December 20, 2022

Cytovale Inc.
Juliet Carrara
Exec. Vice President of Regulatory & Clinical Affairs and Quality Assurance
150 Executive Park Blvd, Suite 4100
San Francisco, California 94134

Re: K220991
Trade/Device Name: IntelliSep test
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: QUT
Dated: March 31, 2022
Received: April 4, 2022

Dear Juliet Carrara:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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

Digitally signed by Bryan M. Grabias -S
Date: 2022.12.20 13:35:28 -05'00'

for

Noel Gerald
Branch Chief
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220991

Device Name
IntelliSep test

Indications for Use *(Describe)*
The Cytovale IntelliSep test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing. It is indicated for use in adult patients with signs and symptoms of infection who present to the Emergency Department. The test is performed on an EDTA anticoagulated whole blood sample.

The IntelliSep test generates an IntelliSep Index value that falls within one of three discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first three days after testing. The IntelliSep test represents the probability of the clinical syndrome of sepsis and is intended to be used alongside other clinical information and clinical judgement. It does not identify the causative agent of infection and should not be used as the sole basis to determine the presence of sepsis. The IntelliSep test is intended for in vitro diagnostic use.

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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1 510(k) Owner / Submitter Information Name

Name: Cytovale, Inc.
Address: 150 Executive Park Blvd, Suite 4100, San Francisco, CA 94134
Telephone: 1-415-417-2188
Contact Person: Juliet Carrara
Email Address: juliet.carrara@cytovale.com

2 Date Summary was Prepared

December 19, 2022

3 Device Name and Classification

Trade Name: IntelliSep test
Instrument Name: Cytovale System
Classification: Class II (Special Controls)
Classification Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis (21 CFR 866.3215)
Product Code: QUT
Panel: 83 - Division of Microbiology Devices

4 Predicate Device Information

Predicate Product	510(k) Number	Date of Clearance	Classification	Regulation	Classification Product Code
VIDAS B·R·A·H·M·S PCT (PCT)	K162827	February 23, 2017	Class II (Special Controls)	866.3215	PRI

Table 1: Predicate device information

5 Device Description

The Cytovale IntelliSep test is a short turn-around time (STAT) test, producing results in 10 minutes or less, to aid in the early identification of patients at risk for having or developing sepsis within three (3) days of testing. It assesses the state of immune activation in patients with clinical suspicion of infection who present in the Emergency Department (ED).

The IntelliSep test is run on the Cytovale System, a laboratory benchtop analyzer depicted in Figure 1.

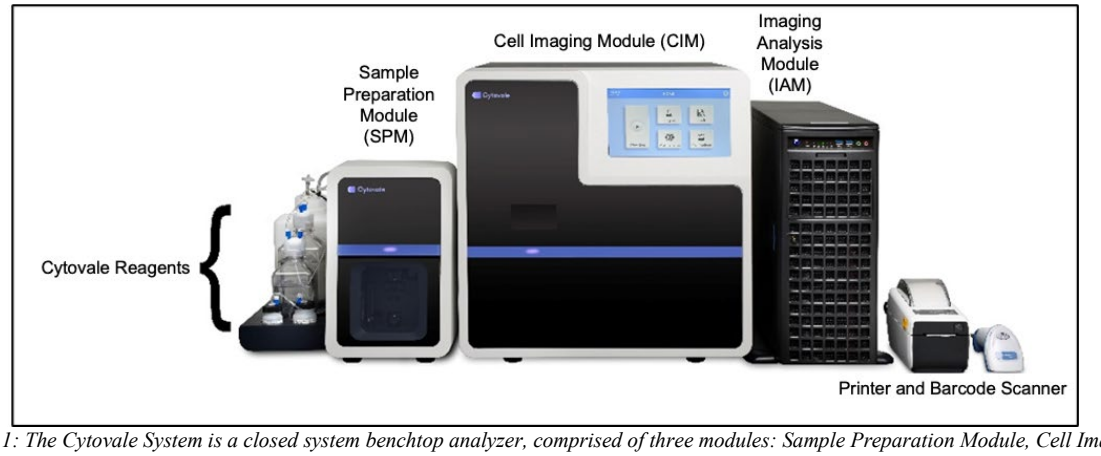

Figure 1: The Cytovale System is a closed system benchtop analyzer, comprised of three modules: Sample Preparation Module, Cell Imaging Module, and Imaging Analysis Module. Also included are the Cytovale System Reagents (Cytovale Reagent Kit, Cytovale Diluent, Cytovale Cleanse), Barcode Scanner and Printer (not shown: IntelliSep Quality Controls, IntelliSep Cartridge, Sample Preparation Tube).

The IntelliSep test requires use of the materials described in Table 2.

IntelliSep test Materials & Equipment	Description
Cytovale System: (Required and supplied) • Sample Preparation Module (SPM) • Cell Imaging Module (CIM) • Imaging Analysis Module (IAM)	A closed system benchtop analyzer as shown in Figure 1. It is comprised of three modules: Sample Preparation Module, Cell Imaging Module and Imaging Analysis Module.
Barcode scanner (Optional and supplied)	Scanner used to automatically enter sample and material identifiers.
Printer (Optional and supplied)	Printer used to print a hard copy of results.
Sample Preparation Tube (Required and supplied)	A single-use, commercial off-the-shelf test tube used for sample preparation.
IntelliSep Cartridge (Required and supplied)	Closed system test cartridge which presents the sample for testing in the Cell Imaging Module.
Cytovale Reagent Kit (Required and supplied)	Nonbiological salt solutions (Reagent A Lysis and Reagent B Quench), for use with the Sample Preparation Module to lyse red blood cells and quench the lysis reaction.
Cytovale Diluent and Cleanse Reagents (Required and supplied)	The Diluent solution is used in the Sample Preparation Module to suspend white blood cells for analysis. The Cleanse is a rinsing solution for the SPM.
IntelliSep Quality Control Kit (Quality controls are required but not supplied)	A two-level Quality Control set, derived from stabilized whole blood. *Note: Per 42 CFR 493.1256, quality controls are required for the IntelliSep test; however, at their discretion, laboratory directors may develop their own quality control materials or order the IntelliSep Quality Control Kit.*

Table 2: Materials and equipment required for the IntelliSep test

To run a test, the laboratory operator transfers 100 µL of whole blood into the sample preparation tube which is then placed into the Cytovale System. The system automatically lyses red blood cells, and washes the purified leukocytes in a diluent, producing a total volume of approximately 1mL of prepared sample, which the operator then transfers to the IntelliSep cartridge for analysis on the Cytovale System.

