May 9, 2025

DiaSys Diagnostic Systems GmbH
% Stephen Gorski
Official Correspondent
Imagenix, Inc.
S65W35739 Piper Road
Eagle, Wisconsin 53119

Re: K242294
Trade/Device Name: DiaSys Procalcitonin FS; DiaSys TruCal Procalcitonin Calibrator Set; DiaSys TruLab Procalcitonin Bi-Level Controls
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: PTF
Dated: July 15, 2024
Received: August 2, 2024

Dear Stephen Gorski:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Deputy Division Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K242294

Device Name
DiaSys Procalcitonin FS; DiaSys TruCal Procalcitonin Calibrator Set; DiaSys TruLab Procalcitonin Bi-Level Controls

Indications for Use *(Describe)*
DiaSys Procalcitonin FS assay is a particle enhanced immunoturbidimetric test intended for the quantitative in vitro determination of procalcitonin (PCT) in human serum and lithium heparin plasma on automated Abbott ARCHITECT c8000 analyzer.

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 TruCal Procalcitonin Calibrator Set is intended for in vitro use for calibration of the DiaSys Procalcitonin FS assay.

TruLab Procalcitonin Bi-Level Controls are an assayed quality control material for monitoring the performance of quantitative in vitro determination of Procalcitonin (PCT) for the DiaSys Procalcitonin FS assay.

For in vitro diagnostic use only.

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.

510(k) Summary in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Contact Person: Mr. Jan Gorka

Position/Title: CEO

Date of Preparation: May 9, 2025

(2) **Trade Name:** DiaSys Procalcitonin FS assay; DiaSys TruCal Procalcitonin Calibrator Set; and DiaSys TruLab Procalcitonin Bi-Level Controls

Common/Classification Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis

Product Code(s): 21 CFR §866.3215; PTF (reagent)

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K071146	VIDAS B.R.A.H.M.S. PCT ASSAY	bioMérieux, Inc.

Reference Device(s):

K Number	Model	Manufacturer
K162297	Diazyme Procalcitonin (pct) Assay, Diazyme Procalcitonin (pct) Calibrator Set, Diazyme Procalcitonin (pct) Control Set	Diazyme Laboratories

Reason for Submission: New Device(s)

(4) **Description of Device:**

The DiaSys Procalcitonin FS assay is a particle enhanced turbidimetric immunoassay (PETIA) test for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and lithium heparin plasma on automated photometric systems.

The test utilizes anti-human PCT polyclonal antibodies (goat) covalently bound to polystyrene particles.

PCT in the sample binds to the anti-PCT antibodies on the particles and causes agglutination. The degree of the turbidity caused by agglutination is optically measured at 660 nm by the automated photometric system and is proportional to the amount of PCT in the sample. DiaSys Procalcitonin FS Reagent specifies settings for an automated photometric analyzer, the Abbott ARCHITECT c8000.

The DiaSys TruCal Procalcitonin Calibrator Set is provided in 6 levels, traceable to a commercial assay for use in the calibration of the DiaSys Procalcitonin FS assay.

The DiaSys TruLab Procalcitonin Bi-Level Controls, Levels 1 (low) and 2 (high) are intended for use as quality control for the DiaSys Procalcitonin FS assay.

DiaSys PCT Calibrators and Bi-Level Controls are ready-to-use, stable, aqueous solutions containing recombinant human full-length PCT and biological additives from bovine origin.

(5) Intended use:

The intended use for the DiaSys Procalcitonin FS assay is the same as the predicate device: quantitative in vitro determination of procalcitonin (PCT) in human serum or lithium heparin plasma.

Indications for Use:

DiaSys Procalcitonin FS assay is a particle enhanced immunoturbidimetric test intended for the quantitative in vitro determination of procalcitonin (PCT) in human serum and lithium heparin plasma on automated Abbott ARCHITECT c8000 analyzer.

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 TruCal Procalcitonin Calibrator Set is intended for in vitro use for calibration of the DiaSys Procalcitonin FS assay.

TruLab Procalcitonin Bi-Level Controls are an assayed quality control material for monitoring the performance of quantitative in vitro determination of Procalcitonin (PCT) for the DiaSys Procalcitonin FS assay.

For in vitro diagnostic use only.

