October 19, 2026

Beckman Coulter, Inc.
Christopher Fulmer
Staff Regulatory Affairs Specialist
1000 Lake Hazeltine Dr.
Chaska, Minnesota 55318

Re: K261109
Trade/Device Name: Access MeMed BV
Regulation Number: 21 CFR 866.3215
Regulation Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis
Regulatory Class: Class II
Product Code: QPS
Dated: April 2, 2026
Received: April 3, 2026

Dear Christopher Fulmer:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

BRYAN M. GRABIAS -S
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Bryan Grabias, Ph. D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261109

Device Name
Access MeMed BV

Indications for Use *(Describe)*
The Access MeMed BV test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric serum and plasma samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. Access MeMed BV is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection, who have had symptoms for less than seven days. The Access MeMed BV test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.

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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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: (TBD)

Date Prepared: April 2, 2026

Submitter Name and Address:
Beckman Coulter, Inc 1000
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Chaska, MN 55318

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Trade Name: Access MeMed BV
Common Name: Immunoassay for Host Biomarkers of Infection
Classification Regulation: 21 CFR 866.3215
Classification Product Code*:* QPS

Predicate Device: MeMed BV (K210254)

Device Description:

The Access MeMed BV test is comprised of three immunoenzymatic assays for the determination of nonmicrobial (host) proteins TRAIL, IP-10, and CRP. The levels of the three analytes in human serum or plasma are detected using the automated Access Immunoassay Systems, and the results are processed through an algorithm that generates a numeric score. The Access MeMed BV test score falls within discrete interpretation bins based on the increasing likelihood of bacterial infection. The table below contains the score bin ranges and the clinical interpretation of those bin ranges.

Score Bin	Clinical Interpretation
0 ≤ score ≤ 10	High likelihood of viral infection (or other non-bacterial etiology)
10 < score < 35	Moderate likelihood of viral infection (or other non-bacterial etiology)
35 ≤ score ≤ 65	Equivocal
65 < score < 90	Moderate likelihood of bacterial infection (or co-infection)
90 ≤ score ≤ 100	High likelihood of bacterial infection (or co-infection)

Access MeMed BV TRAIL is a sequential two-step assay. Anti-human TRAIL goat polyclonal antibody conjugated to alkaline phosphatase is added to a reaction vessel along with a surfactant-containing buffer and sample. After a short incubation, paramagnetic particles coated with anti-human TRAIL mouse monoclonal antibody are added. The human TRAIL binds to the anti-human TRAIL antibody on the solid phase, while the anti-human TRAIL antibody–alkaline phosphatase conjugate reacts with a different antigenic site on the TRAIL molecule.

Access MeMed BV IP-10 is a sequential two-step assay. Anti-human IP-10 goat polyclonal antibody conjugated to alkaline phosphatase is added to a reaction vessel along with a surfactant-containing buffer

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and sample. After a short incubation, paramagnetic particles coated with anti-human IP-10 mouse monoclonal antibody are added. The human IP-10 binds to the anti-human IP-10 antibody on the solid phase, while the anti-human IP-10 antibody–alkaline phosphatase conjugate reacts with a different antigenic site on the IP-10 molecule.

Access MeMed BV CRP is a sequential two-step assay. Sample is diluted and added to a reaction vessel along with a surfactant-containing buffer. After a short incubation, anti-human CRP mouse monoclonal antibody conjugated to alkaline phosphatase, and paramagnetic particles coated with anti-human CRP mouse monoclonal antibody are added. The human CRP binds to the anti-human CRP antibody on the solid phase, while the anti-human CRP antibody–alkaline phosphatase conjugate reacts with a different antigenic site on the CRP molecule.

After an additional incubation each assay follows the same steps: 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 directly proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

Intended Use:

The Access MeMed BV test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric serum and plasma samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. Access MeMed BV is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection, who have had symptoms for less than seven days. The Access MeMed BV test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.

