

## Immunogenetic profiling to assess susceptibility to immune-inflammatory manifestations associated with breast implants

### *The value of genetics in personalised surgical care*

An advanced genetic test designed to support specialist assessment of:

- individual susceptibility to immune-inflammatory manifestations associated with breast implants
- biological susceptibility to symptom profiles reported as Breast Implant Illness
- individual risk stratification before surgery
- clinically relevant information for follow-up in patients with a suggestive medical history





## SILICONE BREAST IMPLANTS

**Silicone breast implants (SBIs)** are medical devices widely used in clinical practice for **aesthetic** breast augmentation or contouring and for **reconstructive** purposes, particularly following oncological surgery or corrective procedures.

Advances in materials, device design and surgical techniques have progressively consolidated their role in plastic and reconstructive surgery.

Although breast implants are generally considered to have a **favourable safety profile**, some patients may experience local complications or, less frequently, systemic manifestations, even when surgery has been performed correctly and in accordance with appropriate technical standards.

### More frequently reported

Pain, oedema, induration, seroma, capsular contracture and localised inflammatory reactions.

### Less frequently reported

Granulomas, immune-mediated phenomena and systemic manifestations of greater clinical significance.





# BREASTIMPLANT

ASIA-BIAI

## BREAST IMPLANT ILLNESS AND THE ASIA FRAMEWORK

In recent literature and regulatory communications, the term **Breast Implant Illness (BII)** is commonly used to describe a heterogeneous group of non-specific symptoms reported by some patients with breast implants.

### Frequently reported symptoms

- Fatigue
- Myalgia
- Arthralgia
- Cognitive difficulties
- brain fog
- Skin rashes
- Other systemic complaints

Some scientific publications have also discussed these presentations within the proposed **Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA)**, also known as Shoenfeld's syndrome. However, the causal mechanisms and nosological criteria of these entities remain under investigation and have not been definitively established.

**NURRENT SCIENTIFIC CONTEXT:** Current hypotheses suggest that, in a subset of patients, symptom profiles described as BII or discussed within the ASIA framework may reflect an individual susceptibility influenced by interactions among **genetic, immunological and environmental factors**.



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## THE GENETIC TEST FOR ASSESSING SUSCEPTIBILITY TO BREAST IMPLANT-ASSOCIATED ADVERSE REACTIONS

**BREASTIMPLANT ASIA-BIAI** is a targeted genetic test designed to assess the presence of specific **immunogenetic profiles** that may be associated with **increased individual susceptibility** to symptoms or manifestations compatible with an **immune-inflammatory** response in people with silicone breast implants.

The test is intended to support the specialist in integrating immunogenetic information into **pre-operative assessment, individual risk profiling** and subsequent **clinical follow-up**.

### Scientific basis

The rationale of the test reflects the possible contribution of genetic susceptibility to variation in the biological response to an implant in certain patient subgroups. It is based particularly on the central role of the **HLA (Human Leukocyte Antigen) system** in immune recognition, antigen presentation and regulation of the immune response. Certain HLA subtypes have been reported in association with manifestations described as Breast Implant Illness.

Specific allelic profiles may influence how the body responds to antigenic or antigen-like stimuli, potentially contributing to **greater susceptibility** to atypical, persistent or prolonged inflammatory responses. These associations are **probabilistic and do not establish causation or predict an individual outcome**.



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## CLINICAL VALUE FOR THE SPECIALIST

**BREASTIMPLANT ASIA-BIAI** is not a diagnostic test. It provides clinically relevant information intended to complement specialist assessment of individual biological susceptibility.

### The test is particularly useful for:

- ➡ Integrating **immunogenetic information** with medical history, clinical findings and the proposed surgical plan.
- ➡ Supporting a more informed and appropriately qualified discussion of **individual susceptibility**.
- ➡ Guiding the assessment of patients with **allergies, immune disorders** or **suspected increased sensitivity**.
- ➡ **Contextualizing** reactions temporally associated with breast implants within the overall clinical picture.

## Supporting personalised plastic and reconstructive surgery

Biological responses to implants can vary considerably between individuals. **BREASTIMPLANT ASIA-BIAI** offers an additional layer of information to support a more **personalised, informed and clinically responsible** approach to plastic and reconstructive surgery.



