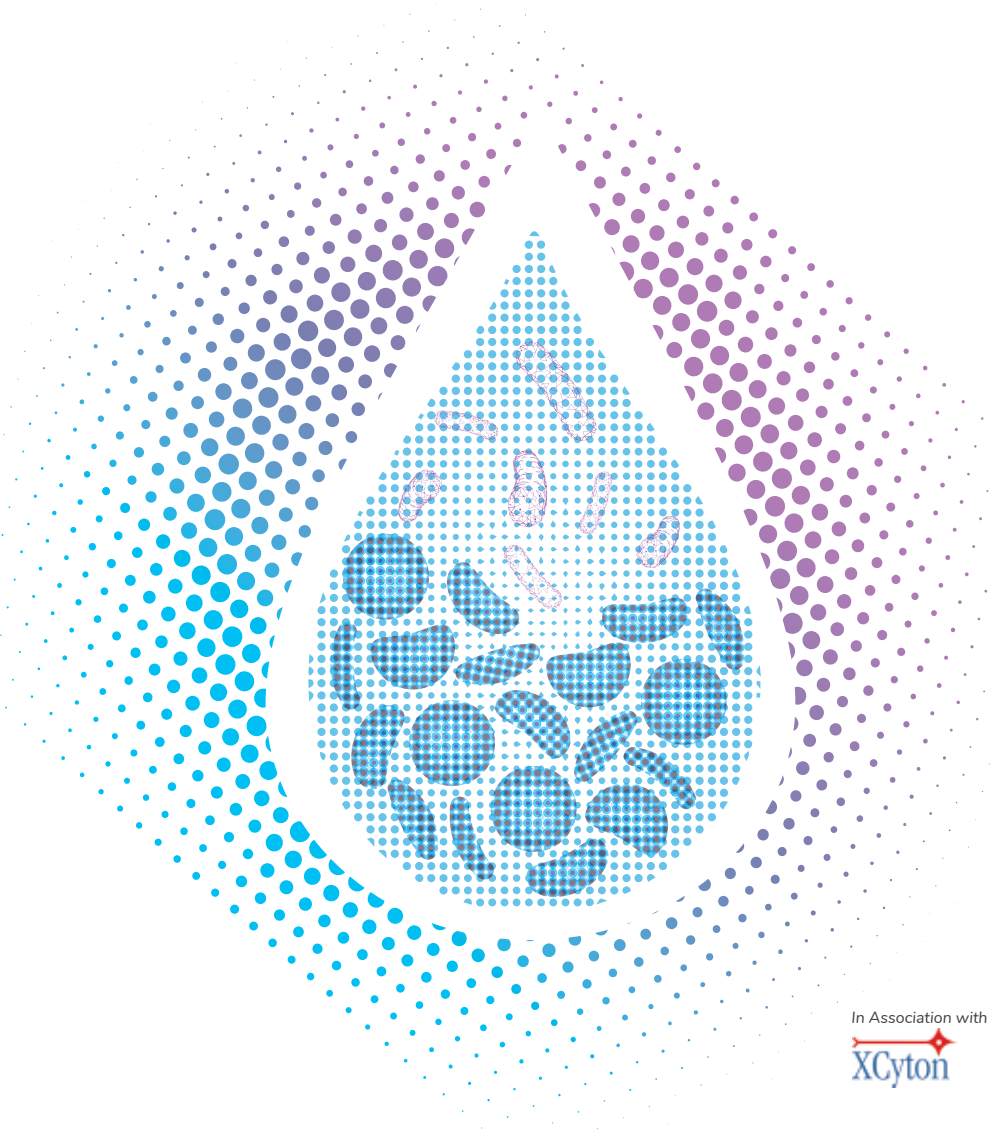
mcra
Infectious Disease Genetics

MEDGENOME

Syndrome Evaluation System (SES) for
Systemic infections



In Association with
XCyton

Prevalance

- According to WHO, 1 in 10 patients get infection while receiving care globally[1]
- The burden of HAI (healthcare associated infection) is several fold higher in low- and middle-income countries than in high-income ones
- Globally, more than 50% of surgical site infections can be antibiotic resistant[1]. In low-and middle-income countries, 11% of patients who undergo surgery are infected in the process[3]

Molecular Basis of diagnosis of infectious diseases[4]

Molecular detection by amplification and hybridization of nucleic acids as a technology has opened a new and innovative era for microbial diagnosis. The use of nucleic acid detection for the diagnosis of infectious diseases in clinical laboratories is facilitated by PCR (Polymerase Chain Reaction), This approach is useful to detect mutations associated to drug resistance directly on biological samples without the requirement of culturing organism.