Device Comparison Table:

The table below contains a comparison of the Access MeMed BV and the predicate device, the MeMed Diagnostics Ltd. MeMed BV test, which was cleared on September 01, 2021.

Device Comparison Table

Features / Characteristics	**Candidate Device** Access MeMed BV	**Predicate Device (K210254)** MeMed BV
General Device Characteristic Similarities		
Intended Use/ Indications for Use	The Access MeMed BV test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric **serum and plasma** samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. Access MeMed BV is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection,	The MeMed BV test is an automated semi-quantitative immunoassay that measures three non-microbial (host) proteins (TRAIL, IP-10, and CRP) in adult and pediatric **serum** samples and is intended for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial from viral infection. The MeMed BV is indicated for use in patients presenting to the emergency department or urgent care center and with samples collected at hospital admission from patients with suspected acute bacterial or viral infection, who have had

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	who have had symptoms for less than seven days. The Access MeMed BV test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.	symptoms for less than seven days. The MeMed BV test generates a numeric score that falls within discrete interpretation bins based on the increasing likelihood of bacterial infection.
Use Population	Hospital care providers and urgent care centers requesting samples to be tested by clinical laboratory technicians for diagnostic purposes.	Same
Assay Principle	Sandwich Immunoassay	Same
Method	Automated Semi-Quantitative	Same
Format	Chemiluminescent Immunoassay	Same
Analyte or Marker	Three non-microbial (host) proteins: • TNF-related apoptosis inducing ligand (TRAIL), • Interferon gamma-inducible protein 10 (IP-10), and • C-reactive protein (CRP)	Same
Output	Score results with risk bins: • 0 ≤ Score ≤ 10: High likelihood of viral infection (or other non-bacterial etiology) • 10 < Score < 35: Moderate likelihood of viral infection (or other non-bacterial etiology) • 35 ≤ Score ≤ 65: Equivocal • 65 < Score < 90: Moderate likelihood of bacterial infection (or co-infection) • 90 ≤ Score ≤ 100: High likelihood of bacterial infection (or co-infection)	Same BV score and risk bins
Score Algorithm	Uses MeMed Diagnostics, Ltd's proprietary algorithm	Same
Hook Effect	No hook effect for: • CRP up to 500 mg/L • IP-10 up to 10,000 pg/mL • TRAIL: up to 1,000 pg/mL	Same
General Device Characteristic Differences		
Sample Type	Serum or Lithium Heparin Plasma	Serum
Measuring Range	TRAIL: 15 - 300 pg/mL IP-10: 100 - 2000 pg/mL CRP: 1.0 - 250 mg/L	TRAIL: 15 – 290 pg/mL IP-10: 96 -1930 pg/mL CRP: 1.0 – 289 µg/mL
Duration	Approximately 20 minutes	Approximately 15 minutes
Sample Volume	170 µL for DxI 9000 180 µL for Access 2	100 µL
Instrument	Access 2 Immunoassay System DxI 9000 Access Immunoassay Analyzer	MeMed Key Analyzer

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Clinical Performance Evaluation

METHODS COMPARISON AND CONCORDANCE

A study based on CLSI EP09c, 3rd Edition was conducted comparing the Access MeMed BV assay to the predicate MeMed BV assay on the DxI 9000 and Access 2 platforms.

Serum samples across the analytical measuring range for TRAIL, IP-10, CRP, and the score were evaluated in a quantitative method comparison study. Correlation between paired Access MeMed BV assay and predicate assay measurements were analyzed for components TRAIL, IP-10, and CRP by using a weighted Deming linear regression model. Absolute bias at each cutoff point was analyzed for the score. Samples reporting doses outside the analytical measuring range for an analyte were removed from the individual analyte analysis but were included in the analysis of the overall score.

A method concordance study compared results between the Access MeMed BV assay and the predicate MeMed BV in the five bins defined by the cutoff points by calculating percent agreement and likelihood ratios.

