

SeptiFast Real-Time PCR for Detection of Bloodborne Pathogens in Patients with Severe Sepsis or Septic Shock

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ABSTRACT

Several studies have been performed investigating the role of a real-time multiplex polymerase chain reaction assay LightCycler® SeptiFast® with inconsistent results. In prospective evaluation of adult patients with severe sepsis or septic shock SeptiFast assay and blood culture results were compared regarding concordance, the impact of SeptiFast assay on antimicrobial therapy adjustment, time to results and the role of SeptiFast assay as a marker of disease severity. 63 blood sample sets were collected from 57 patients. 51 (80.9%) results were concordant negative and 7 (11.1%) concordant positive. In one (1.6%) sample set blood culture was positive and SeptiFast assay negative, in three (4.8%) sample sets with negative blood cultures pathogens were detected by SeptiFast assay and in one (1.6%) patient an additional pathogen was detected by SeptiFast assay. If blood culture is considered as »gold standard«, 1 (1.6%) SeptiFast false negative and 4 (6.3%) false positive results were identified (sensitivity 87.5%, specificity 92.6%, negative predictive value 97.8%). Antibiotic treatment was adjusted according to SeptiFast assay in 4 (6.3%) cases. Time to final results was significantly shorter with SeptiFast assay (32±23 h vs. 97±28 h, $p < 0.0001$). Positive SeptiFast assay was not associated with higher mortality, C-reactive protein or procalcitonin ($p = 0.74$, $p = 0.44$ and $p = 0.12$, respectively). According to our results SeptiFast assay can be used as a valuable add-on to blood culture in diagnostic workup of patients with severe sepsis and septic shock but it cannot replace the blood culture.

Key words: sepsis, polymerase chain reaction, blood cultures, antimicrobial agents, pathogen identification

Introduction

Numerous studies have been performed investigating the role and usefulness of a commercially available real-time multiplex polymerase chain reaction (PCR) assay LightCycler® SeptiFast® (SF) which can detect 25 of the most important sepsis pathogens in the management of patients with sepsis^{1–9}. These studies were performed in different settings, including surgical and medical intensive care patients, pediatric, hematology and cancer patients. Patients with suspected sepsis as well as severe sepsis or septic shock have been recruited^{1–9}. The role of SF as marker of disease severity has been investigated as well, introducing the concept of »DNAemia« in to the treatment of sepsis^{10,11}.

In spite of inconsistent results SF assay remains attractive due to shorter time to results in comparison to

blood cultures (BC) and consecutive possibility for faster adjustment of antibiotic therapy^{1,11}. There is little information on the use of SF assay in population of adult medical patients with severe sepsis or septic shock and no experience of use of SF assay in Slovenia. SF assay and BC results were compared, time to results and the impact of SF assay results on adjustment of antimicrobial therapy in patients with severe sepsis and septic shock were analyzed and the role of positive SF assay as a possible marker of disease severity was studied.

Patients and Methods

This prospective study was conducted in the 12-bed Medical Intensive Care Unit (ICU) at University Medical

Centre Maribor from September 2011 to September 2012. Adult patients who fulfilled the criteria for severe sepsis or septic shock¹² were included. In all patients blood samples for BC and SF assay were taken before empiric antibiotic therapy was initiated. One set of mandatory microbiology samples consisted of a paired collection of BC (one aerobic and one anaerobic bottle from two sites, at least one was from peripheral veins) and 5 ml of EDTA blood for SF assay taken from the same peripheral vein as for BC. Microbiology samples from other body sites were collected when clinically indicated.

For BC 20 mL of blood were collected and 10 mL inoculated in each of aerobic and anaerobic BacT/Alert FAN bottle (bioMerieux, Marcy l'Etoile, France). Inoculated BC bottles and blood samples for SF assay were transported to microbiology department (which is located approximately 4 km away from ICU) on the same day if samples were taken before 6 p.m. or next day if samples were taken after 6 p.m. SF samples were stored at 4 °C if immediate analysis was not possible.

In the microbiology laboratory BC bottles were incubated for a total of 5 days at 37 °C in the BacT/Alert 3D automated BC system (bioMerieux, Marcy l'Etoile, France). All BC bottles signaled as positive were processed according to standard microbiology laboratory procedures. Blood samples for SF assay (Roche Diagnostics, Mannheim, Germany) were processed strictly following manufacturer's instructions¹³.