Syndrome Evaluation System (SES)

A patented technology that comprises of rapid multiplex amplification and accurate identification of the virulence associated genes of the causative agents or organisms. This amazingly fast and accurate platform transcends all conventional diagnostic tests and helpful when organisms are difficult to cultivate or difficult to find. The technologies currently available for diagnosis of infections are grossly inadequate to detect early during the illness and to institute specific therapy in critical illnesses, resulting in loss of function or even loss of life.

The amplification of the gene allows for higher sensitivity of the test and the re-naturation of the amplified signature gene to its chemically identified complementary gene sequence on the SES allows for higher specificity of the test. And the simultaneous detection of multiple pathogens allows for early diagnosis of the infection and initiation of therapy.

The SES Advantage

Rapid	Sample to report in 7 - 10 hours
Higher Accuracy	Detects more number of cases than conventional methods (75% by SES vs 10-15% conventional method)
Cost effectives	Avoids multiple testing and unnecessary investigations and reduces ICU stay & associated cost.
Provides Direct evidence for the presence of infection	Detects DNA of pathogens
Comprehensive	Detects fungi, viruses, parasites and bacteria in a single test. It also detects uni-microbial or poly-microbial infections
Rules in or Rules out infections	

Systemic Infections

A systemic infection is being spread throughout the systems of the body as compared to local infections where the pathogen or symptoms are localized in one area. Systemic infections can also be as severe as local infections & life threatening, example Sepsis etc.

Sepsis

Sepsis or blood poisoning is the leading cause of death in intensive care units. It affects over 26 million people worldwide each year. 258,000 people die from sepsis every year in the U.S. alone. It is the biggest contributor to healthcare associated cost. In India, 1 out of 4 patients admitted in ICU get sepsis, 50% of them die. As many of these patients receive antibiotics prior to getting admitted to the hospitals & ICUs, only in 15% of the patients the causative agents are identified by blood culture. Most of the patients are treated with multiple broad spectrum antibiotics. 62% of sepsis patients need readmissions. 50% of sepsis survivors suffer from post sepsis syndrome. Early diagnosis and institution of appropriate antibiotics remarkably improves survival rates among patients. SES detects bacteria and fungi four times more than culture within a day while culture takes 3-4 days.

Transplant Infections & Febrile Neutropenia

When patients with blood and other cancers are treated with chemotherapy their white blood cells get drastically reduced making these patients very vulnerable to many serious life threatening infections. Mortality in Febrile Neutropenia ranges from 11-25%. Early diagnosis is key to successful management and conventional diagnostics detect nearly 17-20% of cases but are not adequately sensitive to rule out the infections to enable clinicians to reduce toxic antibiotics and antifungals (deescalate).

In India there is a need for 200,000 kidney transplants, 50,000 liver transplants and 50,000 heart transplants per year. Currently India more than 20,000 transplants annually are carried out. In order to retain the transplanted organ and prevent rejection all these patients are kept on longterm immunosuppression. This in turn leads to frequent episodes of life threatening infections in these patients. Timely diagnosis and appropriate intervention are key to keep these patients safe and functional.

Pneumonia

Pneumonia or Lung Infection is caused by a variety of viruses, bacteria and fungi. There are totally 50 million cases of pneumonia every year in India. Among children below the age group of 5, 2,50,000 children die due to severe pneumonia. Many cases of pneumonia lead to sepsis and 50% of all sepsis are caused by severe pneumonia. When a patients are placed on ventilators during management of sepsis hospital acquired Ventilator Associated Pneumonia (VAP) develops.

Tuberculosis

Worldwide, TB is one of the top 10 causes of death, and the leading cause from a single infectious agent (above HIV / AIDS). According to a WHO report, India saw 2.7 million TB cases (incidence + relapse) in 2017. India accounted for 27% of global TB deaths. Globally, 3.5% of new TB cases and 18% of previously treated cases had multi-drug resistant/rifampicin resistant TB (MDR/RR-TB). India is one of the top 3 countries with the largest number of MDR/RR-TB cases that constitute 47% of global MDR/RR-TB cases.