(6) Technological Characteristics:

Comparison of Subject Intended Use and Technological Features to Predicate Device:

Product/Feature	**Subject Device:** DiaSys Procalcitonin FS Assay	**Predicate Device:** VIDAS BRAHMS PCT Assay	**Comment**
Manufacturer	DiaSys Diagnostic Systems GmbH	bioMérieux, Inc.	---
Model Number(s)	Procalcitonin FS; Cat. No. 1 7318 99 43 018 TruCal Procalcitonin Calibrator Set; Cat. No. 1 7310 99 43 082 TruLab Bi-Level Controls Cat. No. 5 9980 99 43 086	VIDAS ® B·R·A·H·M·S PCT™ (PCT) Cat. 30450-01 (60 tests) Kit (30450) contains C1/C2 Controls and S1/S2 Calibrators	Equivalent function - subject device separately specifies the calibrators and controls, the predicate device does not, however they are included in the reagent kit.
510(k) Number	**K242294**	**K071146**	---
Application/Intended use:	Quantitative *in vitro* determination of procalcitonin (PCT) in human serum or Lithium heparin plasma on automated photometric system	Determination of human procalcitonin in human serum or plasma (lithium heparin)	Same
Analyte Measured	Procalcitonin (PCT)	Procalcitonin (PCT)	Same
Environment of Use	IVD: Clinical Laboratory use only	IVD: Clinical Laboratory use only	Same

Product/Feature	**Subject Device:** DiaSys Procalcitonin FS Assay	**Predicate Device:** VIDAS BRAHMS PCT Assay	**Comment**
Indications for Use	DiaSys Procalcitonin FS assay is a particle enhanced immuno-turbidimetric test intended for the quantitative in vitro determination of procalcitonin (PCT) in human serum and lithium heparin plasma on automated Abbott ARCHITECT c8000 analyzer. 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 TruCal Procalcitonin Calibrator Set is intended for in vitro use for calibration of the DiaSys Procalcitonin FS assay. TruLab Procalcitonin Bi-Level Controls are an assayed quality control material for monitoring the performance of quantitative in vitro determination of Procalcitonin (PCT) for the DiaSys Procalcitonin FS assay. For in vitro diagnostic use only.	VIDAS BRAHMS PCT is an automated test for use on the VIDAS instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS BRAHMS PCT assay is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock.	Equivalent function: Similar warnings to the effect that the PCT assay is not to be used as the sole determinant for diagnosis of sepsis, and should be used in conjunction with other clinical signs and symptoms. The subject device warns against the use as an aid in decision making on antibiotic therapy for patients. The predicate device warns that decisions regarding antibiotic therapy should NOT be based solely on procalcitonin concentrations.
Measurement Characteristics			
Assay Principle(s)	Particle enhanced immunoturbidimetric method – for use on automated photometric system(s)	Immunoassay based on sandwich Enzyme-Linked Fluorescent Assay (ELFA) – for use on automated assay	Equivalent function with some differences in assay principle: Immunoturbidimetric principle of subject assay is different from the predicate device (ELFA)
Specified Analyzer(s)	ARCHITECT c8000™	VIDAS and miniVIDAS family of analyzers	Equivalent function on different automated chemistry analyzer(s)
Sample type	Human serum or lithium heparin plasma	Human serum or lithium heparin plasma	Same sample matrices

Product/Feature	**Subject Device:** DiaSys Procalcitonin FS Assay	**Predicate Device:** VIDAS BRAHMS PCT Assay	**Comment**
Sample volume	10 µL	200 µL	Subject device requires less sample volume
Time to obtain readings	10 minutes	20 minutes	Equivalent function
Measurement range	0.23 up to 50 ng/mL (dependent on value of highest calibrator)	0.05 to 200 ng/mL	Equivalent function: assays span the clinical reference range of 0.5 ng/ml to 2.0 ng/ml
Limit of Blank (LOB)	0.081 ng/mL (max value of 4 series)	Limit of Blank (LoB) 0.01 ng/mL (from insert, decision summary does not specify)	Equivalent function: subject assay LOB is below the clinical decision range of 0.5 ng/mL
Limit of Quantitation (LOQ)	0.23 ng/mL (%CV ≤ 20%)	0.05 ng/mL (bias ≤ 10%, % CV ≤ 20%)	Equivalent function: subject assay LOQ is below the clinical decision range of 0.5 ng/mL
Hook(Prozone) Effect	No prozone effect up to 1000 ng/mL	No hook effect found up to concentrations of 2600 ng/ml	Equivalent function for clinical evaluation range
Precision/ Reproducibility	Precision within acceptance criteria: CV ≤ 10% at 0.2-1.0 ng/mL (actual 5.64%); CV ≤ 7% at 1.0-3.0 ng/mL (actual 2.34%); CV ≤ 5% at 3.0-20 ng/mL (actual 1.93%)	total precision: 6.17 - 15.31% CV	Precision values are expressed differently (CV, SD), however generally equivalent magnitude
Reagent			
Reagent measurement volume	120 µl Reagent 1 40 µl Reagent 2	Self-contained reagents integrated into proprietary sample strip	Equivalent function; different packaged volumes
Primary Reagent Constituents	Reagent 1: 0.1 mol/L Tris-buffer, pH 6.5 Reagent 2: 0.1 mol/L Tris-buffer, pH 9.0; Polyclonal antibodies (goat) against human PCT covalently bound to polystyrene particles; Sodium azide (0.9 g/L) as preservative	Solid phase receptacle (SPR): Interior coated with mouse monoclonal anti-human procalcitonin immunoglobulins; proprietary reagent strip contains substrate (4-Methyl-umbelliferyl phosphate) and rinse agents for cycling in and out of the SPR	Equivalent function; different packaged reagent constituents; Subject device has two step reagent construction, predicate device has proprietary reagent strip.