Positive BC (Gram stain, isolated pathogen and antibiotic resistance) were reported to the attending physician by telephone as soon as available. SF assay was performed from 8 a.m. to 4 p.m. on weekdays and from 8 a.m. to 1 p.m. on Saturdays. The results were reported as soon as possible to the attending physician.

Clinical data including age, gender, APACHE II score (Acute Physiology and Chronic Health Evaluation II), ICU and hospital length of stay, laboratory results and concomitant or previous (within 48 h) antibiotic treatment. Complications during sample withdrawal, in-hospital storage, transportation to laboratory and sample analysis were recorded and documented.

The study was approved by the National Medical Ethics Committee of the Republic of Slovenia (Number 130/09/07) and informed consent was obtained from all patients being included in the study.

McNemar test was used to compare blood culture and SF results. The relationship between positive SF test and mortality was tested using the Fisher's exact test. P-value <0.05 was regarded as statistically significant.

Results

In all, 63 sets comprising 2 aerobic BC bottles, 2 anaerobic BC bottles and one blood sample for SF assay were taken from 57 patients (19 female and 38 male, mean age 59.5±14.8 years). Two sets of samples were taken from 6 (11.3%) patients. In-hospital mortality was 52.6%. In-hospital length of stay was 27±28.9 days.

Mean admission APACHE II score was 25±7.6. At the time when samples were taken for BC and SF assay 39 (61.9%) patients had received antibiotic therapy.

In 51 (80.9%) sample sets both methods – BC and SF assay – showed concordant negative results. BC and SF assay were concordantly positive in seven sample sets (Table). In one sample set BC was positive whereas the SF assay yielded negative result (Table, patient No 2). In three sample sets with negative BC pathogens were detected by SF assay (Table, patient No 3, 6, 7) and in one set an additional pathogen was detected by SF assay (Table, patient No 10). If we consider BC as »gold standard«, then 1 (1.6%) SF false negative result and 4 (6.3%) SF false positive results were identified (SF sensitivity 87.5%, specificity 92.6%, positive predictive value 66.4%, and negative predictive value 97.8%). There was no statistically significant difference between SF and BC tests regarding concordance of results ($\chi^2(1)=0.80$, $p=0.37$). No pathogens were detected by BC that are not included in the SF assay detection list.

In 6 patients 2 sets of BC and SF samples were collected. In one of those patients (Table, patient No 10) BC and SF were positive in samples collected on the first day and day 29 of ICU treatment. In the sample set collected on the first day SF was positive for *Enterobacter cloacae/aerogenes* and *Escherichia coli*, while *Enterobacter cloacae* only was isolated from BC. On day 29 SF was positive for *E. cloacae/aerogenes* and *E. cloacae* was isolated from BC (Table 1, patient No. 10*). In the remaining five patients the results were concordantly negative.

In patients with discordant results microbiological samples obtained on the same day from different sites (tracheal aspirate, urine, wound swabs, catheter tips or other) were checked. In 2 (3.2%) cases *Streptococcus pneumoniae* was detected by SF and in tracheal aspirates (Table 1, patients No. 6 and 7). Thus both SF results can be interpreted as true positive.

Three patients with positive SF and negative BC (Table, patients No 3, 6 and 7) received antibiotics at the time when samples were taken or within previous 48 h. In one case coagulase negative staphylococci (*Staphylococcus epidermidis*) were isolated by BC, SF was negative. The same pathogen was isolated on central venous catheter tip and from two BC collected from peripheral vein. In one case a polymicrobial infection was detected by SF (*E. cloacae/aerogenes*, *E. coli*) while *E. cloacae* only was isolated from BC and tracheal aspirate (Table 1, patient No. 10).

Antibiotic treatment was adjusted according to results of SF assay in 4 (6.3%) cases. In 3 cases antibiotic was added (cloxacillin for *Staphylococcus aureus*, vancomycin for *S. aureus* and ertapenem for *E. coli*), in 1 case antibiotic was discontinued (azithromycin for *S. pneumoniae*) (Table 1). A nonsignificant decrease in both C-reactive protein (CRP) and procalcitonin levels after 48 h was observed in cases of antibiotic change (153±43 mg/L vs. 111±11 mg/L, $p=0.11$ for CRP and 15.9±16.7 ng/mL vs. 2.6±2.4, $p=0.24$ ng/mL for procalcitonin).