A microfluidic deformability cytometry technique is used to measure the biophysical properties of thousands of individual leukocytes in rapid succession. These properties have been shown to differ in quiescent white blood cell populations when compared to those in septic patients, enabling for rapid assessment of the host response and the likelihood of having or developing sepsis. Based on these measurements, the test provides a single score, the IntelliSep Index (ISI), ranging from 0.1-10.0, stratified into three discrete interpretation bands (Band 1, Band 2, Band 3) of sepsis likelihood.

6 Intended Use

The Cytovale IntelliSep test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ

dysfunction manifesting within the first 3 days after testing. It is indicated for use in adult patients with signs and symptoms of infection who present to the Emergency Department. The test is performed on an EDTA anticoagulated whole blood sample.

The IntelliSep test generates an IntelliSep Index value that falls within one of three discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first three days after testing. The IntelliSep test represents the probability of the clinical syndrome of sepsis and is intended to be used alongside other clinical information and clinical judgement. It does not identify the causative agent of infection and should not be used as the sole basis to determine the presence of sepsis. The IntelliSep test is intended for in vitro diagnostic use.

7 Indication for Use

See "Intended Use"

8 Overall Comparison Between Subject Device and Predicate

The indications for use for both the subject and predicate devices are comparable, as they are both intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of sepsis in acute patient populations. The indications for use for the subject and predicate devices differ in the type of analytical method used to detect their specific intended assay markers and in the specific subpopulations of acute patients being assessed (e.g., Emergency Dept vs ICU).

Identification and analysis of non-microbial host immune response analytes is the scientific foundation for both the subject and predicate devices. For the predicate device, quantification of procalcitonin is performed to assess the inflammatory response to bacterial infection. The subject device instead quantifies changes in cellular biophysical properties of leukocytes (immune cells) that occur as part of the inflammatory response to infection. While the intended uses of the predicate and subject device are similar, the predicate device measures a released biomarker and the subject device directly evaluates cellular morphology.

Both the predicate and the subject device aid in the identification of sepsis in conjunction with other laboratory findings and clinical assessments. None of the differences constitute a new intended use for the subject device.

Information related to this comparison is tabulated in Table 3.

	Candidate Device	**Predicate Device**
Item	**Cytovale System and IntelliSep test**	**VIDAS B·R·A·H·M·S PCT (K162827)**
Intended Use / Indications for Use	The Cytovale IntelliSep test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing. It is indicated for use in adult patients with signs and symptoms of infection	VIDAS B·R·A·H·M·S PCT is an automated test for use on the instruments of the VIDAS family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS

	Candidate Device	**Predicate Device**
Item	**Cytovale System and IntelliSep test**	**VIDAS B·R·A·H·M·S PCT (K162827)**
	who present to the Emergency Department. The test is performed on an EDTA anticoagulated whole blood sample. The IntelliSep test generates an IntelliSep Index value that falls within one of three discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first three days after testing. The IntelliSep test represents the probability of the clinical syndrome of sepsis and is intended to be used alongside other clinical information and clinical judgement. It does not identify the causative agent of infection and should not be used as the sole basis to determine the presence of sepsis. The IntelliSep test is intended for in vitro diagnostic use.	B·R·A·H·M·S PCT is intended for use as follows: • 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, to aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time, • to aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department, • to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.
Site of Use	To be performed by trained laboratory personnel in a clinical or hospital laboratory setting	To be performed by a trained operator in a professional setting, such as a hospital central laboratory
Specimen Type	Human venous whole blood (K2 EDTA)	Human serum, plasma (lithium heparinate)
Specimen Stability	Five (5) hours after draw at ambient conditions	The sera or plasma separated from the clot can be stored at 2-8°C in stoppered tubes for up to 48 hours; if longer storage is required, freeze at -25 ± 6°C. Six-month storage of frozen samples does not affect the quality of results. Three freeze/thaw cycles were validated
Specimen Processing	1. Automated closed system (Sample Preparation Module) which only operates with proprietary reagents. 2. The operator transfers the processed sample into the IntelliSep Cartridge which is inserted into the Cell Imaging Module for analysis.	Instruments of the VIDAS family: VIDAS, miniVIDAS or VIDAS 3, using conjugate and solid phase antibodies and custom reagents
Analyte(s)	Leukocyte biophysical properties	Procalcitonin (PCT)

	Candidate Device	**Predicate Device**
Item	**Cytovale System and IntelliSep test**	**VIDAS B·R·A·H·M·S PCT (K162827)**
Assay Principle/Method	Microfluidic deformability cytometry	Quantitative immunofluorescent assay, based on Sandwich immunoassay principles, which measures a specific fluorescence signature (fluorescence (ELFA) of 4-methyl-umbelliferyl measured at 450 nm) that is proportional to the antigen (PCT) concentration.
Controls	IntelliSep Quality Control Kit including two levels of controls derived from stabilized whole blood: • Level 1 Control • Level 2 Control	Two levels of antigen concentration. Each vial contains lyophilized recombinant PCT in TRIS NaCl buffer (pH 7.3) and preservatives.
Instrument Platform	Cytovale System	Instruments of the VIDAS family: VIDAS, miniVIDAS or VIDAS 3
Result Output	The IntelliSep Index (ISI, range 0.1 to 10.0) that falls within one of three discrete interpretation bands (Band 1, Band 2, Band 3) based on likelihood of sepsis within three (3) days of testing	Calculated estimate of concentration of circulating PCT, in units of ng/mL
Reagent Stability	1. In original shipping containers unopened at ambient temperature (15-30°C): up to the stated expiration date; 2. After opening, onboard at ambient temperature (15-30°C): 30 days	1. In original shipping containers unopened at 2-8°C: up to the stated expiration date (12 months); 2. After opening, onboard at 2-8 °C: 29 days
Limitations	• Using a different Sample Preparation Tube than the one provided may lead to erroneous results. • Smeared blood on the side of the Sample Preparation Tube may cause the test to fail. Remove blood smears from the sides of the sample preparation tube using the specified lint-free foam swab. Using a different swab other than the one required may lead to no result returned. • 100 µL ± 5 µL of specimen volume is needed for sample preparation. An erroneous result may occur if the volume of the sample transferred to the Sample Preparation Tube is different from the required volume. • Use only EDTA anticoagulated whole blood within 5 hours of collection. • Predictive values (estimated probabilities of sepsis) are dependent on prevalence of disease and likelihood ratios measured for	VIDAS B·R·A·H·M·S PCT (PCT) is not indicated to be used as a standalone diagnostic assay and should be used in conjunction with clinical signs and symptoms of infection and other diagnostic evidence. Decisions regarding antibiotic therapy should NOT be based solely on procalcitonin concentrations. PCT results should always be interpreted in the context of the clinical status of the patient and other laboratory results. Changes in PCT levels for the prediction of mortality, and overall mortality, are strongly dependent on many factors, including pre-existing patient risk factors and clinical course. The need to continue ICU care at Day 4 and other covariates (e.g., age and SOFA score)