DXI 9000 Access Immunoassay Analyzer

396 samples were run using the Access MeMed BV assay on the DxI 9000 analyzer and the MeMed BV assay.

Method Comparison on DxI 9000 analyzer

Analyte	N	Range	Slope (95% CI)	Y-intercept (95% CI)	R (Spearman)	R^2 (Spearman)
TRAIL	358	15-292 pg/mL	1.13 (1.09 to 1.17)	-7.24 (-9.37 to -5.12)	0.97	0.94
IP-10	235	104-1986 pg/mL	1.09 (1.05 to 1.13)	12.34 (3.08 to 21.60)	0.98	0.95
CRP	346	1-240 mg/L	1.08 (1.06 to 1.11)	-0.18 (-0.30 to -0.06)	0.99	0.98
Score	396	0-100	1.03 (1.01 to 1.04)	-0.27 (-0.84 to 0.30)	0.98	0.97

Method Concordance on DxI 9000 Analyzer

Access MeMed BV Score Interpretation	MeMed BV Score Interpretation				
	High likelihood of viral infection (or other non-bacterial etiology)	Moderate likelihood of viral infection (or other non-bacterial etiology)	Equivocal	Moderate likelihood of bacterial infection (or co-infection)	High likelihood of bacterial infection (or co-infection)
High likelihood of viral infection (or other non-bacterial etiology)	156	14	0	0	0
Moderate likelihood of viral infection (or other non-bacterial etiology)	7	68	8	0	0

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Equivocal	0	13	31	9	1
Moderate likelihood of bacterial infection (or co-infection)	0	0	6	24	1
High likelihood of bacterial infection (or co-infection)	0	0	0	10	48
TOTAL	163	95	45	43	50
Bin agreement	95.7% (156/163)	71.6% (68/95)	68.9% (31/45)	55.8% (24/43)	96.0% (48/50)
Overall Agreement	82.6% (327/396) 95% CI: 78.5% - 86%				
Overall Adjacent Bin (±1 bin) Agreement	99.7% (395/396) 95% CI: 98.6% - 100%				

Access 2 Immunoassay Systems

399 samples were run using the Access MeMed BV assay on the Access 2 analyzer and the MeMed BV assay.

Method Comparison on Access 2 analyzer

Analyte	N	Range	Slope (95% CI)	Y-intercept (95% CI)	R (Spearman)	R^2 (Spearman)
TRAIL	359	17-300 pg/mL	1.13 (1.09 to 1.16)	-6.07 (-8.07 to -4.07)	0.97	0.94
IP-10	237	106-1998 pg/mL	1.15 (1.11 to 1.19)	2.19 (-6.93 to 11.31)	0.98	0.95
CRP	351	1-236 mg/L	1.07 (1.04 to 1.10)	-0.11 (-0.21 to -0.00)	0.99	0.98
Score	399	0-100	1.02 (1.00 to 1.03)	-0.82 (-1.40 to -0.24)	0.98	0.96

Method Concordance on Access 2 Analyzer

Access MeMed BV Score Interpretation	MeMed BV Score Interpretation				
	High likelihood of viral infection (or other non-bacterial etiology)	Moderate likelihood of viral infection (or other non-bacterial etiology)	Equivocal	Moderate likelihood of bacterial infection (or co-infection)	High likelihood of bacterial infection (or co-infection)
High likelihood of viral infection (or other non-bacterial etiology)	157	17	0	0	0
Moderate likelihood of viral infection (or other non-bacterial etiology)	7	68	11	0	0
Equivocal	0	10	30	7	0