Product/Feature	**Subject Device:** DiaSys Procalcitonin FS Assay	**Predicate Device:** VIDAS BRAHMS PCT Assay	**Comment**
Calibrators and Controls			
Calibrators: Number and Volume	6 x 1 mL Six-level Calibrator	2 x 2 mL two-level Calibrator S1 and S2	Equivalent function: number of calibrators varies
Controls: Packaged Volume & Quantity	6 x 1 mL Low Level 6 x 1 mL High Level	2 x 2.0 mL C1 2 x 2.0 mL C2	Equivalent function

Considerations of 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] include the following:

- The intended use for the subject DiaSys Procalcitonin FS assay is the same as the predicate VIDAS BRAHMS PCT Assay: quantitative determination of procalcitonin (PCT) levels.
- The subject DiaSys Procalcitonin FS assay specifies a particle enhanced immunoturbidimetric test method, the predicate device specifies the ELFA (Enzyme-Linked Fluorescent Assay) technique. The test methods provide equivalent results.
- Different technological characteristics, where identified, do not raise different questions of safety and effectiveness than the predicate device.

Slight differences in the wording of the subject and predicate device indications for use are not critical to the intended use for assay Procalcitonin (PCT) and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- Differences in wording of the DiaSys Procalcitonin FS assay indications for use include the definitions of their test methods:
    - DiaSys Procalcitonin FS assay is a particle enhanced immuno-turbidimetric test intended for the quantitative in vitro determination of procalcitonin (PCT) in human serum and lithium heparin plasma on automated Abbott ARCHITECT c8000 analyzer.
    - VIDAS BRAHMS PCT is an automated test for use on the VIDAS instruments for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique.
- As described above and elsewhere in this document, the different assay methods provide equivalent function for determination of procalcitonin (PCT).

Therefore, in consideration of the above, the differences identified are not critical to the intended use of the device and do not affect the safety and effectiveness of the device when used as labeled.

(b) (1),(2) Summary of Studies

The DiaSys Procalcitonin (PCT) Assay(s) have been evaluated in accordance with current recognized standards/guidelines per the following:

Analytical Performance:

Precision/Reproducibility per the method(s) of CLSI EP05-A3 and EP15-A3, Precision and Estimation of Bias:
Total Precision

3 samples (human serum) with different values over the measuring range assayed in duplicate over 20 days using the Abbot ARCHITECT c8000 analyzer:
Reported Precision within acceptance criteria:
CV ≤ 10% at 0.2-1.0 ng/mL (actual 5.64%);
CV ≤ 7% at 1.0-3.0 ng/mL (actual 2.34%);
CV ≤ 5% at 3.0-20 ng/mL (actual 1.93%)

3 samples (human plasma) with different values over the measuring range assayed in duplicate over 20 days using the Abbot ARCHITECT c8000 analyzer:
Reported Precision within acceptance criteria:
CV ≤ 10% at 0.2-1.0 ng/mL (actual 8.31%);
CV ≤ 7% at 1.0-3.0 ng/mL (actual 3.24%);
CV ≤ 5% at 3.0-20 ng/mL (actual 2.61%)

Within-run Precision
Five samples (human serum) with values spanning the measurement and reference ranges assayed twenty times each using the Abbot ARCHITECT c8000 analyzer:
CV ≤ 10% at 0.252 ng/mL (actual 16.62%);
CV ≤ 10% at 0.555 ng/mL (actual 3.89%);
CV ≤ 7% at 2.02 ng/mL (actual 2.78%)
CV ≤ 5% at 9.68 ng/mL (actual 2.24%)
CV ≤ 5% at 18.8 ng/mL (actual 2.16%)