	Candidate Device	**Predicate Device**
Item	**Cytovale System and IntelliSep test**	**VIDAS B·R·A·H·M·S PCT (K162827)**
	the clinical trial population as reported in the Clinical Performance Summary. Users should establish or verify that these parameter values are appropriate for the patient population being tested. The clinical performance has not been established in the following populations: • Patients below 18 years of age. • Patients with a history of a hematologic malignancy (any leukemia, lymphoma, or myeloma), myelodysplastic syndrome, or myeloproliferative disorder • Patients who have undergone a hematopoietic stem cell transplant or any solid organ transplant • Patients receiving a cytotoxic chemotherapeutic agent in the past 3 months • Patients who are residents or patients of a hospital-based skilled nursing facility • Patients who received systemic corticosteroids were not excluded from the clinical study. However, the study was not powered to evaluate the performance of the ISI specifically in this population and as such clinical performance has not been established in this population. • Patients with pre-existing end stage renal disease (ESRD) who undergo hemodialysis were not excluded from the clinical study. However, the study was not powered to evaluate the performance of the ISI specifically in this population and as such clinical performance has not been established in this population. • This test was not evaluated for sequential monitoring of patients, or for use in patients past the initial ED encounter. • The clinical study was not adequately powered to evaluate differences in demographics and subpopulations, therefore results should be interpreted in conjunction with clinical assessments and other laboratory findings.	are also significant predictors of 28-day cumulative mortality risk. Certain patient characteristics, such as severity of renal failure or insufficiency, may influence procalcitonin values and should be considered as potentially confounding clinical factors when interpreting PCT values. Increased PCT levels may be observed in severe illness such as polytrauma, burns, major surgery, prolonged or cardiogenic shock. PCT levels may not be elevated in patients infected by certain atypical pathogens, such as Chlamydophila pneumoniae and Mycoplasma pneumoniae. The safety and performance of PCT-guided therapy for individuals younger than age 17 years, pregnant women, immunocompromised individuals or those on immunomodulatory agents, was not formally analyzed in the supportive clinical trials.

Table 3: Comparison between subject device and predicate device

9 Performance Testing

9.1 Clinical Performance Summary

Cytovale conducted a blinded, prospective, observational, multicenter cohort study at five hospitals at four geographically dispersed sites comprised of both academic and community hospital Emergency Departments (EDs) in the United States. The study cohort was representative of the adult population (≥ 18 years of age) typical of those presenting to EDs across the United States with signs or suspicion of infection (defined as meeting two or more Systemic Inflammatory Response Syndrome (SIRS) criteria where one must be aberration of temperature or white blood cell count OR an order placed for cultures of blood, sputum, urine, or sterile body fluids).

599 subjects were enrolled in the study and 572 evaluable subjects were included in the primary analyses. As shown in Table 4, subjects spanned across ranges of age (18 to 103 years of age; 33% of subjects ≥ 65), race (62% white, 30% Black or African American, 2% Asian, and 6% other), ethnicity (6% Hispanic), and sex (44% female). They encompassed those with common comorbidities, including but not limited to diabetes, hypertension, chronic kidney disease, cancer, and obesity. Infection sources affecting or originating from all major organ systems (i.e., respiratory, genitourinary, skin, gastrointestinal, cardiovascular system, central nervous system, and bone) were represented in the study. Additionally, because this study was conducted during the COVID-19 pandemic, 9% of the subjects enrolled in the study were SARS-CoV-2 positive.

The IntelliSep test was performed on an EDTA anticoagulated whole blood sample obtained within 4 hours of the first recorded vital sign (triage). Subsequently, subjects were followed with retrospective chart review for outcome information. Subjects received standard of care and treating physicians were unaware of study enrollment and IntelliSep test results.

Population Characteristic		**Total (N = 572)**	**Sepsis Status (Sepsis-3 Forced)**	
			Positive (N = 152)	**Negative (N = 420)**
Age	Median (Q1 – Q3)	56.0 (40.0 - 68.0)	63.0 (46.0 - 73.0)	53.00 (37.0 - 66.0)
	Subjects ≥ 65 N (%)	187 (32.69%)	69 (45.39%)	118 (28.10%)
Sex N (%)	Female	250 (43.71%)	57 (37.50%)	193 (45.95%)
	Male	322 (56.29%)	95 (62.50%)	227 (54.05%)
Ethnicity N (%)	Hispanic	35 (6.12%)	5 (3.29%)	30 (7.14%)
	Non-Hispanic	527 (92.13%)	145 (95.39%)	382 (90.95%)
	Not Provided	10 (1.75%)	2 (1.32%)	8 (1.90%)
Race N (%)	American Indian or Alaska Native	8 (1.40%)	1 (0.66%)	7 (1.67%)
	Asian	10 (1.75%)	0 (0.00%)	10 (2.38%)
	Black or African American	172 (30.07%)	42 (27.63%)	130 (30.95%)
	Native Hawaiian or Other Pacific Islander	6 (1.05%)	2 (1.32%)	4 (0.95%)
	White	356 (62.24%)	101 (66.45%)	255 (60.71%)
	Other	20 (3.50%)	6 (3.95%)	14 (3.33%)
Source of infection in Subjects Adjudicated as Infected, multiple	Bone / Joint	19 (6.64%)	11 (7.24%)	8 (5.97%)
	Cardiovascular System	20 (6.99%)	13 (8.55%)	7 (5.22%)
	Central Nervous System	13 (4.55%)	12 (7.89%)	1 (0.75%)
	Gastrointestinal / Abdominal	32 (11.19%)	17 (11.18%)	15 (11.19%)