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Moderate likelihood of bacterial infection (or co-infection)	0	0	4	29	2
High likelihood of bacterial infection (or co-infection)	0	0	0	7	50
TOTAL	164	95	45	43	52
Bin Agreement	95.7% (157/164)	71.6% (68/95)	66.7% (30/45)	67.4% (29/43)	96.2% (50/52)
Overall Agreement	83.7% (334/399) 95% CI: 79.8% - 87.0%				
Oveall Adjacent Bin (±1 bin) Agreement	100.0% (399/399) 95% CI: 99.0% - 100.0%				

Expected Values

In accordance with CLSI EP28-A3c, a study of 224 serum samples from apparently healthy adult subjects representative of the United States demographic were tested on both the Access 2 and DxI 9000 platforms to assess the expected reference interval. 116 (51.8%) participants identified as female, 106 (47.3%) as male, and two (0.9%) participants' gender was not specified.

Access MeMed BV Score in Apparently Healthy Population

Platform	Median	2.5th Percentile	97.5th Percentile	90% Confidence Interval (2.5th)	90% Confidence Interval (97.5th)
Access 2	15	2	72	[1-3]	[61-87]
DxI 9000	21	2	77	[1-4]	[67-87]

Reproducibility

Following CLSI EP05-A3 procedures, reproducibility testing was performed at three (3) sites. At each site, the samples were analyzed on DxI 9000 and Access 2 in replicates of three (3) over a five (5) day period with two (2) runs per day, separated by at least 2 hours between runs. Five (5) samples were used for reproducibility testing per the study protocol. Separate aliquots were tested on A2 and DxI 9000. One (1) reagent lot for the reagent packs, quality control (QC) and calibrator was used at each testing site. For each platform, testing generated a maximum of 30 measurements per sample per site and maximum total of 90 measurements per sample.

Access MeMed BV Reproducibility Results for All Sites Combined on Access 2 Immunoassay System

Access 2 Immunoassay System			Repeatability	Between Day	Between Run	Within Laboratory	Between Site	Reproducibility
Sample	N	Mean	%CV	%CV	%CV	%CV	%CV	%CV
TRAIL (pg/mL)								
Sample 1	90	203	3%	0%	1%	3%	1%	3%
Sample 2	90	86	2%	0%	0%	2%	0%	2%
Sample 3	90	43	4%	0%	0%	4%	0%	4%
Sample 4	90	24	2%	0%	1%	3%	1%	3%
Sample 5	90	21	3%	0%	0%	3%	0%	3%

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Access 2 Immunoassay System			Repeatability	Between Day	Between Run	Within Laboratory	Between Site	Reproducibility
Sample	**N**	**Mean**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**
IP-10 (pg/mL)								
Sample 1	90	698	4%	0%	0%	4%	4%	5%
Sample 2	90	181	4%	0%	0%	4%	1%	4%
Sample 3	90	1810	5%	0%	0%	5%	2%	5%
Sample 4	90	1043	3%	1%	0%	3%	3%	4%
Sample 5*	90	<100	NA	NA	NA	NA	NA	NA
Access 2 Immunoassay System			**Repeatability**	**Between Day**	**Between Run**	**Within Laboratory**	**Between Site**	**Reproducibility**
Sample	**N**	**Mean**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**
CRP (mg/L)								
Sample 1	90	4.6	4%	2%	3%	5%	5%	7%
Sample 2	90	46.9	4%	2%	0%	4%	8%	9%
Sample 3	90	91.8	7%	3%	0%	8%	8%	11%
Sample 4	90	195.1	5%	2%	3%	6%	10%	12%
Sample 5	90	11.5	6%	2%	2%	6%	8%	10%

BV Score								
Sample	**N**	**Mean**	**Repeatability**	**Between Day**	**Between Run**	**Within Laboratory**	**Between Site**	**Reproducibility**
			SD	**SD**	**SD**	**SD**	**SD**	**SD**
Sample 1	90	0	0.2	0	0.1	0.3	0	0.3
Sample 2	90	29	1.9	0	0	1.9	1.8	2.7
Sample 3	90	81	1.6	0.9	0.2	1.8	2.4	3.1
Sample 4	90	100	0.3	0.1	0.1	0.4	0.1	0.4
Sample 5	90	89	0.7	0	0	0.7	0.6	0.9

