

## TEST REQUISITION FORM

Each sample must be accompanied by this completed requisition.  
\* Fields are mandatory

Bill type:  MOU  Retail  Research

### Test Details

Test Name:\* (select a test)

#### CNS Infections:

- SES Pan CNS (MGX011)
- SES Meningitis (MGX013)
- SES Encephalitis- Sporadic (MGX015)
- SES AES (MGX017)
- SES Encephalitis- Outbreak (MGX016)
- SES Antibiotic Resistance (ABR) (MGX002)
- SES Meningitis + SES ABR (Combo) (MGX014)
- SES Pan CNS + SES ABR (Combo) (MGX012)

#### Systemic Infections:

- SES Sepsis (MGX001)
- SES Post Transplant/Febrile Neutropenia/Pneumonia (MGX004)
- SES Transplant Viral Panel (MGX006)
- SES Respiratory Viral Panel (MGX007)
- SES Mycobacteria (MGX008)
- SES MDR TB (MGX009)
- SES Community Acquired Pneumonia (MGX010)
- SES Antibiotic Resistance (ABR) (MGX002)
- SES Sepsis + SES ABR (Combo) (MGX003)
- SES Post Transplant / Febrile Neutropenia/Pneumonia + SES ABR (Combo) (MGX005)
- NAAT CheX TB + Neurocysticercosis (MGX018)

#### Eye Infections:

- SES Traumatic / Chronic / Endogenous Endophthalmitis (MGX019)
- SES Post Surgical Endophthalmitis (MGX020)
- SES Pan Uveitis (MGX021)
- SES Fuch's (MGX022)
- SES Uveitis (MGX024)
- SES Viral Retinitis (MGX023)

Specimen:\*

Date and time of specimen collection:\*

Specimen collected by: (name of hospital staff):

### Patient Details

Name:\* (In Capital Letters)

Gender:\*  M  F D.O.B.  DD  MM  YY / Age:\*

Address:

Phone:  E-mail I.D:

### Clinician Details

Clinician's Name:\*

Clinician Contact No:  Clinician Email ID:

Alternate Clinician:

Alternate Clinician Contact No:  Email ID:

Address:  Referring Hospital:\*

Provisional Diagnosis:\*  Date of onset of illness:

### Brief History

Results of investigations done:\*

Medication:\*

Risk (HIV, HCV, HBV)- please specify:\*

I am authorised to order the above tests as I am the treating physician/consulting physician in this case. I confirm that the patient/guardian (in case of minors) has been provided complete information regarding the test, including its limitations in a language of their understanding.

Medical Professional Signature\*

Place

Date and time of handing over sample to logistics person\*

## Informed Consent and Authorization Form

### Information for Patients:

Sepsis is a disease in which bacteria or fungi enter blood stream and spread across the body. These dangerous organisms enter blood from boils in the skin, lungs having pneumonia, from gut after infection or a surgery. Once bacteria enter the blood, the various by products induce reactions in the body in which it can affect kidneys, lungs, liver, brain and heart and blood vessels. Patients at this stage are having 'Severe Sepsis'. In order to save the patients, they will be kept on dialysis or ventilator and intravenous injections of fluids to maintain stable blood pressure. This is called multiple organ dysfunction syndrome (MODS). If blood pressure falls below dangerous levels then drugs are given to increase blood pressure. This stage is called 'Septic Shock'.

The whole treatment is focussed on two things. One to maintain all physiological parameters such as urine output, oxygen supply to the body through lungs and maintenance of blood pressure. Second and most important action is to identify the exact bacterium or fungus responsible for the situation and give the most appropriate antibiotic or antifungal. Your relative has already been put on certain antibiotics which can act on a large number of different bacteria to immediately control the situation. These antibiotics would not be effective on all bacteria and there is a need to switch to antibiotics which can target actual organism affecting this patient. If the actual organism is not known, doctors, in order to save the patient, give multiple powerful last resort antibiotics. However this leads to antibiotic resistance wherein the bacteria no longer respond to these last resort, high ended antibiotics.

Similarly, Meningitis & Encephalitis are severe brain infections which can cause permanent damage like paralysis, blindness etc. It happens when dangerous organisms like bacteria, virus or fungi enter the brain. Delay in diagnosis of these organisms may cause severe irreversible damage to the brain. Identification of these organisms is necessary for treating the patient with appropriate drugs.

Blood from the patient is also sent for 'Blood Culture' a method in which we allow bacteria or fungi present in blood to multiply to a level where they can be easily identified. However this test takes 72 hrs and identifies the organisms in only 15-20% of cases. Similarly, for brain infections, routine tests like analysis and culture of brain fluid, MRI, CT scan, etc are important but not enough to pinpoint the organism which is causing the disease.

There is costlier but faster (less than 24 hrs) test called Syndrome Evaluation System (SES) of XCyton Diagnostics, Bangalore. SES tests identify bacteria, viruses and fungi by genetic material (DNA).

### About Syndrome Evaluation System (SES):

Syndrome Evaluation System (SES) developed by XCyton Diagnostics Pvt. Ltd., Bengaluru, is a commercially available molecular diagnostic test. It is a patented technology which simultaneously detects multiple pathogens be it bacterial, viral, fungal and/or parasite in a single test from a single sample with a processing time of 7 hours. SES amplifies virulence specific (only disease causing organism) and thus will not identify harmless bacteria found in patients. SES panels cover for the organisms which cause 90% of infections in India. All these organisms are spread across different panels under systemic infection, Eye Infection & CNS Infection. It is a syndrome based approach to diagnosis of critical infections and eliminates the need for multiple tests. SES also provides information on common antibiotic resistance markers conferring resistance to antibiotics used in ICU set up such as 3rd & 4th generation Cephalosporins, Carbapenems, Vancomycin, Teicoplanin, Beta-lactamases and Methicillin.