SES Sepsis

Microbe Type	Microorganism
Gram Positive Bacteria	*Staphylococcus aureus* *Streptococcus pneumoniae* *Streptococcus pyogenes* *Group B Streptococcus* *Enterococcus spp.*
Gram Negative Bacteria	*Klebsiella pneumoniae* *Enterobacter aerogenes* *Proteus mirabilis* *Haemophilus influenzae* *Neisseria meningitidis* *Pseudomonas aeruginosa* *Acinetobacter baumannii* *Escherichia coli* *Salmonella spp.* *Bacteroides fragilis* *Leptospira pathogenic spp.*
Fungi	*Aspergillus spp.* *Candida Spp.*
Sample Type : Whole Blood (Peripheral Blood)	

SES Mycobacteria

Microbe Type	Microorganism
Atypical Bacteria	*Mycobacterium tuberculosis* *Mycobacterium chelonae* *Mycobacterium fortuitum* *Mycobacterium spp*
Sample Type : Wound Swab	

SES Respiratory Viral Panel

Microbe Type	Microorganism
DNA Viruses	*Cytomegalovirus* *Adenovirus*
RNA Viruses	*Influenza A, B,C* *Parainfluenza 1,2,3,4* *RSV A and B* *Rhinoviruses* *Enteroviruses* *Coronaviruses OC43, 229E, NL63, HKU1* *Human-Metapneumoviruses* *Parechoviruses* *SARS*
Sample Type : Naso Pharyngeal Wash	

SES- Febrile Neutropenia/ Post Transplant Pneumonia

Microbe Type	Microorganism
Gram Positive Bacteria	*Staphylococcus aureus* *Streptococcus pneumoniae* *Streptococcus pyogenes* *Group B Streptococcus* *Enterococcus spp* *Mycobacterium tuberculosis*
Gram Negative Bacteria	*Klebsiella pneumoniae* *Enterobacter aerogenes* *Proteus mirabilis* *Haemophilus influenzae* *Neisseria meningitidis* *Pseudomonas aeruginosa* *Acinetobacter baumannii* *Escherichia coli* *Salmonella spp.* *Bacteroides fragilis* *Leptospira pathogenic spp.*
Fungi	*Aspergillus spp.* *Candida Spp.* *Cryptococcus neoformans*
DNA Viruses	*Herpes Simplex Virus 1&2* *Cytomegalovirus* *Varicella Zoster Virus* *Human Herpes Virus 6* *Adeno Virus* *John Cunningham Virus* *BK Virus* *Epstein Barr Virus*
Sample Type : Whole Blood (Peripheral Blood)	

SES Post Transplant Viral Panel

Microbe Type	Microorganism
DNA Viruses	*Herpes Simplex Virus 1&2* *Cytomegalovirus* *Varicella Zoster Virus* *Human Herpes Virus 6* *Adeno Virus* *John Cunningham Virus* *BK Virus* *Epstein Barr Virus*
Sample Type : Whole Blood (Peripheral Blood)	

SES Community Acquired Pneumonia

Microbe Type	Microorganism
Gram Positive Bacteria	*Staphylococcus aureus* *Streptococcus pneumoniae*
Gram Negative Bacteria	*Klebsiella pneumoniae* *Haemophilus influenzae* *Pseudomonas aeruginosa* *Acinetobacter baumannii* *Salmonella spp.*
Atypical Bacteria	*Mycoplasma pneumoniae* *Chlamydia pneumoniae*
Fungi	*Pneumocystis jirovecii*
DNA Viruses	*Cytomegalovirus* *Adenovirus*
RNA Viruses	*Influenza A, B,C* *Parainfluenza 1,2,3,4* *RSV A and B* *Rhinoviruses* *Enteroviruses* *Coronaviruses OC43, 229E, NL63, HKU1* *Human-Metapneumoviruses* *Parechoviruses* *SARS*
Sample Type : Naso Pharyngeal Wash	