*IP-10 in this sample is dosed below analytical measuring range

Access MeMed BV Reproducibility Results for All Sites Combined on Dxl 9000 Immunoassay System

Dxl 9000 Immunoassay System			Repeatability	Between Day	Between Run	Within Laboratory	Between Site	Reproducibility
Sample	**N**	**Mean**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**
TRAIL (pg/mL)								
Sample 1	90	214	2%	0%	1%	2%	2%	3%
Sample 2	90	85	3%	1%	0%	3%	3%	5%
Sample 3	90	41	2%	0%	1%	2%	2%	3%
Sample 4	90	25	2%	0%	1%	3%	2%	3%
Sample 5	90	21	2%	0%	1%	2%	2%	3%
Dxl 9000 Immunoassay System			**Repeatability**	**Between Day**	**Between Run**	**Within Laboratory**	**Between Site**	**Reproducibility**
Sample	**N**	**Mean**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**

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IP-10 (pg/mL)								
Sample 1	90	819	3%	0%	1%	3%	4%	5%
Sample 2	90	195	2%	1%	0%	2%	4%	5%
Sample 3	90	1854	3%	0%	1%	3%	3%	4%
Sample 4	90	1140	1%	0%	1%	2%	3%	3%
Sample 5*	90	<100	NA	NA	NA	NA	NA	NA
DxI 9000 Immunoassay System			**Repeatability**	**Between Day**	**Between Run**	**Within Laboratory**	**Between Site**	**Reproducibility**
Sample	**N**	**Mean**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**	**%CV**
CRP (mg/L)								
Sample 1	90	4.5	3%	0%	0%	3%	4%	5%
Sample 2	90	47.1	4%	1%	0%	4%	2%	4%
Sample 3	90	93.2	4%	0%	2%	4%	3%	6%
Sample 4	90	199.2	5%	2%	2%	5%	3%	6%
Sample 5	90	11	3%	1%	1%	3%	2%	4%
BV Score								
Sample	**N**	**Mean**	**Repeatability**	**Between Day**	**Between Run**	**Within Laboratory**	**Between Site**	**Reproducibility**
			SD	**SD**	**SD**	**SD**	**SD**	**SD**
Sample 1	90	0	0	0	0	0	0	0
Sample 2	90	30	2.3	0.6	0	2.4	2	3.1
Sample 3	90	84	1.3	0	0.4	1.3	0	1.3
Sample 4	90	100	0.2	0.1	0	0.2	0	0.2
Sample 5	90	89	0.5	0	0.2	0.5	0.4	0.6

*IP-10 in this sample is dosed below analytical measuring range

Analytical Performance Studies Summary

IMPRECISION

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

- TRAIL, IP-10 and CRP: ≤ 8% CV
- Score: ≤ 12.5 SD

A study based on CLSI EP05-A3 performed on the Access Immunoassay Systems tested multiple samples in duplicate in two runs per day for a minimum of 20 days. Representative data from one lot of reagents on the Access 2 and DxI 9000 are shown in the tables below.

