510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222996

B Applicant

Beckman Coulter, Inc

C Proprietary and Established Names

Access PCT

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PTF	Class II	21 CFR 866.3215 - Device To Detect And Measure Non-Microbial Analyte(S) In Human Clinical Specimens To Aid In Assessment Of Patients With Suspected Sepsis	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Access PCT assay on the Dxl 9000 Access Immunoassay Analyzer.

B Measurand:

Human Procalcitonin (PCT)

C Type of Test:

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for *in vitro* quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For In Vitro Diagnostic Use Only.

D Special Instrument Requirements:

The Access PCT assay is intended for use with the DxI 9000 Access Immunoassay Analyzer.

IV Device/System Characteristics:

A Device Description:

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of ICU admission for progressive to severe sepsis and septic shock.

The Access PCT Calibrators were previously cleared under 510(k) K192271.

A description of the reagent pack is provided below.

- R1a: Dynabeads paramagnetic particles coated with mouse anti-human Procalcitonin monoclonal antibody in a TRIS buffer with surfactant, protein (bovine), ≤ 0.1% sodium azide, and 0.1% ProClin 300
- R1b: 0.10 N Sodium Hydroxide
- R1c: MOPS Buffer with surfactant and protein (bovine, murine), ≤ 0.1 % sodium azide, and 0.1% ProClin 300
- R1d: Rat anti-Procalcitonin recombinant alkaline phosphatase conjugate in a MOPS buffer with surfactant and protein (bovine, murine, recombinant), ≤ 0.1% sodium azide, and 0.1% ProClin 300

B Principle of Operation:

The DxI 9000 Immunoassay Analyzer uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in serum and plasma samples.

The Access PCT assay is a sequential two-step immunoenzymatic ("sandwich") assay. Monoclonal anti-PCT 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 monoclonal anti-PCT antibody are added. The PCT binds to the anti-PCT antibody on the solid phase, while the anti-PCT antibody-alkaline phosphatase conjugate reacts with different antigenic sites on the PCT molecules. 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 directly proportional to the concentration of analyte in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Access PCT, Access PCT Calibrators

B Predicate 510(k) Number(s):
K192271

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222996	K192271
Device Trade Name	Access PCT	Access PCT
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Access PCT assay is a paramagnetic particle, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay System. Measurement of PCT in conjunction with other laboratory findings and	The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill

	clinical assessment aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.	patients on their first day of ICU admission for progression to severe sepsis and septic shock. The Access PCT Calibrators are intended to calibrate the Access PCT assay for the quantitative determination of procalcitonin levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems.
Analyte Measured	Procalcitonin (PCT)	Same
Sample Type	Human Serum or Plasma (LiHep and EDTA)	Same
Method	Automated	Same
Technology	Two-step sandwich immunoassay	Same
Calibration	Utilizes a stored calibration curve	Same
Measuring Range	0.05 to 100 ng/mL	Same
Hook Effect	No hook effect up to procalcitonin concentrations of 5,000 ng/mL	Same
Stability	Stable at 2 to 10°C for 42 days after initial use	Same
Reagent Pack materials	Mouse anti-human procalcitonin monoclonal antibody	Same
General Device Characteristic Differences		
Assay Duration	Approximately 14 minutes	Approximately 20 minutes
Sample Volume	15 µL	35 µL
Instrument	DxI 9000 Access Immunoassay Analyzer	Access 2 Immunoassay system
Substrate	Lumi-Phos PRO substrate	Access Substrate

VI Standards/Guidance Documents Referenced:

- CLSI EP17-A2 Evaluation of Detection for Clinical Laboratory Measurement Procedures, Second Edition

- CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures, Second Edition
- CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline - Third Edition
- CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples, Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A within-laboratory precision study was performed based on CLSI EP05- A3 recommendations. Seven native serum samples spiked with varying concentrations of PCT antigen were tested in duplicate with two runs per day (≥ 20 days), three reagent lots, and three calibrator lots across three different instrument systems (for a total of 80 replicates per sample for each instrument and reagent lot combination). Total imprecision, within run imprecision, between run, and between day variation was evaluated in terms of percent coefficient of variation, %CV.