## WHEN TESTING MAY BE CONSIDERED

Testing may be considered within specialist assessment for:



Individuals with a history of **allergic conditions, immune disorders or suspected increased sensitivity.**



Individuals who have **experienced adverse events** associated with breast implants or other prosthetic devices.



Individuals **considering breast implant surgery** for the first time who wish to assess their biological susceptibility.

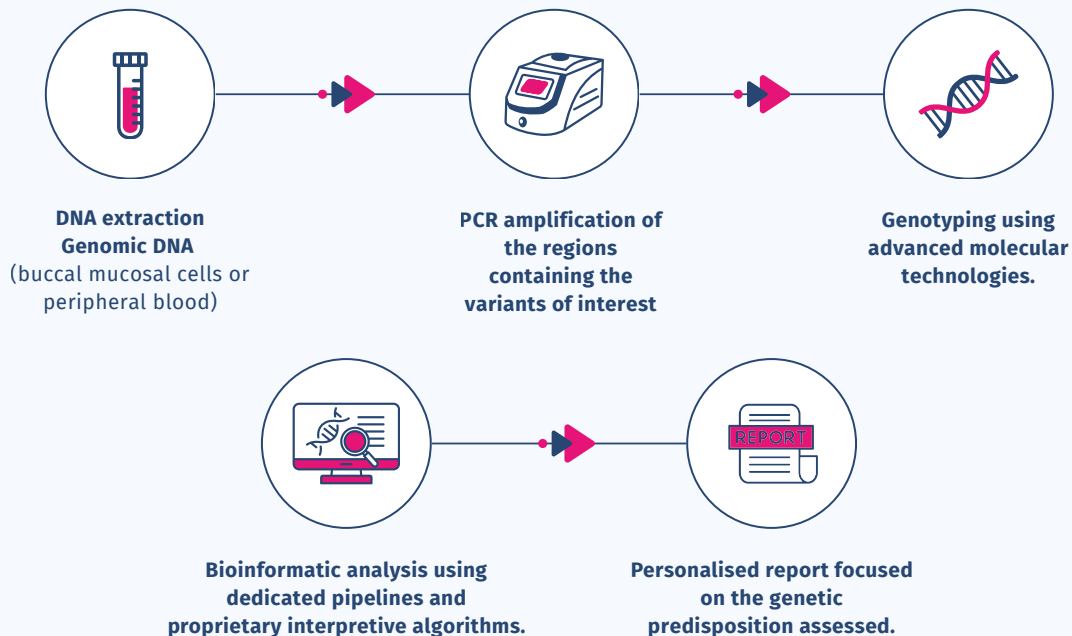
The decision to perform the test should always be considered in the context of the **individual's personal medical history**, overall **clinical condition**, **reason for surgery** and **any concurrent conditions of immunological or inflammatory relevance.**



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## ANALYTICAL WORKFLOW



The genetic result should be integrated with medical history, clinical findings and the specialist's judgement. It does not independently determine the indication for surgery or clinical management.



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## INTERPRETATION OF THE RESULT



### POSITIVE

**Detection of the risk-associated HLA profile** is consistent with increased susceptibility to medium- or long-term immune-mediated adverse reactions following breast implant surgery.

*The result is an indicator of **individual predisposition** that may be relevant to pre-operative counselling and subsequent clinical follow-up. It is not a contraindication to treatment and does not predict with certainty that a complication will occur.*



### NEGATIVE

The **risk-associated HLA profile was not detected**. The test therefore provides no evidence of marker-associated increased susceptibility.

*A negative result does not demonstrate a **reduction in overall risk and does not exclude adverse events**. Other contributing factors may include device characteristics, individual inflammatory responses, concurrent clinical conditions, immunological features not covered by the test, unanalysed genetic determinants and surgical or procedural variables.*

### IMPORTANT

**BREASTIMPLANT ASIA-BIAI** is non-diagnostic and must be interpreted by a qualified healthcare professional in the context of the complete clinical picture.

## A SIMPLE FIVE-STEP PROCESS



**Request  
the kit**



**Complete the  
documentation**



**Collect the  
sample**



**Send the sample  
to the laboratory**



**Receive the  
report**

**Turnaround time**



**~10 working days**

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