassay System |
| Analytical Measuring Range | 0.02 ng/mL to 100 ng/mL (20 pg/mL to 100,000 pg/mL) | 2.1 pg/mL to 27,027 pg/mL |

| Characteristic | Predicate Device<br>Access AccuTnI+3 for Access 2 Immunoassay Systems – k121214 | New Device<br>Access hsTnI on UniCel DxI 800 Access Immunoassay System |
|---|---|---|
| Expected Results (Upper Reference Limit) | 99$^{th}$ percentile of 0.02 with a 95% Confidence Interval (CI) of 0.01- 0.05 ng/mL | • 99$^{th}$ percentile of 17.9 pg/ mL with a 95% Confidence Interval (CI) of 14.7 – 27.1 pg/mL for Lithium Heparin Plasma<br><br>• 99$^{th}$ percentile of 18.1 pg/ mL with a 95% Confidence Interval (CI) of 14.3 – 25.6 pg/mL for Serum |
| Precision | • Total CV of ≤8% at concentrations >0.075 ng/mL.<br>• SD ≤0.006 at concentrations ≤0.075 ng/mL | • ≤ 10% within-laboratory CV for concentrations ≥ 11.5 pg/mL<br>• ≤ 1.15 pg/mL within-laboratory SD for concentrations < 11.5 pg/mL |
| Open Reagent Pack Stability | Stable at 2 to 10°C for 56 days after initial use | Stable at 2 to 10°C for 64 days after initial use |
| Assay Protocol File (APF) | AccuTnI+3 APF with addition of the thermal algorithm | hsTnI APF with addition of the thermal algorithm |

**Summary of Studies**

99th percentile URL: A multicenter prospective study was conducted to establish the 99th percentile URL in a population of apparently healthy adults. Lithium heparin plasma and samples were evaluated. Subjects ranging from 21 to 99 years of age were enrolled at five geographically diverse locations throughout the United States. Forty five percent of the subjects were ≥ 60 years of age.
Subjects were surveyed and were excluded if they met any of the following criteria:

- Disease(s) of/or affecting the cardiovascular system
- Currently taking a medication for cardiovascular disease
- Diabetes
- Chronic kidney disease
- Other serious chronic disease(s) (e.g. cancer, COPD, HIV, lupus erythematosus, etc.)
- Acute bacterial or viral infection
- Pregnancy

The 99$^{th}$ percentile URL values determined for lithium heparin plasma (females, males, and overall), and serum (females, males, and overall) are shown in the following table. All values were determined using the non-parametric statistical method.

**99th percentile URL of a healthy population**

| Sample Type | Population | N | 99th percentile URL pg/mL (ng/L) | 95% CI pg/mL (ng/L) |
|---|---|---|---|---|
| Lithium heparin plasma | Females | 593 | 14.9 | 10.1 – 27.1 |
| | Males | 495 | 19.8 | 15.9 - .38.4 |
| | Overall | 1088 | 17.9 | 14.7 – 27.1 |
| Serum | Females | 592 | 13.6 | 10.0 – 25.6 |
| | Males | 493 | 19.8 | 15.4 – 44.8 |
| | Overall | 1085 | 18.1 | 14.3 – 25.6 |

Clinical performance: A multicenter prospective study was conducted to evaluate the diagnostic accuracy of the Access hsTnI assay using the established 99$^{th}$ percentile URLs. The study was designed to establish the clinical performance of Access hsTnI as an aid in the diagnosis of MI.

The study included 1,854 evaluable subjects from ED patients presenting with chest pain or equivalent ischemic symptoms suggestive of Acute Coronary Syndromes (ACS). A total of 14 geographically diverse, primary care

hospital-associated emergency departments participated, reflecting regional, urban, suburban, and rural patient populations.