The acceptance criteria for within-laboratory imprecision were established as a standard deviation (SD) ≤ 0.012 for values < 0.150 ng/mL and a CV ≤ 8.0% for values ≥ 0.150 ng/mL. Acceptance criteria for within-run imprecision (Repeatability) was established as a SD ≤ 0.009 ng/mL for values < 0.150 ng/mL & CV ≤ 6% for values ≥ 0.150 ng/mL.

The total within-laboratory imprecision included %CVs between 2.2% and 6.1% for PCT concentrations ≥ 0.150 ng/mL and SDs between 0.006 – 0.008 for PCT concentrations < 0.150 ng/mL.

The within-run imprecision included % CVs between 1.9% and 4.7% for PCT concentrations ≥ 0.150 ng/mL and SDs between 0.004 – 0.007 for PCT concentrations < 0.150 ng/mL. Results from the within-laboratory precision study are presented below in Tables 1 to 3.

Table 1: Access PCT Within-Laboratory Precision Study Results Reagent Lot 1

			Repeatability (Within-Run)		Between-run		Between-day		Within- Lab (Total)	
Sample	**N**	**Mean (ng/mL)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	88	0.099	0.004	4.2	0.005	4.7	0.000	0.3	0.006	6.3
Sample 2	88	0.22	0.007	3.3	0.005	2.1	0.003	1.3	0.009	4.1
Sample 3	88	0.42	0.012	2.8	0.005	1.2	0.006	1.3	0.014	3.3
Sample 4	88	0.52	0.012	2.3	0.027	5.1	0.001	0.3	0.029	5.6
Sample 5	88	2.3	0.06	2.5	0.05	2.2	0.02	1.0	0.08	3.5
Sample 6	88	10	0.2	2.2	0.3	2.7	0.2	1.5	0.4	3.7
Sample 7	88	87	2.0	2.3	1.1	1.3	0.0	0.0	2.3	2.6

Table 2: Access PCT Within-Laboratory Precision Study Results Reagent Lot 2

			Repeatability (Within-run)		Between-run		Between-day		Within- Lab (Total)	
Sample	**N**	**Mean (ng/mL)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	88	0.11	0.005	4.8	0.003	3.0	0.002	1.6	0.006	5.9
Sample 2	88	0.23	0.008	3.4	0.000	0.0	0.004	1.7	0.009	3.8
Sample 3	88	0.44	0.012	2.6	0.009	2.1	0.003	0.7	0.015	3.4
Sample 4	88	0.54	0.014	2.7	0.030	5.5	0.000	0.0	0.033	6.1
Sample 5	88	2.4	0.04	1.9	0.03	1.4	0.02	1.0	0.06	2.5
Sample 6	88	11	0.2	2.2	0.3	2.5	0.0	0.0	0.4	3.3
Sample 7	88	94	1.8	1.9	0.7	0.8	0.7	0.8	2.1	2.2

Table 3: Access PCT Within-Laboratory Precision Study Results Reagent Lot 3

			Repeatability (Within-run)		Between-run		Between-day		Within- Lab (Total)	
Sample	**N**	**Mean (ng/mL)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	86	0.11	0.007	6.4	0.003	2.7	0.003	2.7	0.008	7.4
Sample 2	86	0.24	0.010	4.4	0.005	2.1	0.000	0.0	0.012	4.9
Sample 3	86	0.45	0.021	4.7	0.000	0.0	0.008	1.9	0.023	5.0
Sample 4	84	0.55	0.013	2.3	0.029	5.2	0.000	0.0	0.031	5.7
Sample 5	86	2.4	0.06	2.4	0.04	1.9	0.02	0.9	0.08	3.1
Sample 6	86	11	0.3	2.4	0.5	4.3	0.0	0.0	0.5	4.9
Sample 7	86	91	2.1	2.3	1.1	1.2	0.0	0.0	2.4	2.6

The study demonstrated that the Access PCT assay met acceptance criteria for total imprecision on the DxI 9000 with an SD ≤ 0.012 ng/mL for values < 0.150 ng/mL and a CV ≤ 8.0% for values ≥ 0.150 ng/mL. The Access PCT assay also met the within run imprecision (repeatability) acceptance criteria with an SD ≤ 0.009 ng/mL for values < 0.150 ng/mL and CV ≤ 6.0% for values ≥ 0.150 ng/mL.