TABLE 1
SEPTIFAST ASSAY AND BLOOD CULTURE POSITIVE CASES

Patient Number	SF	BC	Other sites	Previous/ concomitant antibiotic therapy	Empiric antibiotic therapy	Change of therapy after SF results	Time to SF results (hours)	Time to final BC results (preliminary BC results) (hours)	Outcome
1	<i>S. aureus</i>	<i>S. aureus</i>	<i>S. aureus</i> (TA)	Amoxicillin/ clavulanate	Moxifloxacin	Cloxacillin	26	78 (23)	Died
2	Negative	<i>S. epidermi- dis</i>	<i>S. epidermi- dis</i> (CVC tip)	Imipenem	Imipenem, vancomycin	No change	12	123 (21)	Died
3	<i>E. cloacae/ aerogenes</i>	Negative	<i>P. aeruginosa</i> (TA)	Ceftriaxone	Ceftriaxone, linezolid	No change	46	138	Survived
4	<i>S. aureus</i>	<i>S. aureus</i>	<i>S. aureus</i> (TA)	Amoxicillin/ clavulanate	Cefepime, clindamycin	Vancomycin	16	56 (16)	Survived
5	<i>E. coli</i>	<i>E. coli</i>	Negative	No previous/ concomitant antibiotic	Cefepime, azithromycin	Ertapenem	19	58 (15)	Died
6	<i>S. pneumo- niae</i>	Negative	<i>S. pneumo- niae</i> (TA)	Amoxicillin/ clavulanate	Meropenem	No change	8	58 (18)	Died
7	<i>S. pneumo- niae</i>	Negative	<i>S. pneumo- niae</i> (TA)	No previous/ concomitant antibiotic	Ceftriaxone, azithromycin	No change	24	56 (24)	Died
8	<i>S. pneumo- niae</i>	<i>S. pneumo- niae</i>	<i>S. pneumo- niae</i> (TA)	Amoxicillin/ clavulanate	Ceftriaxone, azithromycin	Azithromycin discontinued	12	48 (10)	Survived
9	<i>E. coli</i>	<i>E. coli</i>	<i>E. coli</i> (TA)	Amoxicillin/ clavulanate	Piperacillin/ tazobactam	No change	16	52 (16)	Died
10	<i>E. cloacae/ aerogenes, E. coli</i>	<i>E. cloacae</i>	<i>E. cloacae</i> (TA)	Amoxicillin/ clavulanate	Imipenem, vancomycin	No change	8	72 (24)	Survived
10*	<i>E. cloacae/ aerogenes</i>	<i>E. cloacae</i>	<i>E. cloacae</i> (TA)	Meropenem	Imipenem, vancomycin	No change	42	72 (24)	Survived
12	<i>E. cloacae</i>	<i>E. cloacae</i>	<i>E. cloacae</i> (TA)	Piperacillin/ tazobactam	Meropenem	No change	30	48 (24)	Survived

SF – SeptiFast assay, BC – blood cultures, TA – tracheal aspirates, CVC – central venous catheter, * a second set of samples withdrawn from the same patient 29 days later

First information regarding positive BC (Gram stain result from positive BC bottle) was obtained in 21 ± 7 h, and time to final blood culture result was 97 ± 28 h. SF results were obtained in 32 ± 23 h. Time to final result was significantly shorter with SF assay ($p < 0.0001$). The difference between time to first information regarding positive BC and SF result did not reach statistical significance ($p = 0.16$).

Positive SF results were not associated with higher APACHE II scores (25.1 ± 7.9 vs. 25.2 ± 7.6 , $p = 0.97$) or with increased mortality (55.5 vs. 52.1 %, $p = 0.74$). Positive SF results were also not associated with higher CRP or procalcitonin levels (151 ± 38 mg/L vs. 164 ± 50 mg/L, $p = 0.44$ and 15.6 ± 15.6 ng/mL vs. 8.2 ± 12.6 ng/mL, $p = 0.12$, respectively).

A limited evaluation of financial impact of introducing SF assay to management of patients with severe sepsis or septic shock was performed using a set price of 150 EUR per SF assay for material costs only¹⁰. Sixty-three

SF assays were performed, costing approximately 9500 EUR. The estimated cost of detecting one positive SF result was approximately 950 EUR.

Discussion

In the first Slovenian evaluation of the usefulness of SF assay in adult patients with severe sepsis or septic shock the results were comparable to other studies. Both sensitivity and specificity of SF assay in our study were located in the upper range of previously reported data (87.5% and 92.6%, respectively)¹⁻⁸. Our results are in line with the recent metaanalysis, which highlighted the role of SF as rule-in tool for early detection of septic patients⁸.