SES has already been tested on more than 18000 patients and various hospitals like JIPMER, NIMHANS, NH, HCG, AIMS Kerala, Fortis Noida, Ramaiah hospital, KG hospital etc., have already published their data in medical journals on the application of SES in critical infections.

Since you are suffering from a condition which is likely to be caused by an infection, it is very important to diagnose the organism/s which is causing the infection, so that appropriate drugs can be given. This is an additional test along with culture of blood or any other body fluids that routinely is being done in the laboratory of the hospital where you are admitted. Approximately 12 ml of blood (or other body fluid deemed appropriate by the investigator) will be drawn for the purpose of microbial diagnosis. 10 ml will be sent for culture and 2 ml will be sent to XCyton Diagnostics Laboratory at Bangalore. Initial drug therapy will be modified, if needed, according to the SES results as soon as they are received. Further changes in therapy will be made as per the culture results, if needed. Treatment protocol, i.e., selection of drugs

for your therapy will be based on the most appropriate choice as deemed fit by your physician. The treatment for your underlying condition will also be as per the standard hospital protocol and discretion of your physician. The total study duration is for one year, although it may be extended depending on various factors. Data from 100 patients in whom SES test is done would be collected. During the same period, systematic data analysis would be done for a similar number of patients in whom SES test is not done due to factors like affordability and consent

### Possible Results:

**Positive:** Pathogens detected by SES are present in the sample and thus are inferred to be causing the disease in the patient.

**Negative:** The pathogens tested for in SES are not present. Early on during the illness especially within first 72 hrs, it can be confirmatory that significant infection by the organisms tested for is not present. Later on during the illness the guarantee of the negative result reduces.

### Variable that influence the results:

You should be aware and understand that XCyton's SES is to be used by qualified physicians as a Therapeutic Decision Support System, to assist them in evaluating the critical infections described in Appendix 1, and deciding on a course of therapy based on the results provided by SES. Infections will be detected in the vast majority of affected individuals. Under no circumstance however can it be guaranteed that SES will detect the existence or non-existence of each of the potentially detectable infections identified, due to factors such as age of patient at the time of specimen collection, duration of the illness, pharmaceutical agents administered, quality of specimen, health status of the patient and other variables which are outside the parameters of the evaluation process.

### Benefits and Risks:

SES is a faster and more sensitive diagnostic test for diagnosing bacteria, fungi, viruses and parasites in a single test. SES report is available to the clinicians attending to the patient within 24 hours. Although SES is not yet the routine diagnostic test across the world, physicians in India have been routinely using this technology for the past few years and have seen that it gives results not only in two to four times more number of cases when compared to culture, but also much faster. This helps them to quickly take appropriate decisions regarding which drug to be given to patient. Foreseeable benefits of this test include usage of lesser number of antibiotics, overall cost saving for the patient, reduction in antibiotic resistance and appropriate and faster institution of antimicrobials leading to decreased mortality due to infections. However, after this counselling session where we are discussing the potential benefits and risks for you to consent for the test, patient sample would be sent for SES only if you agree to pay for the test, the cost of which will be informed to you in advance.

#### Data Confidentiality:

All records and documents pertaining to your test will be held strictly confidential. Your name will not be disclosed or reported in any publications. Access to any identifiable information about you that is collected during the testing will be limited to participating doctor/s associated with the hospital and their staffs and XCyton Laboratory.

### MedGenome Order Cancellation & Refund Policy v2.6 :

#### Order can be cancelled at any time and will be governed by the below policy:

1. MedGenome Order Cancellation & Refund Policy v2.6 : Order can be cancelled at any time and will be governed by the below policy:

- If cancelled within 2 hours from order booking - Full refund
- If cancelled after 2 hours from order booking - No refund

Please refer most recent version of the MedGenome test menu for turnaround time of specific tests.

**\*Disclaimer:** While the laboratory takes utmost care to return results within the turnaround time, there may be unforeseen circumstances due to which the TAT is sometimes exceeded. In such situation, MedGenome will not be liable.

MedGenome prefers to send the genetic test reports to the referring clinician considering the complexity of the test, patients are advised to contact the referring clinician for the test report.

### Patient/Guardian Authorization

#### By my signature below I attest to the following:

I have read and I understand the information provided on this form.

#### Patient Consent (sign here or on the consent document)

I have read the Informed Consent document and I give permission to MedGenome to perform SES testing as described. I also give permission for my specimen / data to be used in (de-identified) studies at MedGenome to improve SES testing for other patients.

By agreeing to this informed consent below I am confirming that I understand the benefits, risks and limitations associated with SES testing. Furthermore, I am affirming that I recognize the seriousness of conditions for which {I/my child} am being tested, and that disease descriptions, have been made available to me by {my/my child's} health care provider. Finally, if I have the legal authorization to provide this informed consent on behalf of another person, I am attesting that the sample provided belongs to that person.

Patient/Guardian Full Name \_\_\_\_\_

Date of Birth: mm/dd/yyyy \_\_\_\_\_

Relationship with the patient \_\_\_\_\_

Date \_\_\_\_\_ Place \_\_\_\_\_

Patient/Guardian Signature\* \_\_\_\_\_

\*Fields are mandatory