NICU (Neonatal Intensive Care Unit) SUPPORT SYSTEM

AFIAS IL-6/PCT/CRP

Boditech Med with you
From First Moment of Life.

Find out more on www.boditech.co.kr

Time Matters - Early detection of sepsis

Neonatal sepsis can be devastating, leading to high morbidity and mortality in newborns, and is recognized as a global health challenge. The highest sepsis incidence across all age groups is found in neonates affecting an estimated 3 million babies worldwide (22 per 1000 live births) with a mortality of 11–19% and unquantified long-term neurological defects. [2]

Early-onset sepsis is developed from **≤3 days to 7days** and a mortality rate 24.4%. **Early detection and treatment of the newborn infant with suspected sepsis are essential** to prevent severe and life-threatening complications.

BODITECH MED SOLUTION

Test directly in ICU within 12 minutes.

Boditech Med's In-vitro diagnostic devices are small and compact-size to save ICU space. It's three steps help you receive the result within few minutes of blood test. First, COLLECT the whole blood from infant's heel, second, INSERT tip in the cartridge, Finally PRESS the 'start' button. An automatic system will help to detect **the earliest stage of sepsis at the ICU, anywhere, anytime within 12 minutes.**

Without **AFIAS**

Take hours to days

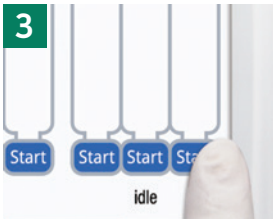
Draw blood → Send to Lab → Centrifugation → Lab test Culture blood test

With **AFIAS**

AFIAS-1

COLLECT

INSERT

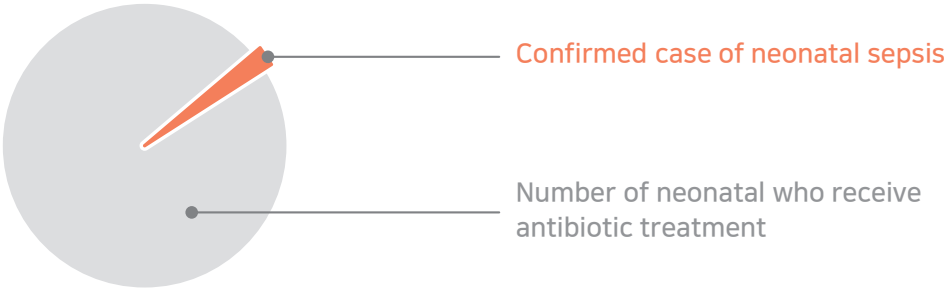


PRESS

Getting it right - Exact diagnosis sepsis

Diagnosis of neonatal sepsis is difficult because of the **variable and nonspecific clinical presentation.** Therefore, many newborns with nonspecific symptoms are started on antibiotic treatment before the presence of sepsis has been proven. [1] Antibiotic abuse is associated with antibiotic resistance, microbiome alterations, and dysbiosis. [4]

Despite the low incidence of confirmed neonatal sepsis, at approximately two per 1,000 live births, because of diagnostic testing limitation, a significant number of neonates (up to 7% - 13%) are routinely evaluated and treated for possible neonatal sepsis. 56,524 neonates die each year from resistance-attributable neonatal sepsis deaths caused by bacteria resistance to first-line antibiotics in India, the toll in Pakistan is 25,692 neonates. [5] **Exact detection and prescribing of appropriate antibiotics** will remain the main challenge.



BODITECH MED SOLUTION

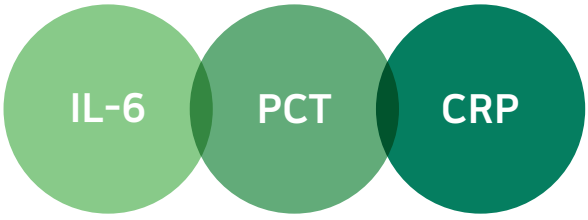
Rule Out for Neonatal Sepsis

☑ IL-6 (Interleukin-6) / PCT (Procalcitonin) / CRP (C-reactive protein) Package

Boditech Med provides the quantitative result of IL-6, PCT, CRP levels, which able to detect rapid and exact detection of infant's condition.

Using a combination of reliable biomarkers can help to measure more information than single markers.

Boditech Med NICU package can **give conviction of NOT using antibiotics to infants by ruling out neonatal sepsis.**



- ✓ Early detection
- ✓ Bacterial infection specific detector
- ✓ Reliable late on-set sepsis detector

Track the point - Appropriate antibiotic therapy

Recent reports of neonatal networks show that there are significant practice differences among NICUs related to the initiation of antibiotics in suspected sepsis and also in the duration of antibiotics. The variability among NICUs was surprising and ranged from 10% to 92%. In 5 NICUs, more than 60% of neonates received such management, whereas in 4 NICUs, this was done in fewer than 20% of infants. [8]

Inappropriate or excessive antibiotic use has been associated with altered bacterial colonization, resulting in the emergence of resistant organisms and increased rates of fungemia, necrotizing enterocolitis (NEC), and mortality. [9]