SES Antibiotic resistance markers

Rifampicin Resistance

IHN Resistance

SES Antibiotic resistance markers

ESBL: Detects genes that confers resistance to Extended Spectrum Beta Lactams

Carbapenem: Detects both, Betalactamases and Metallo Betalactamases

NDM-1: Detects New Delhi Metallo Betalactamases

Van A: Detects resistance to Vancomycin and Teicoplanin

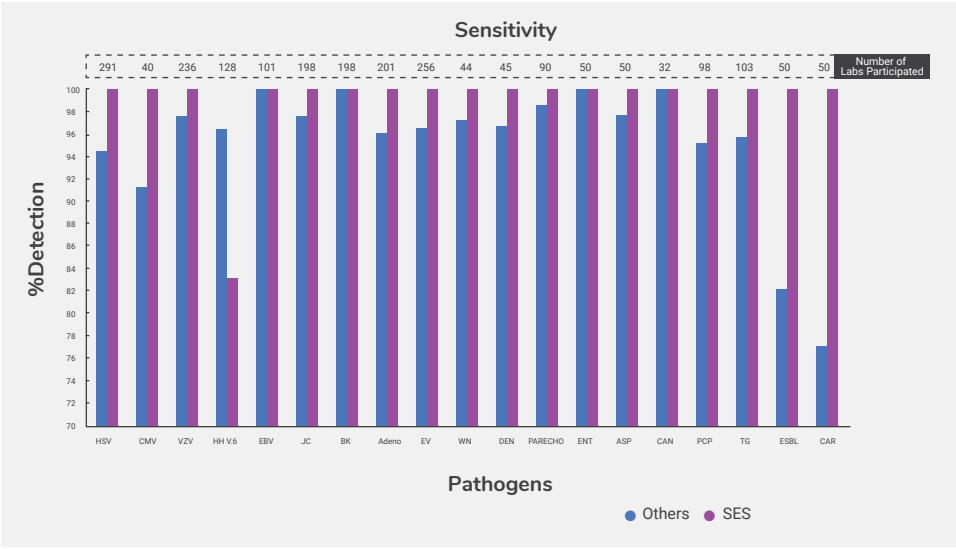
Van B: Detects resistance to Vancomycin (Teicoplanin Sensitive)

Methicillin: Detects resistance to Methicillin

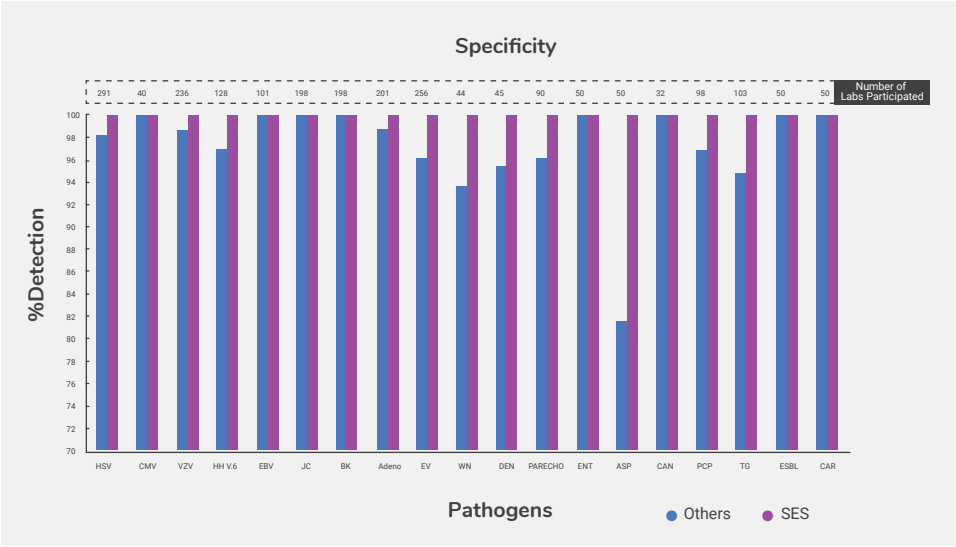
Performance of SES Testing-Quality Considerations

The SES test scored exceptionally in International Proficiency Test conducted by Quality Control for Molecular Diagnostics (QCMD), an independent International External Quality Assessment (EQA) / Proficiency Testing (PT) organisation

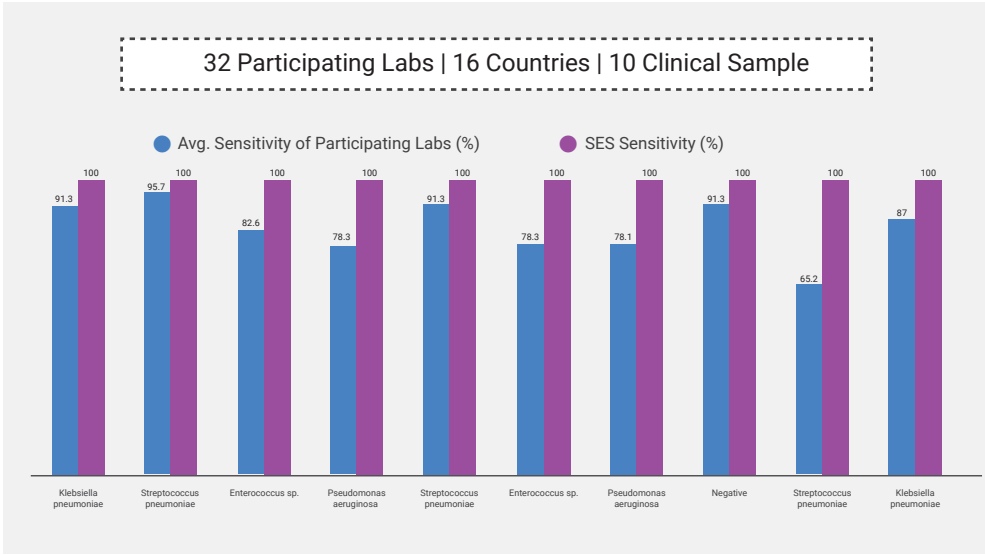
1. International Proficiency Testing- SES sensitivity