True MI statuses of all subjects were adjudicated by an independent panel of expert physicians using criteria consistent with the Universal Definition of Myocardial Infarction. Adjudicators were blinded to the assay results and the attending physicians' diagnosis. All results presented below were based on the adjudicated diagnoses. The MI incidence was 13% (238/1854).
Samples were tested at three independent clinical laboratories on DxI 800 systems. Testing was performed using serum and lithium heparin plasma samples. Study results are shown in Tables below. Results are presented for the following time intervals between ED presentation and specimen collection:

• Time of presentation (baseline), ≥1 - 3 hours, ≥ 3 – 6 hours and ≥ 6 – 9 hours after admission

**Clinical Sensitivity and Specificity**
Diagnostic sensitivity (% MI correctly diagnosed) and specificity (% Non-MI correctly diagnosed) were calculated per CLSI Guideline I/LA21-A2. Estimates of sensitivity and specificity were determined by dividing the number of patients correctly diagnosed by the Access hsTnI assay (n) by the total number of patients with an adjudicated diagnosis (N).

**Positive Predictive Value (PPV) and Negative Predictive Value (NPV)**
PPV (probability of MI diagnosis in patients with elevated cTnI) and NPV (probability of non-MI diagnosis in patients with non-elevated cTnI) were calculated per CLSI Guideline I/LA21-A2. Estimates of PPV were determined by dividing the number of patients with elevated cTnI values and adjudicated MI diagnoses (n) by the total number of patients with elevated cTnI values (N). Estimates of NPV were determined by dividing the number of patients with non-elevated cTnI values and adjudicated non-MI diagnoses (n) by the total number of patients with non-elevated cTnI values (N).

Predictive value analysis is directly related to the prevalence of disease in the intended use population. The overall MI prevalence of 13% in this study is consistent with literature and public health findings, and indicates that the study population is representative of the intended use population. Since predictive value analysis is prevalence dependent; results will vary by region and facility.

**Clinical Performance of Access hsTnI Using the Calculated 99th Percentile Cutoffs. Presented at Multiple Time Intervals After Admission to the Emergency Department**

| 99th percentile URL cutoff, pg/mL (ng/L) | Hours After Admission to ED | Sensitivity | | Specificity | | PPV | | NPV | |
|---|---|---|---|---|---|---|---|---|---|
| | | % (n/N) | 95% CI | % (n/N) | 95% CI | % (n/N) | 95% CI | % (n/N) | 95% CI |
| **Lithium heparin plasma** | | | | | | | | | |
| Overall: 17.9 | Baseline | 88 (89/101) | 80 – 94 | 89 (502/567) | 86–91 | 58 (89/154) | 50-66 | 98 (502/514) | 96-99 |
| | ≥ 1-3 hour | 94 (128/136) | 89 - 97 | 90 (981/1092) | 88–92 | 54 (128/239) | 47-60 | 99 (981/989) | 98-100 |
| | ≥ 3-6 hour | 94 (143/152) | 89 - 97 | 90 (1044/1163) | 88-92 | 55 (143/262) | 48-61 | 99 (1044/1053) | 98-100 |
| | ≥ 6-9 hour | 99 (70/71) | 92-100 | 85 (383/450) | 82-88 | 51 (70/137) | 42-60 | 100 (383/384) | 99-100 |
| Females: 14.9 | Baseline | 83 (25/30) | 65- 94 | 91 (234/256) | 87-95 | 53 (25/47) | 38-68 | 98 (234/239) | 95-99 |
| | ≥ 1-3 hour | 93 (40/43) | 81-99 | 92 (490/535) | 89-94 | 47 (40/85) | 36-58 | 99 (490/493) | 98-100 |
| | ≥ 3-6 hour | 96 (48/50) | 86-100 | 92 (509/556) | 89-94 | 51 (48/95) | 40-61 | 100 (509/511) | 99-100 |
| | ≥ 6-9 hour | 100 (22/22) | 85-100 | 88 (198/225) | 83-92 | 45 (22/49) | 31-60 | 100 (198/198) | 98-100 |
| Males: 19.8 | Baseline | 89 (63/71) | 79-95 | 87 (271/311) | 83-91 | 61 (63/103) | 51-71 | 97 (271/279) | 94-99 |
| | ≥ 1-3 hour | 96 (89/93) | 89-99 | 88 (490/557) | 85-91 | 57 (89/156) | 49-65 | 99 (490/494) | 98-100 |
| | ≥ 3-6 hour | 94 (96/102) | 88-98 | 88 (536/607) | 86-91 | 58 (96/167) | 50-65 | 99 (536/542) | 98-100 |
| | ≥ 6-9 hour | 98 (48/49) | 89-100 | 81 (183/225) | 76-86 | 53 (48/90) | 43-64 | 100 (183/184) | 97-100 |