Five samples (human plasma) with values spanning the measurement and reference ranges assayed twenty times each using the Abbot ARCHITECT c8000 analyzer:
CV ≤ 10% at 0.314 ng/mL (actual 8.00%);
CV ≤ 10% at 0.475 ng/mL (actual 6.94%);
CV ≤ 7% at 1.910 ng/mL (actual 2.93%)
CV ≤ 5% at 9.851 ng/mL (actual 1.94%)
CV ≤ 5% at 17.953 ng/mL (actual 1.96%)

For all measured concentrations the CV is within acceptance criteria except for the CV for the human serum sample close to the assay LoQ (Limit of Quantitation), which is determined to be acceptable given its proximity to the LoQ.

Linearity/Assay Reportable Range per the method of CLSI EP06-A
Linearity in human serum and plasma is evaluated by assaying dilutions of stock solutions at least in quadruplicate. Mean values (y-axis) versus target values (x-axis) are plotted and linear regression is applied. Acceptance criteria were met:
Linearity < 0.5 ng/mL is with ± 0.1 ng/mL,
between 0.5 ng/mL to 5 ng/mL within ± 20%,
at > 5 ng/mL within ± 10%.

Detections Limits: LOB, LOD, LOQ per the method of CLSI EP17-A2
LOB and LOQ were evaluated in human serum and plasma. Acceptance criteria were LoB ≤ 0.2 ng/mL; LoQ ≤ 0.5 ng/mL – acceptance criteria were met as follows:
Limit of Blank (LOB): 0.081 ng/mL (max value of 4 series)

Limit of Detection (LOD): 0.23 ng/mL (LOD = LOQ) (%CV ≤ 20%)
Limit of Quantitation (LOQ) 0.23 ng/mL (%CV ≤ 20%)

Interference: per the method of CLSI EP07-A3
Sequential dilutions of the interfering substances are mixed in equal parts with aliquots of human samples at approximate PCT concentrations of 0.5 and 2.0 ng/mL, and each mixture is tested in five replicates. The mean measured PCT values (y-axis) are plotted against the concentration of the interfering substance (x-axis). No significant interference was observed, defined as a shift in PCT concentration greater than ±15%, when the following substances were tested at the concentrations indicated in the table below.

Interference by	Interferent concentration tested
Ascorbic acid	151 mg/dL
α-CGRP	12 µg/mL
Azithromycin	1.44 mg/dL
β-CGRP	12 µg/mL
Bilirubin (conjugated)	72.5 mg/dL
Bilirubin (unconjugated)	71.4 mg/dL
Calcitonin	10.8 ng/mL
Cefotaxime	189 mg/dL
Cromolyn	28.8 mg/L
Dobutamine	22.9 µg/mL
Dopamine	27.3 mg/dL
Doxycycline	6.61 mg/dL
Enoxaparin	24000 U/L
Ethanol	720 mg/dL
Furosemide	4.2 mg/dL
HAMA	480 ng/mL
Hemolysis	1200 mg/dL
Ibuprofen	63.1 mg/dL
Imipenem	2.52 mg/mL
Katacalcin	6 ng/mL
Lipemia (triglycerides)	1910 mg/dL
Noradrenalin	4.2 µg/mL
Pantoprazole	4.32 mg/dL
Rheumatoid factor	1020 IU/mL
Salmeterol Xinafoate	104 ng/mL

Interference by	Interferent concentration tested
Scopolamine-N-butyl bromide	72 mg/L
Total Protein	139 g/L
Vancomycin	3.78 mg/mL
N-Terminus interferes.	
There is the possibility that other substances (e.g. ingestion, drugs or during specimen preparation) and medical conditions may lead to deviating results. Detailed information on every possible interfering substance or medical condition is beyond the scope of this script.	

Stability per the method(s) of CLSI EP25-A

Real time stability

Real time stability testing of Procalcitonin FS reagent at 2 - 8°C was performed with three manufacturing lots - stability was checked by recovery of controls. Each lot was tested after manufacturing and subsequently within specific intervals. Recovery in % was calculated by dividing the value of the tested controls stored at 2 - 8°C by the target value, followed by multiplying the result by 100. Results of the continued real-time stability study confirm a stability of 25 months.

Results therefore support the stability claim of 24 months from the date of production.

In-use Stability

In-use stability of Procalcitonin FS reagent was checked by recovery of controls. One lot was tested after manufacturing and subsequently within specified intervals. After first opening, the tested controls were stored with closed cap at 2 - 8°C. Recovery in % was calculated by dividing the value of the tested controls stored at 2 - 8°C by the target, followed by multiplying the result by 100. Measured data fulfill the stability criteria for in-use stability. Results of the in-use stability study confirm a stability of at least 25 months.