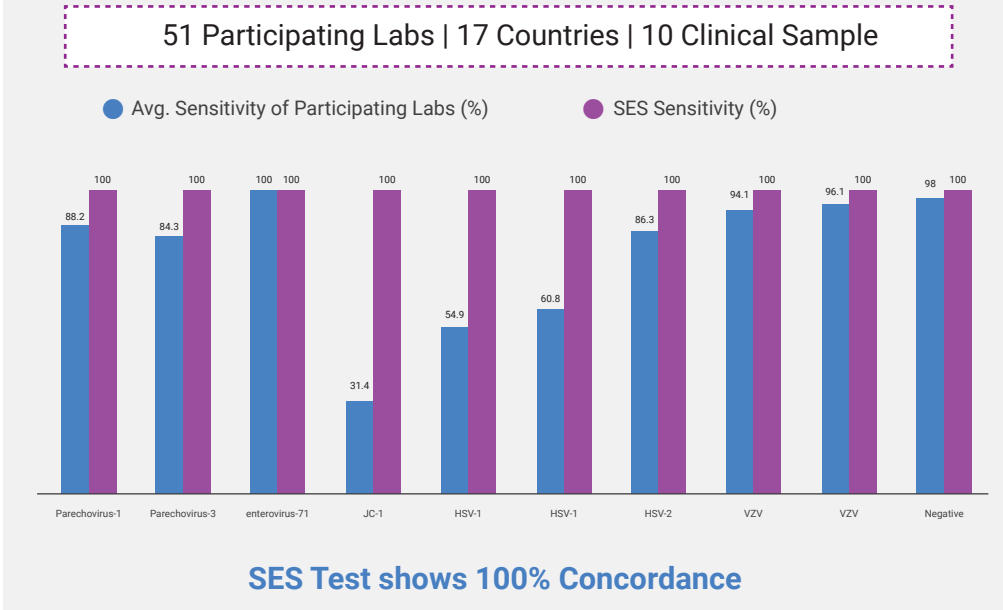
2. International Proficiency Testing- SES specificity



3. Validation for SES Sepsis Panel



4. Validation for SES Viral Panel Pathogens



SES Test shows 100% Concordance

Sample Requirements:

Test	Sample Type	Other Sample Type
SES Sepsis	WHOLE BLOOD (PERIPHERAL BLOOD)	BAL, TISSUE or Any sterile body fluid
SES- FEBRILE NEUTROPENIA/ POST TRANSPLANT/PNEUMONIA	WHOLE BLOOD (PERIPHERAL BLOOD)	BAL, TISSUE or Any sterile body fluid
SES- TRANSPLANT VIRAL PANEL	WHOLE BLOOD (PERIPHERAL BLOOD)	BAL, TISSUE or Any sterile body fluid
SES-COMMUNITY ACQUIRED PNEUMONIA	Naso pharyngeal wash	BAL/Tracheal aspirate
SES-Respiratory Viral Panel	Naso pharyngeal wash	BAL/Tracheal aspirate
SES-Mycobacteria	Wound swab	BAL, TISSUE or Any sterile body fluid

Acceptance Criteria of Sample

- Freshly collected blood sample/ other body fluids
- Samples volume greater than 2ml
- Sample collected only in potassium EDTA vacutainer

Rejection Criteria of Sample

- Blood samples/ other body fluids stored for more than 24 hours
- Heparinised blood sample or other body fluid
- Blood sample collected from central line
- Sample collected in in-house sterilised injection vials/Falcon tubes/ test tubes or wide mouth containers

Precaution during sampling

- Sterilise the collection site to prevent skin contaminants getting into the sample
- Collect sample directly into the vacutainer