Population Characteristic		Total (N = 572)	Sepsis Status (Sepsis-3 Forced)	
			Positive (N = 152)	Negative (N = 420)
sources included per subject (N, % of infected)	Respiratory System	125 (43.71%)	81 (53.29%)	44 (32.84%)
	Skin	57 (19.93%)	21 (13.82%)	36 (26.87%)
	Urine & Urine System / Genitourinary	76 (26.57%)	49 (32.24%)	27 (20.15%)
	Other or Unknown	24 (8.39%)	11 (7.24%)	13 (9.70%)
SARS-CoV-2 Testing N (%)	Number Tested	391 (68.36%)	128 (84.21%)	263 (62.62%)
	Number Positive (of Tested)	54 (13.81%)	37 (28.91%)	17 (6.46%)
	Number Positive (of Total)	54 (9.44%)	37 (24.34%)	17 (4.05%)

Table 4: Study population characteristics per sepsis status (Sepsis-3 consensus definition in the forced adjudication scheme)

The performance of the IntelliSep test was evaluated by comparison to non-reference retrospective physician adjudication. As detailed below, all subjects were adjudicated by two qualified physicians following the consensus definitions for Sepsis-2 and Sepsis-3. Discordant results were arbitrated through a committee meeting that included a third physician. The adjudication process determined each case to be 'Sepsis' or 'Not sepsis' with 'unanimous', 'consensus' or 'forced' determinations for both Sepsis-2 and Sepsis-3 consensus definitions. No cases were excluded due to inability to arbitrate. All study personnel, including study adjudicators, were blinded to the IntelliSep test results.

A multi-tiered adjudication process was utilized to standardize and reduce the inherent subjectivity and variability of using a non-reference comparator. Approximately 30 days after the subject was enrolled, a chart review, using a structured case report form (CRF), was performed. All sites were required to extract the same information to enable adjudication based on the case report form. The information captured included demographics, laboratory results, vital signs, past medical history, hospital encounter information, infectious disease information, medications, and discharge disposition. Additionally, objective evidence of infection (present at the time of ED presentation) and organ dysfunction (manifesting within 3 days following ED presentation) using the Sequential (sepsis-related) Organ Failure Assessment (SOFA) score was captured. Furthermore, a clinical impression was prepared by designated study-trained physicians that were not involved in the subject's care.

Information obtained from the Demographic and Clinical Case Report Forms, Objective Evaluation, and the clinical impression was then compiled into a case report summary (CRS) and sent to two independent adjudicators. If the two adjudicators agreed in their determination, the case was considered 'unanimous' adjudication. If there was disagreement, the CRS was sent to a third adjudicator and a consensus meeting was held. If all could agree, the case fell under 'consensus' or if following discussion consensus could not be reached, a 'forced' (majority two out of three) adjudication determination was reached. The study independent adjudication committee comprised of physicians with board certification in Medical or Surgical Critical Care (CC), Infectious Diseases (ID), Emergency Medicine (EM) or Internal Medicine (IM) or related fields, from different institutions who were not participating as an Investigator in the Study. Individual cases were assigned to the adjudicators by a third-party vendor, without involvement from Cytovale. Adjudicators were blinded to the identity of the Site Investigators and Medical Monitors.

The prevalence of sepsis, using the forced Sepsis-3 consensus definition adjudication scheme, was 26.6%. Results across all approaches to analyzing retrospective physician adjudication results were consistent, i.e., a clear relationship was observed between IntelliSep Index (ISI) and the increasing likelihood of having or developing sepsis within 3 days across (Figure 2). Irrespective of the comparator scheme chosen, the probability of sepsis in the three ISI IntelliSep test Interpretation Bands was statistically distinct, defined as non-overlapping 80% confidence intervals between the bands (Table 5 through Table 7). It is important to note that the algorithm for calculating the ISI ranges for the interpretation bands were defined based on prior sepsis-focused studies. No information from patients in this study influenced the calculations or interpretation bands of the ISI.