The rate of pathogens detected by SF and not by BC (6.3%) as well as the rate detected by BC and not by SF (1.6%) was lower compared to other studies. The main reason for these lower rates might be perhaps a relatively low number of patients included in the study. In two pa-

tients an identical pathogen (*S. pneumoniae*) was identified in tracheal aspirates, which suggests a true positive result. Results of several studies assessing the diagnostic utility of the real-time PCR for *S. pneumoniae* in blood and respiratory samples for the diagnosis of pneumococcal pneumonia indicated that real-time PCR performs better than culture¹⁴. In three patients with positive SF result negative BC can be explained by antibiotic treatment at the time of sample collection.

Some previous reports showed that detection of pathogen DNA is associated with higher organ dysfunction scores and points to higher mortality^{10,15}. Positive SF test has also been associated with higher levels of inflammatory markers¹⁰. In contrast, in our study positive SF result was not associated with either mortality or higher APACHE II scores.

Rapid institution of appropriate antibiotic therapy is important in treating patients with sepsis^{16,17}. Initial selection of antibiotic therapy is usually empiric¹². Even though broad-spectrum antibiotics are used as empiric therapy^{12,16,17}, changes of antibiotic therapy or additional antimicrobial agents are needed in 40–60% of patients once a pathogen is isolated¹⁸. In this study antibiotic treatment was adjusted according to results of SF assay in 4 (6.3%) cases. In 3 cases an antibiotic was added and in one case antibiotic was discontinued. In all cases the decision to alter antibiotic therapy was considered with regard to the clinical state and laboratory results of the patients at that time. A decrease in inflammatory markers may suggest a correct decision⁸. Administration of inadequate antimicrobial treatment to critically ill is associated with greater mortality when compared to adequately treated patients¹⁹ and change of antibiotic later in the course of treatment seems not to lower mortality²⁰. These studies were performed using standard microbiology methods. In other studies, antibiotic treatment adjustment would have been needed in about 10% of SF results^{2–5,10}.

Introduction of SF assay into routine clinical management is complex. The advantage of shorter turnaround

time of SF assay in comparison to BC is optimal when the assay is performed on a daily basis and immediately after sample collection. That was not the case in our study, resulting in preliminary BC results being obtained faster than SF results. However, even with SF analysis not performed on Saturday afternoons and Sundays, a significant time benefit was present when comparing final results. In order to take full advantage of shorter SF analysis, it would probably make sense to have a dedicated team responsible only for SF analysis, and not to impose SF analysis to a system that has been developed around the needs of a standard method²¹, as was the case in our study. However, such an approach would result in higher cost of SF assay.

Shorter SF assay turnaround times facilitate early, targeted antibiotic treatment, possibly resulting in use of fewer antibiotics and lower total ICU treatment costs. Economic saving afforded by the use of the PCR assay has been demonstrated in septic shock patients²² and in patients with candidemia²³. Because of a relatively small patient cohort we only performed a limited evaluation of financial impact of introduction of SF assay to clinical practice. High cost of ICU treatment itself reduces the financial impact of SF test.

Other PCR based techniques (e.g. VYOO®, SIRS-Lab GmbH, Jena, Germany and SepsisTest™, Molzym, Bremen, Germany) are being tested with roughly similar results^{24,25}. Additionally, other approaches which significantly shorten the time to identify causative agent of sepsis, such as matrix-assisted laser desorption/ionisation-time of flight (MALDI-TOF) mass spectrometry and fluorescence in situ hybridization (FISH). These techniques enable rapid identification of pathogens, however, do not shorten the time to susceptibility testing result²².

According to the results of our study SF assay can be used as a valuable add-on to conventional blood culture in diagnostic workup of patients with severe sepsis and septic shock but it cannot replace the blood culture.