Results support the in-use stability claim of 24 months from the date after opening.

Specimen Stability

Specimen stability testing were performed to the conditions specified on the DiaSys Procalcitonin FS reagent package insert:

- 24 hours at 20-25°C
- 5 days at 2-8°C
- 14 days at -20°C

15 human samples covering the entire analytical range of the DiaSys Procalcitonin FS test were measured at pre-determined times using the specified Abbot ARCHITECT c8000 analyzer. Studies were performed for both sample matrices, human serum and lithium heparin plasma, and including measurements at least 10% over the specified durations. For each test series, the acceptance criteria was within ± 15% of the concentration at time zero, and the slope of the regression line is accepted if within ± 10%.

Test results for specimen stability for the three stated conditions met the acceptance criteria.

Stability Test – Additional Freeze-Thaw Cycle
As with the stability testing above, 15 human samples covering the analytical range of the Procalcitonin FS assay were measured using the specified Abbot ARCHITECT c8000 analyzer, at time 0, then after one freeze/thaw cycle, and again after a second freeze thaw cycle. Both serum and plasma samples were tested.

All samples tested at the two freeze/thaw cycles met the acceptance value of within 15% of the concentration at time zero.

Hook Effect
No hook/prozone effect up to 1000 ng/mL.

Comparison Studies
Method Comparison
Two method comparison studies were performed per the method of CLSI EP09-A3 was performed with predicate device – VIDAS Brahms PCT Assay (K071146) and the Abbott ARCHITECT c8000 analyzer.

First method comparison study [2021]
At least 100 native patient samples were measured two times with each method. Analysis of the mean patient recovery measured by validated method (x-axis) against mean patient recovery measured by evaluation method (y-axis) by Passing & Bablok.
Results met acceptance criteria of Slope: 0.85 – 1.15; Intercept: ± 1.0 ng/mL; Correlation coefficient R: ≥ 0.95; n ≥ 100 as follows:
N = 120
Slope = 1.08
Intercept = 0.105 ng/mL
R = 0.991

PCT Cutoff	Negative Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)
0.5 ng/mL	93.9% (79.8% to 99.3%)	100% (95.9% to 100%)
2.0 ng/mL	93.3% (85.1% to 97.8%)	97.8% (88.2% to 99.9%)

Second method comparison study [2025]
At least 200 native patient samples were measured two times with each method. Analysis of the mean patient recovery measured by validated method (x-axis) against mean patient recovery measured by evaluation method (y-axis) by Passing/Bablok.
Results met acceptance criteria of Slope: 0.85 – 1.15; Intercept: ± 1.0 ng/mL; Correlation coefficient R: ≥ 0.95; n ≥ 100 as follows:
N = 210
Slope = 0.940
Intercept = 0.017 ng/mL
R = 0.965

PCT Cutoff	Negative Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)
0.5 ng/mL	98% (92.9% to 99.8%)	100% (96.7% to 100%)
2.0 ng/mL	100% (97.5% to 100%)	94% (85.4% to 98.4%)

Matrix Comparison per the method of CLSI EP09-A3 was performed with human serum and lithium heparin plasma.
At least 20 native patient samples were measured two times for each matrix. Analysis of the mean patient recovery measured in serum matrix (x-axis) against mean patient recovery measured in heparin plasma matrix (y-axis) by Passing & Bablok.
Results of matrix study met acceptance criteria of Slope: 0.85 – 1.15; Intercept: ± 1.0 ng/mL; Correlation coefficient $R \geq 0.98$; $n \geq 20$.

FDA Special Controls
The DiaSys Procalcitonin (PCT) Assay(s) have been analyzed to the requirements of FDA Special Controls per 21 CFR § 866.3215.

Risk Management
Risk management has been performed in accordance with the following standard and includes the following risk management documentation:

- ISO 14971:2019, Medical devices—Risk management—Application of risk management to medical devices
- Procalcitonin (PCT) Assay Risk Analysis performed in accordance with ISO 14971
- Procalcitonin (PCT) Assay FMEA

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the DiaSys Procalcitonin FS assay is equivalent to the predicate device as supported by the referenced verification and validation testing.

The results of all tests demonstrate that the DiaSys Procalcitonin FS assay, DiaSys TruCal Procalcitonin Calibrator Set; and DiaSys TruLab Procalcitonin Bi-Level Controls meet specified requirements for performance and substantial equivalence to the referenced predicate device.