2. Linearity:

Two studies were performed to determine the linearity of the Access PCT assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. In both studies one DxI 9000 Immunoassay Analyzer, three reagent lots, and one calibrator lot were used. Three quality controls were run in replicates of two on each day to verify the system was in control.

In the first study, serum samples covering the full range of the assay were used for the linearity determination. A native sample containing a concentration of PCT at the low end of the measuring interval was obtained. The high sample was prepared by spiking PCT antigen into a low serum sample until a concentration above the Access PCT S6 calibrator was achieved. In addition to the high and low PCT concentration samples, seven mixtures were assessed. These samples were prepared independently by using incrementally larger proportions of the high sample diluted with the low sample, to achieve procalcitonin concentrations that covered the range of the assay. The low sample was run in replicates of eight, and all other samples were run in replicates of four. Assay results were analyzed by a weighted linear regression and the analysis of linearity is summarized in Table 4 below. Acceptance criteria were established as a detectable non-linearity within ± 0.012 ng/mL for values ≤ 0.150 ng/mL and ± 10% for values > 0.150 ng/mL. The statistical analysis of data showed that the results met the acceptance criteria.

Table 4: Access PCT Full Measuring Range Linearity Analysis

Calibrator Lot 921984	Mean (ng/mL)	Expected Concentration (ng/mL)	Linear fit (ng/mL)	Nonlinearity (rounded to specification)
Pack Lot 922598	0.011	0.011	0.011	-0.000001 ng/mL
	17.158	16.543	16.526	4%
	33.586	33.074	33.040	2%
	49.514	49.605	49.554	-0.1%
	65.469	66.136	66.069	-1%
	81.717	82.668	82.583	-1%
	98.793	99.199	99.097	-0.3%
	112.478	115.730	115.612	-3%
	132.261	132.261	132.126	0.1%
	0.011	0.011	0.011	-0.000004 ng/mL
	16.770	16.803	16.157	4%
	32.670	33.594	32.303	1%

Pack Lot 922422	49.648	50.386	48.450	2%
	63.093	67.178	64.596	-2%
	78.321	83.970	80.742	-3%
	94.387	100.762	96.889	-3%
	110.510	117.554	113.035	-2%
	134.346	134.346	129.181	4%
Pack Lot 922077	0.011	0.011	0.011	-0.000001 ng/mL
	17.423	16.762	16.422	6%
	33.364	33.512	32.833	2%
	48.438	50.263	49.245	-2%
	63.584	67.014	65.656	-3%
	80.325	83.764	82.067	-2%
	96.042	100.515	98.479	-2%
	115.958	117.266	114.890	1%
	134.016	134.016	131.301	2%

In the second study, serum samples covering the low range of the assay were prepared and used for linearity determination. A native sample containing a concentration of PCT at the low end of the measuring interval was obtained. The high sample was prepared at concentration near 3 ng/mL by spiking PCT antigen into a low serum sample until a concentration of about 3 ng/mL was achieved. In addition to the high and low PCT concentration samples, seven mixtures were evaluated in this study. These samples were prepared independently by using incrementally larger proportions of the high sample diluted with the low sample, to achieve concentrations that covered the low range of the assay. The low sample was run in replicates of eight, and all the other samples were run in replicates of four. The assay results were analyzed by weighted linear regression and the analysis of linearity is summarized in Table 5 below. Acceptance criteria were established as a detectable non-linearity within ± 0.012 ng/mL for values ≤ 0.150 ng/mL and ± 10% for values > 0.150 ng/mL. The statistical analysis of data showed that the results met the acceptance criteria.

Table 5: Access PCT Low End Linearity Analysis

Calibrator Lot 921984	Mean (ng/mL)	Expected Concentration (ng/mL)	Linear fit (ng/mL)	Nonlinearity (rounded to specification)
Pack Lot 922598	0.010	0.010	0.010	-0.00003 ng/mL
	0.414	0.389	0.389	6%
	0.787	0.768	0.767	3%
	1.134	1.148	1.146	-1%
	1.510	1.527	1.525	-1%
	1.857	1.906	1.904	-2%
	2.245	2.285	2.282	-2%
	2.617	2.665	2.661	-2%
	3.044	3.044	3.040	0.1%
	0.010	0.010	0.010	-0.00003