REFERENCES

1. CHANG SS, HSIEH WH, LIU TS, LEE SH, WANG CH, CHOU HC, YEO YH, TSENG CP, LEE CC, PLoS One, 5 (2013) 29. DOI: 10.1371/journal.pone.0062323. — 2. GRIF K, FILLE M, WÜRZNER R, WEISS G, LORENZ I, GRUBER G, ESCHERTZHUBER S, NACHBAUR D, LASS-FLÖRL C, ORTH D, Wien Klin Wochenschr, 7-8 (2012) 124. DOI: 10.1007/s00508-012-0159-4. — 3. YANAGIHARA K, KITAGAWA Y, TOMONAGA M, TSUKASAKI K, KOHNO S, SEKI M, SUGIMOTO H, SHIMAZU T, TASAKI O, MATSUSHIMA A, IKEDA Y, OKAMATO S, AIKAWA N, HORI S, OBARA H, ISHIZAKA A, HASEGAWA N, TEKEDA J, KAMIHIRA S, SUGAHARA K, ASARI S, MURATA M, KOBAYASHI Y, GINBA H, SUMIYAMA Y, KITAJIMA M, Crit Care, 4 (2010) 14. DOI: 10.1186/cc9234. — 4. TSALIK EL, JONES D, NICHOLSON B, WARING L, LIESENFELD O, PARK LP, GLICKMAN SW, CARAM LB, LANGLEY RJ, VAN VELKINBURGH JC, CAIRNS CB, RIVERS EP, OTERO RM, KINGSMORE SF, LALANI T, FOWLER VG, WOODS CW, J Clin Microbiol, 1 (2010) 48. DOI: 10.1128/JCM.01447-09. — 5. AVOLIO M, DIAMANTE P, ZAMPARO S, MODOLO ML, GROSSO S, ZIGANTE P, TOSONI N, DE ROSA R, STANO P, CAMPORESE A, Shock, 1 (2010) 34. DOI: 10.1097/SHK.0b013e3181d49299. — 6. LUCIGNANO B, RANNO S, LIESEN-

7. PAOLUCCI M, STANZANI M, MELCHIONDA F, TOLOMELLI G, CASTELLANI G, LANDINI MP, VARANI S, LEWIS RE, SAMBRI V, Diagn Microbiol Infect Dis, 2 (2013) 75. DOI: 10.1016/j.diagmicrobio.2012.10.012. — 8. MAUBON D, HAMIDFAR-ROY R, COURBY S, VESIN A, MAURIN M, PAVESE P, RAVANEL N, BULABOIS CE, BRION JP, PELLOUX H, TIMSIT JF, J Infect, 4 (2010) 61. DOI: 10.1016/j.jinf.2010.07.004. — 9. VINCE A, LEPEJ SZ, BARSIC B, DUSEK D, MITROVIC Z, SERVENTI-SEIWERTH R, LABAR B, J Med Microbiol, 10 (2008) 57. DOI: 10.1099/jmm.0.47797-0. — 10. BLOOS F, HINDER F, BECKER K, SACHSE S, MEKONTSO DESSAP A, STRAUBE E, CATTOIR V, BRUN-BUISSON C, REINHART K, PETERS G, BAUER M, Intensive Care Med, 2 (2010) 36. DOI: 10.1007/s00134-009-1705-z. — 11. PAGANI L, AFSHARI A, HARBARTH S, Crit Care, 6 (2011) 15. DOI: 10.1186/cc10425. — 12. DELLINGER RP, LEVY MM, CARLET JM, BION J, PARKER MM, JAESCHKE R, REINHART K, ANGUS DC, BRUN-BUISSON C, BEALE R, CALANDRA T, DHAINAUT JF, GERLACH H, HARVEY M, MARINI JJ, MARSHALL J, RANIERI M, RAMSAY G, SEVRANSKY J, THOMP-