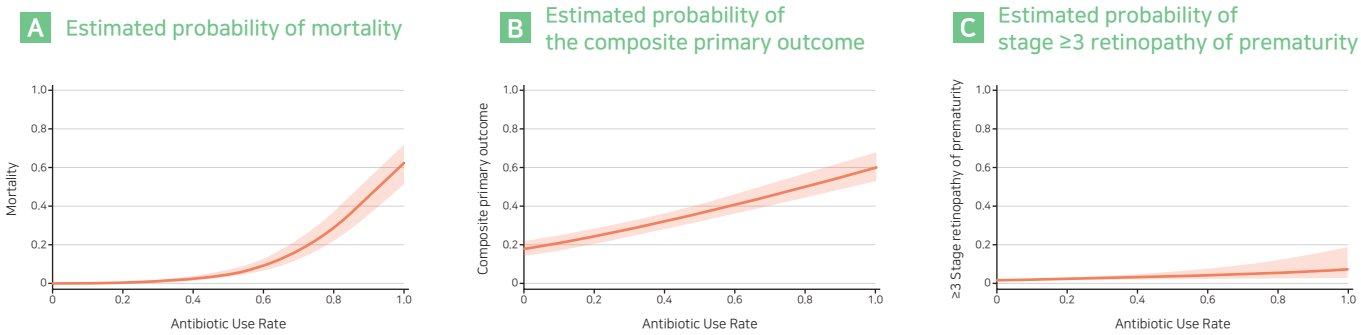


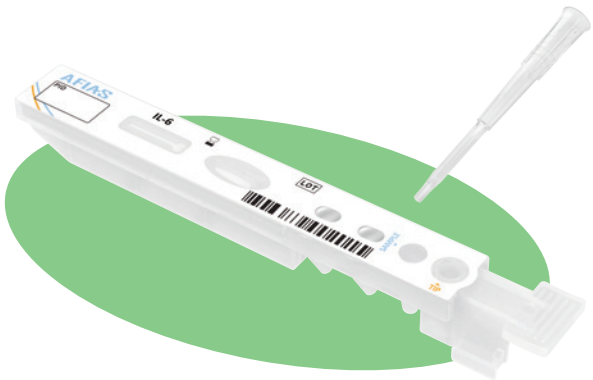
Figure A,B,C) Antibiotic use rate and estimated probabilities of outcomes [9]

BODITECH MED SOLUTION

For multiple blood collection

Simple blood collection - 30 µL Whole blood from infant's heel

The C-tip is a unique invention of Boditech Med Inc. Boditech capillary tip can not only help to use a small volume of whole blood but also can be able to test automatic system directly. It is simple but accurate tool that minimizes neonate or newborn's pain and risk. It is ideal for multiple blood collections to check the newborn's condition continuously and decide whether to stop antibiotics.



Boditech Med NICU PANEL

☑ IL-6 (Interleukin-6)

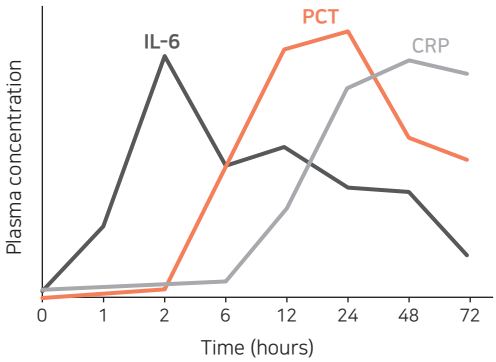
Interleukin-6 (IL-6) acts as a pro-inflammation cytokine and a key mediator of inflammation. During the acute phase of an infection, B and T lymphocytes are stimulated to produce IL-6 cytokine, which in turn induces hepatocyte production of acute phase reactants such as CRP. As **an early phase biomarker**, IL-6 has superior sensitivity.

☑ PCT (Procalcitonin)

Procalcitonin (PCT) is the peptide prohormone of calcitonin and an acute phase reactant, independent of calcitonin levels, that is associated with the immunomodulation and vascular response associated with systemic inflammatory response syndrome (SIRS). Produced by monocytes and hepatocytes, concentrations of PCT increase early within 2-4 hours, after an exposure to a **bacterial pathogen** during the acute stage of sepsis. Levels peak at 6.8 hours and remain elevated for the next 24 hours, with a half-life of 24-30 hours.

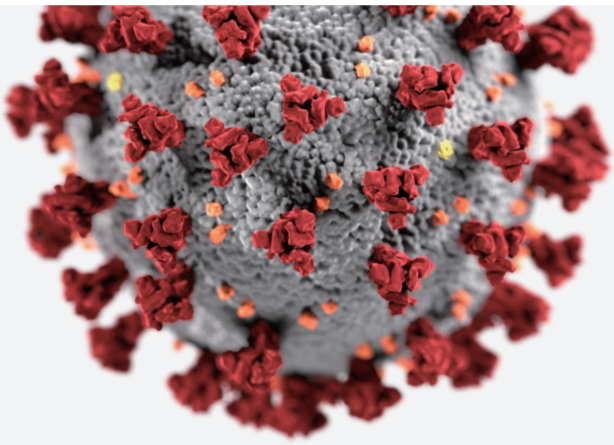
☑ CRP (C-Reactive Protein)

Among the acute phase reactants, CRP, produced in the liver, is a frequently used laboratory test for the diagnosis of neonatal sepsis. This biomarker has a half-life of 24-48 hours. CRP can be a reliable late marker for sepsis with changing patterns or continuous decreased levels useful to monitor progress or guide clinicians in decisions related to duration of antibiotic treatment.