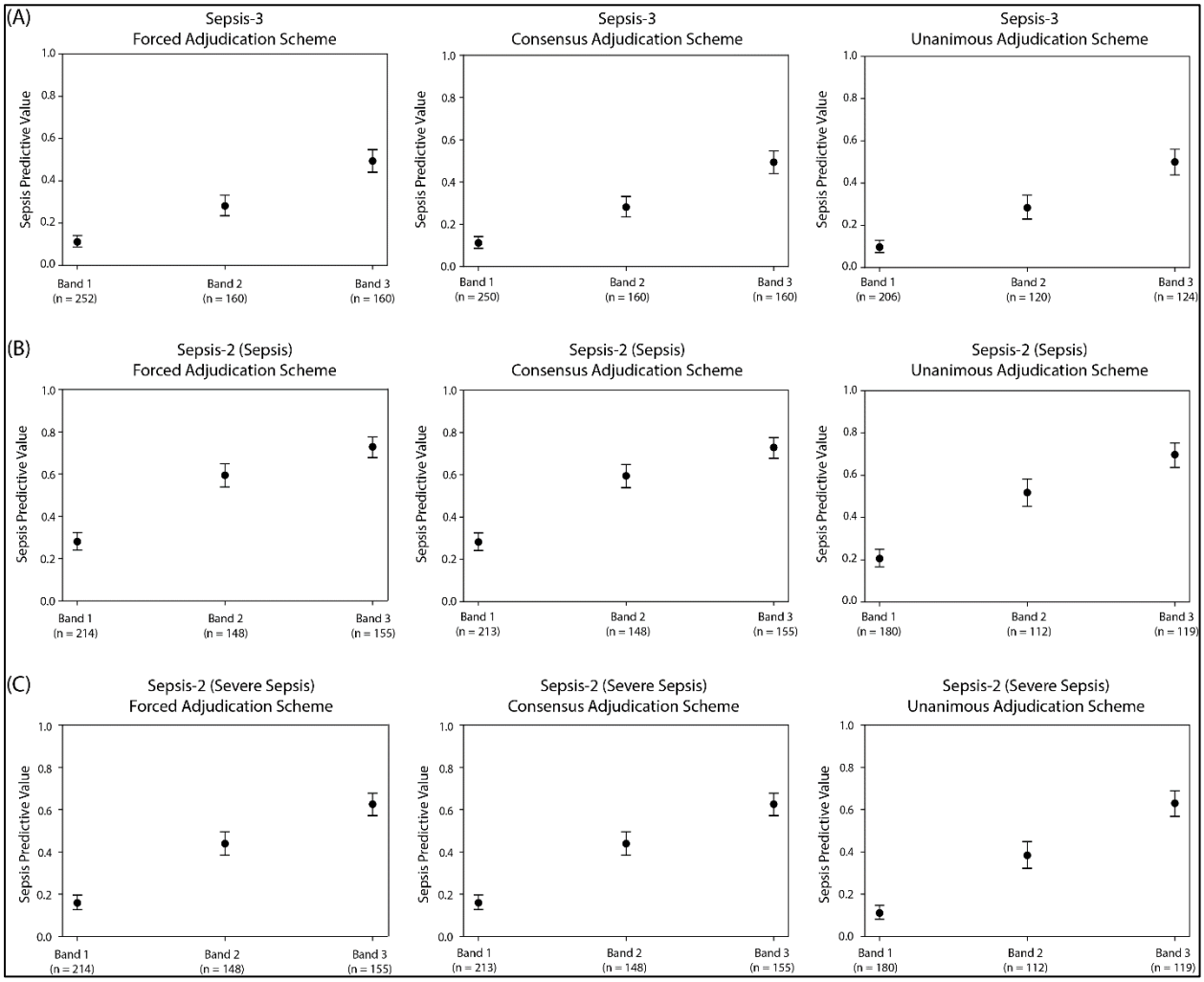

Figure 2: Plots of sepsis predictive value in each band across all approaches to analyzing retrospective physician adjudication results: (A) Sepsis-3 consensus definition, (B) Sepsis per Sepsis-2 consensus definition, (B) Severe Sepsis per Sepsis-2 consensus definition, (C) Severe Sepsis per Sepsis-2 consensus definition, for forced, consensus, and unanimous adjudication schemes.

Sepsis-3 consensus definition, forced adjudication scheme (n=572)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	28	224	11.1% (8.6%, 14.1%)	0.35
Band 2	45	115	28.1% (23.5%, 33.2%)	1.08
Band 3	79	81	49.4% (44.0%, 54.7%)	2.69
			Sepsis Prevalence	
Total	152	420	26.6%	NA
Sepsis-3 consensus definition, consensus adjudication scheme (n=570)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	28	222	11.2% (8.7%, 14.2%)	0.35
Band 2	45	115	28.1% (23.5%, 33.2%)	1.08
Band 3	79	81	49.4% (44.0%, 54.7%)	2.68
			Sepsis Prevalence	
Total	152	418	26.7%	NA
Sepsis-3 consensus definition, unanimous adjudication scheme (n=450)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	20	186	9.7% (7.1%, 12.9%)	0.31
Band 2	34	86	28.3% (23.0%, 34.3%)	1.14
Band 3	62	62	50.0% (43.9%, 56.1%)	2.88
			Sepsis Prevalence	
Total	116	334	25.8%	NA

Table 5: Distribution of subjects, sepsis prevalence, and sepsis likelihood ratios in the three ISI IntelliSep test Interpretation Bands for Sepsis-3 consensus definition for forced, consensus, and unanimous adjudication schemes.

Sepsis-2 (sepsis) consensus definition, forced adjudication scheme (n=517)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	60	154	28.0% (24.0%, 32.4%)	0.38
Band 2	88	60	59.5% (53.9%, 64.9%)	1.44
Band 3	113	42	72.9% (67.8%, 77.6%)	2.64
			Sepsis Prevalence	
Total	261	256	50.5%	NA
Sepsis-2 (sepsis) consensus definition, consensus adjudication scheme (n=516)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	60	153	28.2% (24.2%, 32.5%)	0.38
Band 2	88	60	59.5% (53.9%, 64.9%)	1.43
Band 3	113	42	72.9% (67.8%, 77.6%)	2.63
			Sepsis Prevalence	
Total	261	255	50.6%	NA
Sepsis-2 (sepsis) consensus definition, unanimous adjudication scheme (n=411)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value Prevalence (80% CI)	Sepsis Likelihood Ratio
Band 1	37	143	20.6% (16.7%, 24.9%)	0.34
Band 2	58	54	51.8% (45.3%, 58.2%)	1.41
Band 3	83	36	69.8% (63.7%, 75.3%)	3.02
			Sepsis Prevalence	
Total	178	233	43.3%	NA

Table 6: Distribution of subjects, sepsis prevalence, and sepsis likelihood ratios in the three ISI IntelliSep test Interpretation Bands for sepsis per Sepsis-2 consensus definition for forced, consensus, and unanimous adjudication schemes.

Sepsis-2 (severe sepsis) consensus definition, forced adjudication scheme (n=517)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	34	180	15.9% (12.7%, 19.6%)	0.31
Band 2	65	83	43.9% (38.4%, 49.5%)	1.28
Band 3	97	58	62.6% (57.2%, 67.7%)	2.74
			Sepsis Prevalence	
Total	196	321	37.9%	NA
Sepsis-2 (severe sepsis) consensus definition, consensus adjudication scheme (n=516)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	34	179	16.0% (12.8%, 19.7%)	0.31
Band 2	65	83	43.9% (38.4%, 49.5%)	1.28
Band 3	97	58	62.6% (57.2%, 67.7%)	2.73
			Sepsis Prevalence	
Total	196	320	38.0%	NA
Sepsis-2 (severe sepsis) consensus definition, unanimous adjudication scheme (n=411)				
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)	Sepsis Likelihood Ratio
Band 1	20	160	11.1% (8.2%, 14.7%)	0.25
Band 2	43	69	38.4% (32.3%, 44.8%)	1.23
Band 3	75	44	63.0% (56.8%, 68.9%)	3.37
			Sepsis Prevalence	
Total	138	273	33.6%	NA

Table 7: Distribution of subjects, sepsis prevalence, and sepsis likelihood ratios in the three ISI IntelliSep test Interpretation Bands for severe sepsis per Sepsis-2 consensus definition for forced, consensus, and unanimous adjudication schemes.

The IntelliSep ISI risk stratification score trended upwards with the adjudication determination of sepsis independent of demographic groups (age, sex, race, and ethnicity; Table 8). Additionally, trends were observed between increasing ISI values across the Interpretation bands and hospital care metrics (e.g., hospital admission, ICU admission and transfer, hospital length of stay, and administration of antibiotics; Table 9). It is important to note, that the study was not designed nor powered to evaluate endpoints with regards to severity of illness or hospital care metrics (e.g., mortality, severity of illness scores, hospital admission and length

of stay, etc.) and any significant trends or correlations observed between these metrics and the ISI and its Interpretation bands are only observational.