- SON BT, TOWNSEND S, VENDER JS, ZIMMERMAN JL, VINCENT JL, Intensive Care Med, 1 (2008) 34. — 13. LightCycler SeptiFast Test, Package Insert, Roche Diagnostics GmbH, 2006. — 14. AVNI T, MANSUR N, LEIBOVICI L, PAUL M, J Clin Microbiol, 2 (2010) 48. DOI: 10.1128/JCM.01636-09. — 15. FAIX JD, Crit Rev Clin Lab Sci, 1 (2013) 50. DOI: 10.3109/10408363.2013.764490. — 16. GARNACHO-MONTERO J, GARCIA-GARMENDIA JL, BARRERO-ALMODOVAR A, JIMENEZ-JIMENEZ FJ, PEREZ-PAREDES C, ORTIZ-LEYBA C, Crit Care Med, 12 (2003) 31. — 17. GARNACHO-MONTERO J, ORTIZ-LEYBA C, HERRERA-MELERO I, ALDABÓ-PALLÁS T, CAYUELA-DOMINGUEZ A, MARQUEZ-VACARO JA, CARBAJAL-GUERRERO J, GARCIA-GARMENDIA JL, J Antimicrob Chemother, 2 (2008) 61. — 18. DEGORICIJA V, SHARMA M, LEGAC A, GRADISER M, SEFER S, VUCICEVIC Z, Croat Med J, 3 (2006) 47. — 19. IBRAHIM EH, SHERMAN G, WARD S, FRASER VJ, KOLLEF MH, Chest, 1 (2000) 118. — 20. KUMAR A, ROBERTS D, WOOD KE, LIGHT B, PARRILLO JE, SHARMA S, SUPPES R, FEINSTEIN D, ZANOTTI S, TAIBERG L, GURKA D, KUMAR A, CHEANG M, Crit Care Med, 6 (2006) 34. — 21. KOTSAKI A, GIAMARELLOS-BOURBOULIS EJ, Expert Opin Med Diagn, 3 (2012) 6. DOI: 10.1517/17530059.2012.667799. — 22. ALVAREZ J, MAR J, VARELA-LEDO E, GAREA M, MATINEZ-LAMAS L, RODRIGUEZ J, REGUEIRO B, Anaesth Intensive Care, 6 (2012) 40. — 23. BLOOS F, BAYER O, SACHSE S, STRAUBE E, REINHART K, KORTGEN A, J Crit Care, 1 (2013) 28. DOI: 10.1016/j.jcrc.2012.07.011. — 24. BLOOS F, SACHSE S, KORTGEN A, PLETZ MW, LEHMANN M, STRAUBE E, RIEDEMANN NC, REINHART K, BAUER M, PLoS One, 7 (2012) 9. DOI: 10.1371/journal.pone.0046003. — 25. LEITNER E, KESSLER HH, SPINDELBOECK W, HOENIGL M, PUTZ-BANKUTI C, STADLBAUER-KÖLLNER V, KRAUSE R, GRISOLD AJ, FEIERL G, STAUBER RE, J Microbiol Methods, 3 (2013) 92. DOI: 10.1016/j.mimet.2012.12.012.

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SEPTIFAST PCR TEST ZA OTKRIVANJE UZROČNIKA U BOLESNIKA S TEŠKOM SEPSOM ILI SEPTIČKIM ŠOKOM

SAŽETAK

Mnoge studije, koje su istraživale ulogu polimerazne lančane reakcije LightCycler® SeptiFast®, su pokazale nedosljedne rezultate. U prospektivnoj procjeni odraslih bolesnika s teškom sepsom ili septičkim šokom istraživali smo: usklađenost rezultata SeptiFast testa i hemokultura, utjecaj SeptiFast testa na prilagodbu antimikrobne terapije, vrijeme do rezultata SeptiFast testa i ulogu SeptiFast testa kao pokazatelja težine bolesti. Prikupili smo 63 krvna uzorka od 57 bolesnika. 51 rezultat (80,9%) je bio usklađen negativno, a 7 rezultata (11,1%) je bilo usklađeno pozitivno. U jednom uzorku (1,6%) su hemokulture bile pozitivne, a SeptiFast test negativan. U tri uzorka (4,8%) s negativnim hemokulturama je SeptiFast test bio pozitivan. U jednog bolesnika (1,6%) smo SeptiFast testom otkrili dodatnog uzročnika. Ako se hemokulture smatraju »zlatnim standardom«, dobili smo 1 (1,6%) SeptiFast lažno negativan rezultat i 4 (6,3%) SeptiFast lažno pozitivna rezultata (osjetljivost 87,5%, specifičnost 92,6%, negativna prognostička vrijednost 97,8%). U 4 (6,3%) primjera je antibiotska terapija bila prilagođena rezultatu SeptiFast testa. Vrijeme do konačnog rezultata je bilo signifikantno kraće s SeptiFast testom (32 ± 23 h vs. 97 ± 28 h, $p < 0,0001$). Pozitivan SeptiFast test nije bio povezan s višim mortalitetom ($p = 0,74$), višim C-reaktivnim proteinom ($p = 0,44$) ili višim prokalcitoninom ($p = 0,12$). Prema našim rezultatima, SeptiFast test se može koristiti kao vrijedan dodatak hemokulturama u dijagnostičkoj obradi bolesnika s teškom sepsom i septičkim šokom, ali ne može zamijeniti hemokulture.