**Clinical Performance of Access hsTnI Using the Calculated 99th Percentile Cutoffs. Presented at Multiple Time Intervals After Admission to the Emergency Department**

| 99th percentile URL cutoff, pg/mL (ng/L) | Hours After Admission to ED | Sensitivity | | Specificity | | PPV | | NPV | |
|---|---|---|---|---|---|---|---|---|---|
| | | % (n/N) | 95% CI | % (n/N) | 95% CI | % (n/N) | 95% CI | % (n/N) | 95% CI |
| **Serum** | | | | | | | | | |
| Overall: 18.1 | Baseline | 87 (96/110) | 80-93 | 89 (534/598) | 87-92 | 60 (96/160) | 52-68 | 97 (534/548) | 96-99 |
| | ≥ 1-3 hour | 95 (134/141) | 90-98 | 90 (999/1110) | 88-92 | 55 (134/245) | 48-61 | 99 (999/1006) | 99-100 |
| | ≥ 3-6 hour | 95 (147/155) | 90-98 | 90 (1074/1200) | 88-91 | 54 (147/273) | 48-60 | 99 (1074/1082) | 99-100 |
| | ≥ 6-9 hour | 97 (66/68) | 90-100 | 85 (398/468) | 82-88 | 49 (66/136) | 40-57 | 100 (398/400) | 98-100 |
| Females: 13.6 | Baseline | 83 (24/29) | 64-94 | 89.4% (237/265) | 85-93 | 46 (24/52) | 32-61 | 98 (237/242) | 95-99 |
| | ≥ 1-3 hour | 95 (41/43) | 84-99 | 91 (493/543) | 88-93 | 45 (41/91) | 35-56 | 100 (493/495) | 99-100 |
| | ≥ 3-6 hour | 96 (49/51) | 87-100 | 90 (519/579) | 87-92 | 45 (49/109) | 35-55 | 100 (519/521) | 99-100 |
| | ≥ 6-9 hour | 100 (20/20) | 83-100 | 86 (202/235) | 81-90 | 38 (20/53) | 25-52 | 100 (202/202) | 98-100 |
| Males: 19.8 | Baseline | 86 (70/81) | 77-93 | 87.1% (290/333) | 83-91 | 62 (70/113) | 52-71 | 96 (290/301) | 94-98 |
| | ≥ 1-3 hour | 96 (94/98) | 90-99 | 88 (498/567) | 85-90 | 58 (94/163) | 50-65 | 99 (498/502) | 98-100 |
| | ≥ 3-6 hour | 95 (99/104) | 89-98 | 88 (546/621) | 85-90 | 57 (99/174) | 49-64 | 99 (546/551) | 98-100 |
| | ≥ 6-9 hour | 96 (46/48) | 86-100 | 82 (191/233) | 76-87 | 52 (46/88) | 41-63 | 99 (191/193) | 96-100 |

Imprecision: The within-laboratory (total) % CV ranged from 2.8% to 10% for hsTnI concentrations ≥ 11.5 pg/mL for serum and lithium heparin plasma samples. The within-laboratory (total) SD ranged from 0.22 to 0.75 for hsTnI for concentrations < 11.5 pg/mL for serum and lithium heparin plasma samples.

High-dose Hook Effect: The Access hsTnI assay demonstrated no high-dose hook effect up to at least 2,000,000 pg/mL.

Linearity: The Access hsTnI assay has demonstrated to be linear across the range of the assay (2.1 to approximately 27,027 pg/mL) in both serum and lithium heparin plasma samples.