Additionally, subjects who have received systemic corticosteroids and subjects with pre-existing end stage renal disease (ESRD) who undergo hemodialysis were not excluded from the clinical study, however, the study was not powered to evaluate the performance of the ISI specifically in these subpopulations.

Population Characteristic		IntelliSep test Results		
		Band 1 (N = 252)	**Band 2 (N = 160)**	**Band 3 (N = 160)**
Age	Median (Q1 – Q3)	54.0 (39.5 - 67.0)	56.0 (39.0 - 68.0)	58.0 (41.5 - 71.0)
	Subjects ≥ 65, N (%)	77 (30.56%)	54 (33.75%)	56 (35.00%)
Sex, N (%)	Female	106 (42.06%)	68 (42.50%)	76 (47.50%)
	Male	146 (57.94%)	92 (57.50%)	84 (52.50%)
Ethnicity, N (%)	Hispanic	20 (7.94%)	8 (5.00%)	7 (4.38%)
	Non-Hispanic	227 (90.08%)	148 (92.50%)	152 (95.00%)
	Not Provided	5 (1.98%)	4 (2.50%)	1 (0.62%)
Race (%)	American Indian or Alaska Native	2 (0.79%)	3 (1.88%)	3 (1.88%)
	Asian	7 (2.78%)	2 (1.25%)	1 (0.62%)
	Black or African American	76 (30.16%)	47 (29.38%)	49 (30.62%)
	Native Hawaiian or Other Pacific Islander	3 (1.19%)	0 (0.00%)	3 (1.88%)
	White	154 (61.11%)	104 (65.00%)	98 (61.25%)
	Other	10 (3.97%)	4 (2.50%)	6 (3.75%)

Table 8: Study population demographic characteristics per IntelliSep test interpretation bands.

Population Characteristic		Total (N = 572)	IntelliSep test Results		
			Band 1 (N = 252)	**Band 2 (N = 160)**	**Band 3 (N = 160)**
All-Cause Cumulative In-Hospital Mortality N (%)	3-day	3 (0.52%)	1 (0.40%)	0 (0.00%)	2 (1.25%)
	7-day	9 (1.57%)	3 (1.19%)	1 (0.62%)	5 (3.12%)
	30-day	24 (4.20%)	6 (2.38%)	7 (4.38%)	11 (6.88%)
Admitted to Hospital, N (%)		360 (62.94%)	123 (48.81%)	107 (66.88%)	130 (81.25%)
Admitted to ICU, N (%)		71 (12.41%)	20 (7.94%)	23 (14.38%)	28 (17.50%)
Transferred to ICU within 3 Days, N (%)		25 (4.37%)	1 (0.40%)	15 (9.38%)	9 (5.62%)
Length of stay Median (Q1-Q3)	Alive at 30 days	3.0 (0.0 - 7.0)	2.0 (0.0 - 4.0)	4.0 (0.0 - 8.0)	5.0 (3.0 - 9.0)
	Deceased in-hospital within 30 days	8.5 (6.5 - 14.5)	9.0 (5.5 - 12.0)	9.0 (8.5 - 12.5)	8.0 (5.0 - 16.5)
ICU Length of stay Median (Q1 - Q3)	Alive at 30 days	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
	Deceased in-hospital within 30 days	6.5 (2.0 - 12.5)	5.5 (0.0 - 11.5)	8.0 (7.0 - 11.0)	5.0 (2.0 - 10.0)
Antibiotics Prescribed N (%)	Yes	301 (52.62%)	99 (39.29%)	81 (50.62%)	121 (75.62%)
	No	267 (46.68%)	152 (60.32%)	77 (48.12%)	38 (23.75%)
	Unknown	4 (0.70%)	1 (0.40%)	2 (1.25%)	1 (0.62%)

Table 9: Study population severity of illness and hospital course characteristics per IntelliSep test interpretation bands. Note: In the calculation of APACHE II scores, for subjects for whom a lab value was not collected per standard of care, the value was considered normal.

9.2 Descriptive (Non-Powered) Analyses

In addition to examining study endpoints, descriptive non-powered analyses were performed to explore test performance by demographic subgroups. These non-powered descriptive analyses evaluated the association of IntelliSep Index (expressed in terms of its Interpretation Bands) with the predictive value of sepsis (an adjudicated non-reference method) using the Sepsis-3 consensus standard definition, for demographic subgroups split by age and sex.

The association was examined by the non-overlap of the 80% confidence intervals around point estimates for the probability of sepsis in Band 1 and Band 3 These descriptive analyses were performed using a forced adjudication scheme with evaluable subjects and are shown in Table 10 and Figure 3 (age, <65 and ≥65 years) and Table 11 and Figure 4 (sex, male and female).

Age < 65, Sepsis-3 consensus definition, forced adjudication scheme (n=385)			
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)
Band 1	17	158	9.7% (6.9%, 13.2%)
Band 2	25	81	23.6% (18.3%, 29.7%)
Band 3	41	63	39.4% (33.0%, 46.2%)
Age ≥ 65, Sepsis-3 consensus definition, forced adjudication scheme (n=187)			
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)
Band 1	11	66	14.3% (9.3%, 20.8%)
Band 2	20	34	37.0% (28.2%, 46.8%)
Band 3	38	18	67.9% (58.6%, 76.1%)

Table 10: Descriptive (Non-Powered) Analysis: Results for Sepsis-3 Forced by Age Group

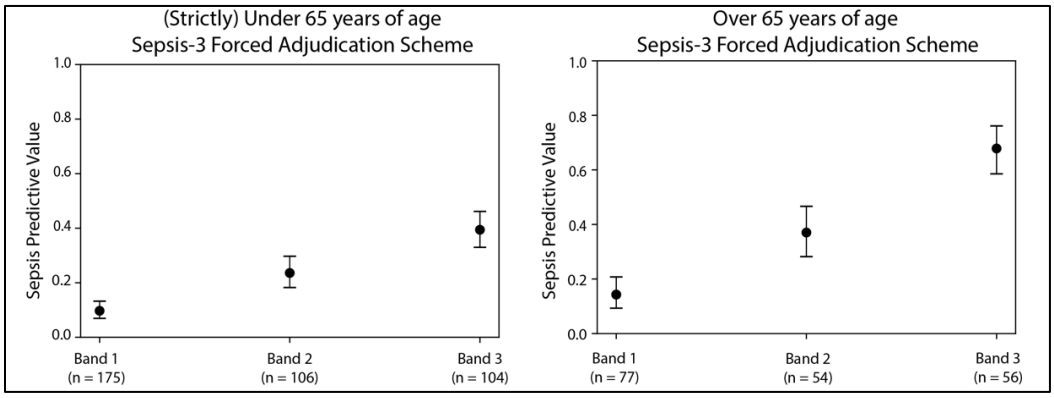

Figure 3:Plot of sepsis predictive value (% of subjects adjudicated as septic) in each band for Sepsis-3 Forced by Age Group