				ng/mL
Pack Lot 922422	0.426	0.399	0.403	6%
	0.812	0.788	0.797	2%
	1.201	1.178	1.190	1%
	1.561	1.567	1.583	-1%
	1.969	1.956	1.977	-0.4%
	2.344	2.346	2.370	-1%
	2.669	2.735	2.764	-3%
	3.124	3.124	3.157	-1%
Pack Lot 922077	0.010	0.010	0.010	-0.0003 ng/mL
	0.441	0.395	0.403	10%
	0.814	0.781	0.795	2%
	1.228	1.167	1.188	3%
	1.559	1.553	1.581	-1%
	1.944	1.938	1.973	-1%
	2.284	2.324	2.366	-3%
	2.643	2.710	2.759	-4%
	3.096	3.096	3.152	-2%

The results of both studies met the acceptance criteria, indicating that the Access PCT assay is linear on the DxI 9000 Immunoassay System throughout the analytical measuring interval.

3. Analytical Specificity/Interference:

   No significant changes were made to the Access PCT assay. Please refer to the original published decision summary (K192271) for additional information on analytical specificity.

4. Assay Reportable Range:

   The assay reportable range is the same as the predicate, 0.05 ng/mL – 100 ng/mL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The Access PCT calibrator traceability and stability were previously cleared. Please see the original published decision summary for K192271 for additional information.

6. Limit of Blank (LoB), Detection (LoD) and Quantitation (LoQ):

   Studies were performed to determine the LoB, LoD and LoQ in the Access PCT assay consistent with recommendations in CLSI EP17-A2 (Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition).

   LoB

   For estimation of LoB, three DxI 9000 Immunoassay Systems were used in the study design with three reagent lots and one calibrator lot. The Access PCT Calibrators are a seven-level

calibrator set intended to calibrate the Access PCT assay for the quantitative determination of procalcitonin levels in human serum and plasma using the Access Immunoassay Systems. The zero calibrators (S0) contain lyophilized HEPES buffer with protein (bovine), ≤ 0.1 % sodium azide, and 0.1% ProClin300. Four S0 calibrators were used for the LoB determination. Samples were evaluated over three days including one run per day and five replicates per run for each pack lot. Three quality control samples were also run in replicates of two on each day.

LoB estimates were calculated for each combination of reagent lot and instrument based on a non-parametric approach and the maximum observed LoB was taken as the reported value for the measurement procedure. LoB was determined using the 95% nonparametric percentile of the replicates for each of three reagent lots.

The LoB estimate of the PCT assay was 0.002 ng/mL and met the acceptance criteria of ≤ 0.005 ng/mL.

LoD

For estimation of LoD, three DxI 9000 Immunoassay Systems were used in the study with three reagent lots and one calibrator lot. Nine serum samples containing low levels of PCT analyte were prepared. Samples were evaluated over five days including one run per day and nine replicates per run for each reagent lot. Three quality controls were run in replicates of two on each day.

The LoD was determined by fitting the precision profile model between within-lab standard deviation (SD) and concentration. The SD was multiplied by the 95th percentile of the standard normal distribution and added to the LoB to calculate the LoD per CLSI EP17-A2. The maximum observed LoD is taken as the reported value for the measurement procedure.

The LoD estimate of the PCT assay was 0.003 ng/mL which met the acceptance criteria of ≤ 0.01 ng/mL.

LoQ

Studies were performed to determine the Limit of Quantitation (LoQ) of the Access PCT assay on the DxI 9000 Immunoassay System based on recommendations in CLSI EP17- A2 (Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition). Three DxI 9000 Immunoassay Systems were used in the study design with three reagent lots and one calibrator lot.

For estimation of LoQ, thirteen native serum samples containing low levels of PCT analyte were measured. Samples were evaluated across five days in replicates of nine per run with one run per day. A minimum of 40 replicates for each sample on each reagent lot were evaluated. Three quality controls were run in replicates of two on each day.

A variance components model was used to estimate the within run and within-laboratory (total) %CV for each sample on each instrument and reagent lot combination. A log-log quadratic precision model was fitted to within-laboratory (total) %CV versus observed sample mean. The fitted precision profile was used to calculate the

20% CV LoQ. The maximum observed LoQ was taken as the reported value for the measurement procedure. The acceptance criterion was 20% Within- Laboratory CV LoQ at ≤ 0.02 ng/mL.