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Access 2 Imprecision

TRAIL										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	200	3.5	2	3.8	2	0.0	0.002	5.1	3
Sample 2	80	83	1.8	2	1.4	2	0.0	0.003	2.3	3
Sample 3	80	42	1.1	3	0.8	2	0.9	2	1.7	4
Sample 4	80	24	0.8	3	0.0	0.002	0.3	1	0.8	3
Sample 5	80	21	0.6	3	0.0	0.001	0.2	1	0.6	3
IP-10										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
			SD	%CV	SD	%CV	SD	%CV	%CV	SD
Sample 1	80	720	25.9	4	0.0	0	24.0	3	35.4	5
Sample 2	80	181	4.2	2	2.8	2	7.0	4	8.6	5
Sample 3	80	1874	45.0	2	59.8	3	80.4	4	109.8	6
Sample 4	80	1066	30.6	3	13.0	1	29.6	3	44.5	4
Sample 5	80	32	0.7	2	0.8	2	1.0	3	1.5	5
CRP										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
			SD	%CV	SD	%CV	SD	%CV	%CV	SD
Sample 1	80	4.6	0.1	3	0.2	4	0.0	0	0.3	5
Sample 2	80	48.8	2.2	5	2.4	5	0.0	0	3.2	7
Sample 3	80	96.9	3.6	4	5.7	6	3.7	4	7.7	8
Sample 4	80	207.7	12.9	6	10.9	5	0.0	0	16.9	8
Sample 5	80	11.7	0.4	4	0.5	4	0.3	2	0.7	6
Score										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD		SD		SD		SD	
Sample 1	80	0	0.1		0.0		0.0		0.1	
Sample 2	80	33	1.7		1.7		0.0		2.4	
Sample 3	80	84	1.2		1.4		0.0		1.9	
Sample 4	80	100	0.2		0.0		0.0		0.2	
Sample 5	80	90	0.7		0.0		0.1		0.7	

DxI 9000 2 Imprecision

TRAIL										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	213	3.7	2	2.8	1	0.0	0.002	4.7	2
Sample 2	80	83	1.3	2	3.5	4	1.4	2	4.0	5
Sample 3	80	41	0.7	2	1.5	4	0.0	0.0003	1.7	4
Sample 4	80	25	0.4	1	0.4	2	0.3	1	0.6	3
Sample 5	80	21	0.3	1	0.9	4	0.0	0.01	0.9	4
IP-10										
Sample	N	Mean Concentration (pg/mL)	Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
			SD	%CV	SD	%CV	SD	%CV	%CV	SD
Sample 1	80	787	14.3	2	12.6	2	14.8	2	24.1	3
Sample 2	80	193	4.1	2	7.6	4	6.4	3	10.7	6

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Sample 3	80	1806	36.1	2	110.8	6	0.1	0.01	116.6	6
Sample 4	80	1105	15.6	1	10.5	1	16.0	1	24.7	2
Sample 5	80	35	0.6	2	1.4	4	0.8	2	1.7	5

CRP										
Sample	**N**	**Mean Concentration (pg/mL)**	**Repeatability (Within-run)**		**Between-run**		**Between-day**		**Within-Laboratory (Total)**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**%CV**	**SD**
Sample 1	80	4.5	0.1	3	0.0	0	0.1	1	0.1	3
Sample 2	80	45.8	1.7	4	2.9	6	0.0	0	3.3	7
Sample 3	80	90.5	4.6	5	5.4	6	0.0	0	7.1	8
Sample 4	80	195.1	8.6	4	5.7	3	0.0	0	10.3	5
Sample 5	80	10.8	0.3	3	0.6	5	0.3	3	0.7	7

Score						
Sample	**N**	**Mean Concentration (pg/mL)**	**Repeatability (Within-Run)**	**Between-Run**	**Between-Day**	**Within-Laboratory**
			SD	**SD**	**SD**	**SD**
Sample 1	80	0	0.0	0.0	0.0	0.0
Sample 2	80	31	1.2	2.5	0.2	2.8
Sample 3	80	84	1.5	0.0	0.6	1.6
Sample 4	80	100	0.1	0.0	0.0	0.1
Sample 5	80	89	0.5	0.6	0.1	0.8

INTERFERING SUBSTANCES

Serum samples with a high (likely bacterial) and low (likely viral) test score were spiked with the substances listed in the following table. The spiked samples were run on the DxI 9000 Access Immunoassay Analyzer and the Access 2 Immunoassay System. The values were calculated based upon CLSI EP07-A3. 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, defined as a bias of more than ± 12.5 score units using the highest test concentrations provided in the table below.