Females, Sepsis-3 consensus definition, forced adjudication scheme (n=250)			
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)
Band 1	9	97	8.5% (5.2%, 13.1%)
Band 2	19	49	27.9% (20.8%, 36.1%)
Band 3	29	47	38.2% (30.7%, 46.1%)
Males, Sepsis-3 consensus definition, forced adjudication scheme (n=322)			
IntelliSep Result	Adjudicated +	Adjudicated -	Sepsis Predictive Value (80% CI)
Band 1	19	127	13.0% (9.5%, 17.3%)
Band 2	26	66	28.3% (22.1%, 35.1%)
Band 3	50	34	59.5% (52.0%, 66.7%)

Table 11: Descriptive (Non-Powered) Analysis: Results for Sepsis-3 Forced by Sex

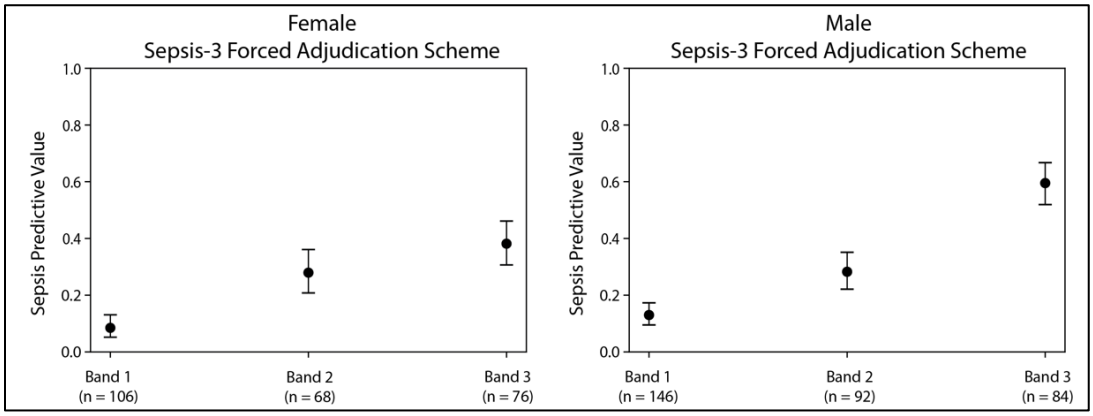

Figure 4: Plot of sepsis predictive value (% of subjects adjudicated as septic) in each band for Sepsis-3 Forced by Sex

9.3 Analytical Performance

9.3.1 Analytical Sensitivity

Analytical sensitivity (limit of detection, limit of blank, and limit of quantitation) performance testing is not applicable to the IntelliSep test.

9.3.2 Precision and Repeatability / Reproducibility

9.3.2.1 Within-Laboratory Precision (Repeatability)

The within-laboratory precision for the IntelliSep test was measured according to CLSI EP05-A3. Testing was conducted at 3 sites. At each site, 4 donor samples covering the range of ISI were tested. For each sample, 2 operators performed runs on 2 instruments in triplicates, for a total of 144 tests.

Number of tests	Components of within-laboratory precision			Total Within-laboratory Precision
	Repeatability (within run)	Between Operators	Between Instruments	
	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation
144	0.44	0.10	0.16	0.48

Table 12: Summary of results, Within-Laboratory Precision

The following tables expand upon the total within-laboratory precision values described above, showing the within-laboratory precision values per site.

Within Laboratory Precision, Site 1						
Sample	N	Mean ISI	Repeatability (within run)	Between Operators	Between Instrument	Within-Laboratory Precision
			Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation
#1	12	3.98	0.17	0.02	0.20	0.26
#2	12	4.01	0.80	0.53	0.00	0.96
#3	12	4.90	0.25	0.06	0.00	0.26
#4	12	7.13	0.45	0.04	0.11	0.46

Table 13: Within-Laboratory Precision results, Site 1

Within Laboratory Precision, Site 2						
Sample	**N**	**Mean ISI**	**Repeatability (within run)**	**Between Operators**	**Between Instrument**	**Within-Laboratory Precision**
			Standard Deviation	**Standard Deviation**	**Standard Deviation**	**Standard Deviation**
#5	12	3.24	0.41	0.00	0.40	0.57
#6	12	4.88	0.42	0.34	0.22	0.58
#7	12	5.10	0.29	0.00	0.31	0.42
#8	12	6.08	0.31	0.00	0.00	0.31

Table 14: Within-Laboratory Precision results, Site 2

Within Laboratory Precision, Site 3						
Sample	**N**	**Mean ISI**	**Repeatability (within run)**	**Between Operators**	**Between Instrument**	**Within-Laboratory Precision**
			Standard Deviation	**Standard Deviation**	**Standard Deviation**	**Standard Deviation**
#9	12	2.56	0.37	0.09	0.16	0.42
#10	12	4.68	0.37	0.18	0.18	0.45
#11	12	5.53	0.36	0.00	0.10	0.37
#12	12	6.41	0.48	0.22	0.00	0.53

Table 15: Within-Laboratory Precision results, Site 3

A supplemental within-laboratory precision study was performed at one site with 4 donor samples, spanning the high end of the ISI range with scores between 7.3-10.0 ISI. For each sample, 2 operators performed runs on 2 instruments in triplicates, and repeated the testing at least one hour after the initial testing for a total of 96 tests.

Components of within-laboratory precision across samples, Supplemental Study						Within-laboratory Precision
Sample	**N**	**Repeatability (within run)**	**Between-Run**	**Between-Operator**	**Between-Instrument**	
		Standard Deviation	**Standard Deviation**	**Standard Deviation**	**Standard Deviation**	**Standard Deviation**
#13	24	0.29	0.07	0.00	0.00	0.30
#14	24	0.43	0.34	0.00	0.00	0.55
#15	24	0.37	0.56	0.00	0.15	0.69
#16	24	0.39	0.21	0.14	0.07	0.47

Table 16: Supplemental Within-Laboratory Precision study results

9.3.2.2 Reproducibility

Total reproducibility was calculated by adding within-laboratory precision and Across Sites reproducibility. The Across Site reproducibility was measured according to CLSI EP05-A3 using IntelliSep Quality Control Kit samples. Testing was conducted at 3 sites using the same lots of control material. At each site, testing was performed for 40 non-consecutive days for both Quality Control levels, for a total of 240 tests.