References

1. https://www.who.int/infection-prevention/en/
2. https://www.who.int/infection-prevention/publications/burden_hcai/en/
3. https://www.who.int/infection-prevention/publications/ssi-prevention-guidelines/en/
4. https://www.intechopen.com/books/nucleic-acids-from-basic-aspects-to-laboratory-tools/ nucleic-acid-based-diagnosis-and-epidemiology-of-infectious-diseases
5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3401822/
6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5955554/
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5043220/
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5613608/
9. https://emedicine.medscape.com/article/430550-overview
10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008944/
11. https://borgenproject.org/pneumonia-in-india/
12. http://www.ijo.in/article.asp?issn=0301-4738;year=2017;volume=65;issue=8;spage=673;epage=677;aulast=Lalitha
13. https://www.chanrejournals.com/index.php/indiainflammation/article/view/249/html

14. https://www.sepsis.org/wp-content/uploads/2017/05/Sepsis-Fact-Sheet-2018.pdf

15. Divatia JV, Amin PR, Ramakrishnan N, Kapadia FN, Todi S, Sahu S. et al. Intensive Care in India: The Indian Intensive Care Case Mix and Practice Patterns Study.Indian J Crit Care Med. 2016 Apr;20(4):216-25

16. R Frost, H Newsham, S Parmar, A Gonzalez-Ruiz. Impact of delayed antimicrobial therapy in septic ITU patients. Crit Care. 2010; 14(Suppl 2): P20.

17. Bhat BV, Prasad P, Ravi Kumar VB, Harish BN, Krishnakumari K, Rekha A, et al. Syndrome Evaluation System (SES) versus Blood Culture (BACTEC) in the Diagnosis and Management of Neonatal Sepsis - A Randomized Controlled Trial. Indian J Pediatr. 2016 Jan 6.

18. Bergmann T, Sculler JP. Myelosuppression and infective complications. In: Souhami RL, Tannock I, Hohenberger P, Horiot JC, editors. Oxford Textbook of Oncology. 2nd ed. New York: Oxford University Press; 2002. p. 575-87.

19. Kuderer NM, Dale DC, Crawford J, Cosler LE, Lyman GH. Mortality, morbidity, and cost associated with febrile neutropenia in adult cancer patients. Cancer 2006;106:2258-66.

20. de Naurois J, Novitzky-Basso I, Gill MJ, Marti FM, Cullen MH, Roila F. ESMO Guidelines Working Group. Management of febrile neutropenia: ESMO Clinical Practice Guidelines. Ann Oncol 2010;21:252-6.

21 Freifeld AG, Bow EJ, Sepkowitz KA, Boeckh MJ, Ito JI, Mullen CA, et al.Infectious Diseases Society of America. Clinical practice guideline for the use of antimicrobial agents in neutropenic patients with cancer: 2010 Update by the Infectious Diseases Society of America. Clin Infect Dis 2011;52:427-31.

22. Khayr W, Haddad RY, Noor SA. Infections in hematological malignancies. Dis Mon 2012;58:239-49.

23. https://organindia.org/wp-content/uploads/2014/11/ORGAN-Research-Report.pdf

Notes

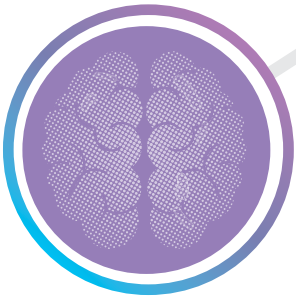
Notes

XCyton

MEDGENOME

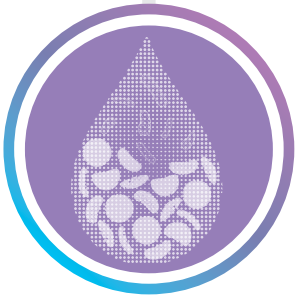
Micra by MedGenome offers advanced test for genetic and molecular testing in infectious diseases

micra



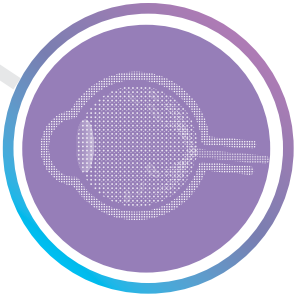
CNS Infections

- Meningitis
- Meningo-encephalitis
- Acute Encephalitis Syndrome



Systemic Infections

- Sepsis
- Febrile Neutropenia
- Pneumonia
- Respiratory Infections



Eye Infections

- Endophthalmitis
- Uveitis
- Fuch's Disease
- Retinitis

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For more information

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