Substance	Highest Concentration Added
Acetaminophen (paracetamol)	0.156 mg/mL
Acetylsalicylic acid (aspirin)	0.03 mg/mL
Alcohol (ethanol)	0.5% V/V
Amoxicillin	54 µg/mL
Ampicillin	75 µg/mL
Azithromycin	11.1 µg/mL
Bilirubin (conjugated)	0.4 mg/ml
Bilirubin (unconjugated)	0.4 mg/ml
Biotin	3,510 ng/mL
Caffeine	108 µg/mL
Cetirizine HCL	4.35 µg/mL
Dextromethorphan	15.6 ng/ml
Doxycycline	18 µg/mL

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HAMA (human anti-mouse Ab)	360 ng/ml
Hemoglobin	10 mg/mL
Heparin	3,300 U/L
Human serum albumin (HSA)	60 mg/ml
Ibuprofen	219 µg/mL
Levofloxacin	36 µg/mL
Loratadine	87 ng/mL
Nicotine	969 ng/mL
Oxymetazoline HCl	0.0006 µg/mL
Phenylephrine	30 ng/mL
Prednisolone	1,200 ng/mL
Rheumatoid Factor (RF)	500 IU/mL
Triglycerides (Triolein)	15 mg/mL

CROSS REACTIVITY

A study evaluated the potential for cross-reactivity of substances that are similar in structure to TRAIL, IP-10 and CRP. Serum samples with a high (likely bacterial) and low (likely viral) test score were spiked with 50 ng/mL of the substances listed in the following table. The spiked samples were run on a DxI 9000 Access Immunoassay Analyzer and Access 2 Immunoassay System. The values were calculated based upon CLSI EP07-A3, guidelines. No cross-reactivity was observed for the following substances at the tested concentration, as defined by a bias of no more than ± 12.5 score units.

TRAIL Cross-reactants – Substances evaluated at 50 ng/mL	
4-1BB Ligand	TNF-α 50
CD40 Ligand	TNF-β 50
LT α1/β2	Adiponectin
LT α2/β1	
IP-10 Cross-reactants – Substances evaluated at 50 ng/mL	
BLC/BCA-1	IL-8
ENA-78	I-TAC
GCP-2	NAP-2
GROα	MIG
GROγ	SDF-1α
IFNγ	SDF-1β
CRP Cross-reactants – Substances evaluated at 50 ng/mL	
Pentraxin 2/SAP	Pentraxin 3/TSG-14

Linearity

A linearity study was performed for the Access MeMed BV assay (CRP, IP-10, and TRAIL immunoassays) on the Access 2 Immunoassay Instrument and DxI 9000 Access Immunoassay Analyzers, following a protocol based on CLSI EP06-Ed2. Serum and lithium heparin plasma samples were used to establish linearity across the analytical measuring range for each analyte. The assay demonstrates acceptable

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linearity across the analytical measuring ranges (15 to 300 pg/mL for TRAIL, 100-2000 pg/mL for IP-10, and 1-250 mg/L for CRP) for all analytes.

Limit of Blank, Limit of Detection, and Limit of Quantitation

Studies were performed to determine the Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) of the Access MeMed BV assay using a protocol based on CLSI EP17- A2 (Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition). One DxI 9000 Access Immunoassay Analyzer and one Access 2 Immunoassay Instrument were used in each study design with three reagent lots and one calibrator lot per analyte.

Limit of Blank

LoB estimates were calculated for each combination of reagent lot and instrument based on a non-parametric approach and the maximum observed LoB across all reagent pack lots for an analyte tested on each platform is taken as the reported value for the measurement procedure. LoB was determined using the 95th percentile of the distribution of observed blank replicates for each reagent pack lot per analyte per platform.

The Limit of Blank determined for the Access MeMed BV assay is set forth in the table below.