The use of single biomarker in conjunction with other biomarkers improve its diagnostic usefulness in neonatal sepsis.

Boditech Med NICU panel help care
do not miss any moment of neonatal.



To prevent any possible risk
Various test line for infants

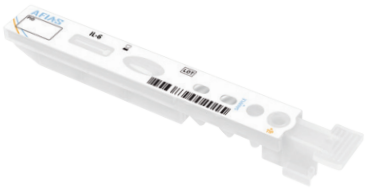
The outbreak database [10] show the 5 most frequent viral agents in NICUs were rotavirus (23.44%) respiratory syncytial virus (17.19%), enterovirus (15.63%), hepatitis A virus (10.94%), and adenovirus (9.38%).
Boditech Med has various panel to prevent nosocomial infection in NICU.

Rotavirus / Norovirus / Adenovirus / Hepatitis A / Hepatitis B / TSH / NTpro-BNP

Boditech Med NICU PANEL

Device information

	AFIAS-1	AFIAS-6
Dimensions	180.6 mm (L) x 320.6 mm (W) x 206.4 mm (H)	420mm (L) x 336 mm (W) x 293 mm (H)
Cat#	FPRR019	FPRR020



Reagents

Item	Sample Type	Sample Volume	Working Range	T A T	Cartridge#
IL-6	WB/S/P	30 µL for C-tip	2-2,500 pg/mL	12 min	SMFP-74
PCT	WB/S/P	50 µL for C-tip	0.1-100 ng/mL	12 min	SMFP-7
PCT Plus	WB/S/P	30 µL for C-tip	0.02-50 ng/mL	12 min	SMFP-32
CRP	WB/S/P	10 µL for C-tip	0.5-200 mg/L	3 min	SMFP-2
TSH	WB/S/P	50 µL for C-tip	0.4-80 µlU/mL	15 min	SMFP-20
TSH Plus	WB/S/P	30 µL for C-tip	0.08-50 µlU/mL	12 min	SMFP-38
Rota	Feces	Spot	Qualitative (0-200 COI)	12 min	SMFP-25
Noro	Feces	Spot	Qualitative (0-200 COI)	12 min	SMFP-26
Rota/Adeno combo	Feces	Spot	Qualitative (0-200 COI)	12 min	SMFP-43
Anti-HBs (Hepatitis B Antibody)	WB/S/P	100 µL	0-500 COI	15 min	SMFP-16
HBsAg (Hepatitis B Antigen)	WB/S/P	100 µL	0-300 COI	12 min	SMFP-15
Anti-HCV (Hepatitis C Antibody)	WB/S/P	100 µL	0-300 COI	12 min	SMFP-17

References

1) MartinStockerMD et al, Procalcitonin-guided decision making for duration of antibiotic therapy in neonates with suspected early-onset sepsis: a multicentre, randomised controlled trial (NeoPIns), The Lancet, Volume 390, Issue 10097, 26 August–1 September 2017, Pages 826-829

2) Eleanor J. Molloy et al, Neonatal sepsis: need for consensus definition, collaboration and core outcomes, *Pediatric Research* volume 88, pages2–4(2020)

3) Mehrdad Mirzarahim, at el. The role of interleukin-6 in the early diagnosis of sepsis in premature infants, Pediatric Reports 2017; volume 9:7305

4) Augusto Sola, Abuse of Antibiotics in Perinatology: Negative Impact for Health and the Economy, NeoReviews August 2020, 21 (8) e559-e570; DOI: https://doi.org/10.1542/neo.21-8-e559

5) Ramanan Laxminarayan, Antimicrobial resistance—a threat to neonate survival, THE LANCET, Volume 4, ISSUE 10, e676-e677, October 01, 2016, DOI:https://doi.org/10.1016/S2214-109X(16)30221-2

6) Jean Guibourdenche Antoine Bedu Loïc Petzold , Biochemical markers of neonatal sepsis: value of procalcitonin in the emergency setting, *Annals of Clinical Biochemistry.* 2002;39(2):130-135. doi:10.1258/0004563021901874

7) Liqin Gao et al, Early diagnosis of bacterial infection in patients with septicopyemia by laboratory analysis of PCT, CRP and IL-6, Experimental and Therapeutic Medicine, June-2017 Volume 13 Issue 6, 3479-3483, https://doi.org/10.3892/etm.2017.4417

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9) Joseph Y. Ting et al, Association Between Antibiotic Use and Neonatal Mortality and Morbidities in Very Low-Birth-Weight Infants Without Culture-Proven Sepsis or Necrotizing Enterocolitis, JAMA Pediatr. 2016;170(12):1181-1187. doi:10.1001/jamapediatrics.2016.2132

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BIO TECHNOLOGY

boditech

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