The 20% CV LoQ estimate for the Access PCT assay was 0.002 ng/mL which met the acceptance criteria of less than or equal to 0.02 ng/mL.

7. Assay Cut-Off:

See the Method Comparison section below for bias estimation at medically relevant concentrations.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was completed to compare the performance of the Access PCT assay on the DxI 9000 Access Immunoassay Analyzer to the Access PCT assay on the Access 2 Immunoassay System using a protocol based on CLSI EP09c-A3, Method Procedure Comparison and Bias Estimation Using Patient Samples: Approved Guideline – Third Edition.

A total of one hundred and twenty native serum samples were evaluated in the method comparison study. The study was run on three DxI 9000 instruments and three Access 2 instruments and utilized a total of three reagent pack lots and three calibrator lots. Three commercial quality controls were run in duplicate each day.

The comparison between paired measurements was analyzed by fitting the observations from the Access PCT Assay on the DxI 9000 instrument into a linear regression model versus the observations from the Access PCT Assay on Access 2 using the Passing-Bablok method. The acceptance criteria were $R^2 \geq 0.95$ with a slope of 1.00 ± 0.10 and encompassed within the 95% confidence interval when compared to the Access PCT Assay on Access 2 Instrument. Results of the regression analysis are described in Table 6 below.

Table 6. Regression Analysis of Access PCT Assay (DxI 9000 vs. Access 2)

N	DxI 9000 Range Of Observations (ng/mL)	Access 2 Range Of Observations (ng/mL)	Intercept (ng/mL) [95% CI]	Slope [95% CI]	Correlation Coefficient (R)	R^2
120	0.038- 81	0.042-80	-0.0038 [.035,0.017]	0.99 [0.947-100]	1.00	1.00

To evaluate if the reference ranges for the Access PCT assay established on the Access 2 are maintained on the DxI 9000 instrument, bias was estimated at the concentrations corresponding to the 95% Upper Reference Interval within a population of healthy male and female subjects as determined on the predicate Access 2 system. The Passing-Bablok regression was used to derive

bias estimates at each specified concentration, including confidence intervals. The combined results of slope and intercept by Passing-Bablok analysis are summarized in Table 6.

Table 7 below describes the bias estimate at the PCT Upper Reference limit.

Table7: Bias estimate at the PCT Upper Reference Limit

Concentration (ng/mL)	Mean difference (ng/mL)	95% CI (ng/mL)		Relative difference
0.065	-0.0045	-0.037	0.018	- 7.0%

A concordance analysis between the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer was performed with cut-off values of 0.5 ng/mL and 2.0 ng/mL. The results are shown in Table 8 and Table 9 below.

Table 8: Method Concordance at 0.5 ng/mL

	Access 2		
DxI 9000	**≤ 0.5 ng/mL**	**> 0.5 ng/mL**	**Total**
≤ 0.5 ng/mL	10	0	10
> 0.5 ng/mL	0	110	110
Total	10	110	120
Negative percent agreement 100% CI [72.2% - 100%] Positive percent agreement 100% CI [96.6%% - 100%]			

Table 9. Method Concordance at 2.0 ng/mL

	Access 2		
DxI 9000	**≤ 2.0 ng/mL**	**> 2.0 ng/mL**	**Total**
≤ 2.0 ng/mL	24	1	25
> 2.0 ng/mL	1	94	95
Total	25	95	120
Negative percent agreement 96% CI [80.5% - 99.3%] Positive percent agreement 98.96% CI [94.3% - 99.8%]			

An overall concordance analysis between the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer for all of the Clinical Decision Points are shown in Table 10 below.

Table 10: Concordance for Clinical Decision Points

	Access 2			
DxI 9000	**≤ 0.5 ng/mL**	**> 0.5 to ≤ 2.0 ng/mL**	**> 2.0 ng/mL**	**Total**
≤ 0.5 ng/mL	10	0	0	10
> 0.5 to ≤ 2.0 ng/mL	0	14	1	15
> 2.0 ng/mL	0	1	94	95
Total	10	15	95	120

2. Matrix Comparison:

   Please refer to the original published decision summary for K192271.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

See method comparison study section above.
Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock. The interpretation of Access PCT assay are as follows:

PCT Concentration (ng/mL)	Interpretation
< 0.5	Low risk of severe sepsis and/or septic shock
> 2.0	High risk of severe sepsis and/or septic shock

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.