Limit of Blank (LoB)	Maximum Observed Result	Design Criteria
TRAIL	for DxI 9000 TRAIL 0.2 pg/mL	≤ 15 pg/mL
	for Access 2 TRAIL 0.37 pg/mL	
IP-10	for DxI 9000 IP-10 0.017 pg/mL	≤100 pg/mL
	for Access 2 IP-10 0.6 pg/mL	
CRP	for DxI 9000 CRP 0.002 mg/L	≤1.0 mg/L
	for Access 2 CRP 0.0 mg/L	

Limit of Detection

Samples were tested in replicates of nine per run with one run per day and five total days on each pack lot and instrument. A minimum of 40 replicates for each sample on each pack lot was tested. Commercial quality controls were run in replicates of two on each day to verify the systems were in control.

The Limit of Detection determined for the Access MeMed BV assay is set forth in the table below.

Limit of Detection (LoD)	Maximum Observed Result	Design Criteria
TRAIL	for DxI 9000 TRAIL Plasma 0.5 pg/mL	≤ 15 pg/mL
	for DxI 9000 TRAIL Serum 0.5 pg/mL	
	for Access 2 TRAIL Plasma 0.7 pg/mL	
	for Access 2 TRAIL Serum 0.7 pg/mL	
IP-10	for DxI 9000 IP-10 Plasma 0.23 pg/mL	≤100 pg/mL
	for DxI 9000 IP-10 Serum 0.07 pg/mL	
	for Access 2 IP-10 Plasma 0.93 pg/mL	
	for Access 2 IP-10 Serum 0.77 pg/mL	
CRP	for DxI 9000 CRP Plasma 0.007 mg/L	≤1.0 mg/L
	for DxI 9000 CRP Serum 0.004 mg/L	
	for Access 2 CRP Plasma 0.008 mg/L	
	for Access 2 CRP Serum 0.012 mg/L	

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Limit of Quantitation

Samples were tested in replicates of nine per run with one run per day and five total days on each pack lot and instrument. A minimum of 40 replicates for each sample on each pack lot was tested. Two quality controls were run in replicates of two on each day to verify the systems were in control.

The Limit of Quantitation determined for the Access MeMed BV assay is set forth in the table below.

Limit of Quantitation (LoQ) ≤ 20% within- lab CV	Maximum Observed Result	Design Criteria
TRAIL	for DxI 9000 TRAIL Plasma 3 pg/mL	≤ 15 pg/mL
	for DxI 9000 TRAIL Serum 2 pg/mL	
	for Access 2 TRAIL Plasma 2 pg/mL	
	for Access 2 TRAIL Serum 2 pg/mL	
IP-10	for DxI 9000 IP-10 Plasma 4 pg/mL	≤100 pg/mL
	for DxI 9000 IP-10 Serum 1 pg/mL	
	for Access 2 IP-10 Plasma 3 pg/mL	
	for Access 2 IP-10 Serum 1 pg/mL	
CRP	for DxI 9000 CRP Plasma 0.07 mg/L	≤1.0 mg/L
	for DxI 9000 CRP Serum 0.03 mg/L	
	for Access 2 CRP Plasma 0.07 mg/L	
	for Access 2 CRP Serum 0.02 mg/L	

Matrix Comparison

A sample type comparison study was performed on the Access MeMed BV was performed using a protocol based upon CLSI EP35-ED1. Matched native serum and lithium heparin plasma samples were tested in the study (sixty on Access 2 Immunoassay Systems and fifty-three on DxI 9000 Access Immunoassay Analyzer). Each sample was tested in replicates of three. The results of the study demonstrate serum and lithium heparin plasma samples are suitable for use on the Access MeMed BV.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access MeMed BV is substantially equivalent to the MeMed Diagnostics Ltd. MeMed BV test system (K210254) as demonstrated through the information and data provided in this submission. The performance and clinical testing presented in this submission provides evidence that the device is safe and effective for its intended use.

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