Limit of Blank (LoB): The highest measurement result observed with no analyte present in the samples is 1.2 pg/mL.

Limit of Detection (LoD): The lowest concentration of analyte in both serum and lithium heparin plasma that can be detected is 2.1 pg/mL.

Limit of Quantitation (LoQ): The lowest concentration of analyte in both serum and lithium heparin plasma samples that can be quantitatively determined with within-laboratory imprecision of CV ≤ 10% is 4.6 pg/mL and with within-laboratory imprecision of CV ≤ 20% is 2.1 pg/mL.

Analytical Specificity: Potential cross-reactive substances were added to lithium heparin plasma and serum samples at two concentrations of cTnI (approximately 10 pg/mL and one containing approximately 100 pg/mL) Stock solutions of potential cross-reactants were prepared volumetrically using calibrated pipettes and the appropriate solvent. This stock solution was added directly to the lithium heparin plasma and serum samples in no more than 5% (v/v) final concentration. Control samples were prepared in the same manner using the solvent, without the cross-reactant added. Control and test samples were tested on the UniCel DxI 800 instrument within 24 hours of preparation, using three reagent lots. Of the compounds tested, none were found to cause significant cross-reactivity, as defined by a shift in concentration within ± 10% for samples > 11.5 pg/mL. For sample concentrations ≤ 11.5 pg/mL, the change in concentration between diluent control and test sample must be within 2SD, where 2SD is defined as 2.30 pg/mL.

Interfering Substances: Potential interferents were tested at one concentration within the reference interval or the therapeutic concentration range as directed by EP7-A2 (Interference Testing in Clinical Chemistry-Approved Guideline, Second Edition). Lithium heparin plasma and serum samples containing cTnI concentrations of approximately, 10 pg/mL (ng/L) and 100 pg/mL (ng/L) were spiked with the substances below and run on a single DxI Immunoassay System. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). Of the compounds tested, none were found to cause significant interference, as defined by a shift in concentration within ± 10% for samples > 11.5 pg/mL. For sample concentrations ≤ 11.5 pg/mL, the change in concentration between diluent control and test sample must be within 2SD, where 2SD is defined as 2.30 pg/mL.

**Interfering Substances**

| Substance | Highest Concentration Added | Substance | Highest Concentration Added |
|---|---|---|---|
| Acetaminophen | 50 mg/dL | Fibrinogen | 1000 mg/dL |
| Acetylsalicylic Acid | 65 mg/dL | Furosemide | 40 mg/dL |
| Atenolol | 1 mg/dL | Hemoglobin | 4 mg/mL |
| Atorvastatin | 20 µg/mL | Human Serum Albumin | 6000 mg/dL |
| Bilirubin (conjugated) | 40 mg/dL | Ibuprofen | 50 mg/dL |
| Bilirubin (unconjugated) | 20 mg/dL | Intralipid | 3000 mg/dL |
| Bivalirudin | 42 µg/mL | Sodium Heparin | 28.8 U/mL |
| Caffeine | 10 mg/dL | Methyldopa | 2.5 mg/dL |
| Captopril | 5 mg/dL | Nitrofurantoin | 6.4 mg/dL |
| Cinnarizine | 40 mg/dL | Nystatin | 2 mg/dL |
| Clopidogrel | 75 µg/mL | Phenobarbital | 20 µg/mL |
| Cocaine | 2 mg/dL | Rifampicin | 60 µg/mL |
| Cyclosporine | 5 µg/mL | Rosuvastatin | 20 µg/mL |
| Digoxin | 200 ng/mL | Tissue Plasminogen Activator (TPA) | 2.5 µg/mL |
| Dopamine | 65 mg/dL | Verapamil | 16 mg/dL |

**Conclusion:**

The Access hsTnI is equivalent to the currently marketed Access AccuTnI+3 assay. The verification and validation data provided in this submission demonstrates that the safety and efficacy of this device is equivalent to the Access AccuTnI+3 predicate device.