Sample	Number of tests	Repeatability	Across Sites
		Standard Deviation	Standard Deviation
QC Level 1	120	0.66	0.34
QC Level 2	120	0.49	0.25
Both levels	240	0.59	0.30

Table 17: Summary of results, Reproducibility

Combining the within-lab precision (0.48 units) with the Across Sites reproducibility (0.30 units) resulted in a total reproducibility of 0.57 units.

9.3.2.3 Reagents Lot-to-Lot Reproducibility

The Cytovale reagents (consisting of the Cytovale Reagent Kit, Diluent and Cleanse solutions) lot-to-lot reproducibility was tested according to CLSI EP26-A using IntelliSep Quality Control samples.

Testing was performed on two lots of reagents for each of the three types listed above. For each lot of reagents, each IntelliSep Quality Control level (L1 and L2) was tested five times over three days, resulting in 60 IntelliSep tests. An equivalence test examined if the Cytovale reagents sets have an absolute mean difference of less than 1.0 ISI unit.

Sample	Reagent Set #1 mean ISI minus Reagent Set #2 mean ISI (Cytovale Cat. No. CV-REA-001)		Acceptance criteria *The 90% CI Lower and Upper Bounds are within (-1.0, 1.0) units of ISI*
	Mean	90% CI	
QC Level 1	0.06	(-0.12, 0.24)	Pass
QC Level 2	-0.01	(-0.21, 0.19)	Pass

Table 18: Summary of results, Reagents Lot-to-Lot Reproducibility

9.3.2.4 Cartridge Lot-to-Lot Reproducibility

The IntelliSep Cartridge lot-to-lot reproducibility was tested according to CLSI EP26-A using donor samples.

Two lots of IntelliSep Cartridges were evaluated during this reproducibility study, where three donor samples across three IntelliSep Index ranges (Low, Moderate and High) were evaluated. Five replicates of each sample were tested, resulting in 30 IntelliSep tests.

Sample	Cartridge Lot #1 mean ISI minus Cartridge Lot #2 mean ISI		Acceptance criteria *The 90% CI Lower and Upper Bounds are within (-1.0, 1.0) units of ISI*
	Mean	90% CI	
Donors	-0.47	(-0.68, 0.26)	Pass

Table 19: Summary of results, Cartridge Lot-to-Lot Reproducibility

9.3.3 Analytical Measuring Range

Nonclinical analytical sensitivity, linearity, and detection limit(s)/cutoff testing is inapplicable to the IntelliSep test. Clinical sensitivity, clinical specificity, and clinical cut-off information were evaluated as part of the clinical validation study (reference Section 9.1).

9.3.4 Interference

9.3.4.1 Interfering Substances

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested according to CLSI EP07. Interferences were tested up to the listed concentrations and no impact on results was observed. Cross-reactivity evaluations are inapplicable to the IntelliSep test.

Substance	Concentration	Control Group Mean ISI	Test Group Mean ISI	Mean Difference
Unconjugated Bilirubin	40 mg/dL	3.4	3.8	-0.4
Conjugated Bilirubin	40 mg/dL	2.8	3.0	-0.2
Triglycerides	1500 mg/dL	2.5	2.7	-0.2
Hemolysate	1000 mg/dL	2.7	2.7	0.0
Hemoglobin	1000 mg/dL	3.3	3.3	0.0

Table 20: Summary of results, Interfering Substances testing

9.3.4.2 Sample Carry-Over

The study to evaluate sample carry-over was based on the principles of CLSI EP10-A3-AMD and measured the impact to the ISI due to carryover between two samples whose cells have different biophysical properties.

The study was conducted over 5 days at 1 site with 1 instrument and 1 operator. Two levels from the IntelliSep Quality Control Kit (L1 and L2) were evaluated using eleven replicates of L1 ("L" or "Low") and ten replicates of L2 ("H" or "High") cycled between each other. On each test day, a specified carryover sample order test set was performed to determine the impact on ISI of an L2 sample preceding an L1 sample ("HL"), and an L1 sample preceding an L2 sample ("LH"). No sample carry-over effect was found as shown in the following table.

Day	LL Mean ISI	HL Mean ISI	LL - HL Difference (ISI)	HH Mean ISI	LH Mean ISI	HH - LH Difference (ISI)
Day 1	2.46	2.22	0.24	7.28	7.40	-0.12
Day 2	2.14	2.20	-0.06	7.00	7.24	-0.24
Day 3	2.36	2.32	0.04	7.14	6.90	0.24
Day 4	2.34	2.42	-0.08	7.18	6.90	0.28
Day 5	1.98	2.00	-0.02	7.02	7.08	-0.06
Total	2.26	2.23	0.03	7.12	7.10	0.02

Table 21: Summary of results, Sample Carry-Over

9.3.5 Stability

9.3.5.1 Onboard Stability of Cytovale Reagents

The stability of the three Cytovale reagents (Cytovale Reagent Kit, Diluent and Cleanse) was tested according to CLSI EP25-A using IntelliSep Quality Control Kit samples. All three Cytovale reagents are stable for up to 30 days when stored onboard the Cytovale System.

9.3.5.2 Sample Stability

The stability of K2-EDTA anti-coagulated whole blood samples was tested according to CLSI EP25-A using 20 donor samples spanning the range of ISI values. The K2-EDTA sample may be used for the IntelliSep test for up to 5 hours after blood draw.

9.4 Healthy Reference Range

The reference range for the IntelliSep test was measured according to CLSI EP28-A3C. In a population of 243 self-reported healthy individuals (49% Female), the 95% Reference Range for the IntelliSep Index was calculated as 1.0-4.6 ISI.

Population	ISI Reference Range (2.5%-97.5%)	ISI Lower Reference Limit (90% CI)	ISI Upper Reference Limit (90% CI)
Female	0.9-4.7	0.7-1.1	4.3-4.9
Male	0.7-4.7	0.4-1.2	4.1-4.7
All	1.0-4.6	0.9-1.2	4.2-5.0

Table 22: Summary of results, Healthy Reference Range

10 Proposed Labeling

The labeling is sufficient and it meets the requirements of 21 CFR Parts 801 and 809, as applicable, and the special controls for this device under 21 CFR 866.3215.

11 Conclusions

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