



Test Information

A

Products of Conception (POC) for comprehensive chromosome screening of Chromosomes 1-22, X&Y

Gestational age:

Date of Procedure: **DD / MM / YYYY**

Procedure Authorisation No:

Medical History (Optional)

Number of Miscarriages (including current)

IVF Pregnancy Yes No

Reason for testing

- Abnormal features (specify if possible)
- Spontaneous pregnancy loss
- Recurrent pregnancy loss
- Blighted ovum/Anembryonic pregnancy
- Molar pregnancy (indicate full or partial)
- Missed miscarriage
- History of pregnancy with chromosomal anomalies (specify)

Comments:

Healthcare Provider Information

B

Healthcare Provider: <input type="text"/>	Healthcare Provider signature: <input type="text"/>
Centre/Clinic Name: <input type="text"/>	Date: DD / MM / YYYY
Phone: <input type="text"/>	
Email For Report: <input type="text"/>	

Patient Information

C

Patient

Last Name: <input type="text"/>	First Name: <input type="text"/>
Phone: <input type="text"/>	Email: <input type="text"/>
Date of Birth: DD / MM / YYYY	ID/Passport No: <input type="text"/>
Medical Aid Name: <input type="text"/>	Medical Aid No: <input type="text"/>
Medical Aid Plan: <input type="text"/>	

By signing this I declare that I have read, understood and agree to the contents of the informed consent agreement (on the back of this form) in its entirety and authorise Next Genetics to analyse the DNA from the sample provided and report the data to my referring doctors. I acknowledge and agree to the costs of the genetic testing, and agree to settle any and all invoices issued to me by Next Genetics, by the stipulated date. I acknowledge that the claim will be submitted directly to my medical aid for reimbursement, and note that in the event that my medical aid does not cover the claim, I will be liable for the full amount

Patient Signature:

Date: **DD / MM / YYYY**

Please send the form to genetics@nextbio.co.za
For any queries, complaints or feedback, please contact us on +27 (0)11 697 2900
or email us on genetics@nextbio.co.za

Place patient sticker here



PRODUCTS OF CONCEPTION SCREENING (POCSCREEN):

Below is a summary of the important aspects of the process. You should feel free to ask any and all questions you have about it. Your healthcare provider (HCP) in genetics, obstetrics, and reproductive medicine is your best source of information about this process. In addition, you may request a referral from your HCP for formal genetic counselling before signing this consent form.

You give permission and consent to your existing and previous HCP, discussing and exchanging information about you and your family (this may include, but is not limited to your medical reports and indications for genetic testing, for example). In addition, your test results will be disclosed to your referring HCP and possibly his/her staff.

You understand that the staff of Next Genetics are not acting in any way as your HCP but are functioning solely as your HCP's chosen testing laboratory, in the provision of genetic testing for the products of conception sample

POC testing uses Next generation sequencing (NGS) technology to screen products of conception for abnormal chromosome numbers, and large genetic deletions and/or duplications of chromosomal material.

I CONFIRM THAT I HAVE BEEN INFORMED OF THE FOLLOWING:

1. The purpose of POCscreen testing is to screen for chromosomal aneuploidy, or large deletions/duplications of genetic material.
2. Conventional POCscreen testing is validated for detecting chromosomal aberrations at a resolution of >10 mega base pairs.
3. The limit of detection for mosaicism on the POCscreen test is 20%.
4. POCscreen cannot accurately detect triploidy/tetraploidy.
5. POCscreen cannot detect balanced chromosomal rearrangements.
6. Next Genetics is not responsible for delays or failures in transit due to factors outside of their reasonable control, including but not limited to weather or air travel conditions.
7. Loss or damage of samples can occur and result in the inability to perform the test(s) or report test results.
8. Specimen transport and/or collection issues may impact the ability to perform the requested test(s).
9. Next Genetics retains the right to reject samples that do not meet its standards for testing.
10. The Next Genetics laboratory will only undertake the specific test ordered by your HCP.

You give permission and consent to the sequencing and analysis of DNA isolated from the products submitted for testing. Your results may indicate that additional testing may be considered, you can discuss this with your HCP or a genetic counsellor. You acknowledge that you have read, understood and accept the information above.

Upon completion of your genetic testing, Next Genetics may store test data to perform analysis for research studies for as long as Next Genetics deems it useful for research purposes. Next Genetics will remove all personal information from your test data prior to conducting such research studies and will not include your name or other personal information in the results of any research studies or publications. As your name and personal information will be removed from the test information, you will be given no notice or compensation if the research leads to development of new test techniques, inventions, or discoveries. You renounce any and all rights to, ownership of, and interest in any data obtained by Next Genetics, and acknowledge that neither you nor your heirs will acquire any rights or license to, ownership of, or interest in any research, commercial products, techniques, inventions, discoveries or intellectual property arising or derived from or relating to the use of your data, or information gained from your genetic testing.

I further consent to the storage of all biological material sent to Next Genetics, as well as genetic data generated from such. DNA isolated from products submitted for testing will be kept for a minimum of 24 months, in accordance with international guidelines.

I accept that the maximum amount of any and all liability which Next Genetics (and its respective shareholders, directors, officers, employees and agents, including marketing agents and other representatives) may incur to the Client in terms of the screening, or in respect of any and all actions or omissions of Next Genetics under any and all circumstances shall be the total amount paid by the Client to Next Genetics as set out hereunder.

COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA):

- You understand that Next Genetics takes the privacy of its patients very seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of private patient information in line with the Protection of Personal Information Act (POPIA).
- You acknowledge that your personal information may be disclosed within the Next Genetics team for the purposes of providing services.
- You acknowledge that your personal information may be disclosed by Next Genetics in response to a specific request by a law enforcement agency, subpoena, court order, or as required by law.
- You confirm that the information supplied is true and correct and that you are responsible for updating your information to ensure that it remains correct.
- You acknowledge that your personal and special personal information will be kept for the required storage and retention periods according to and in line with legislation/regulations applicable to the medical and healthcare industry.
- In providing the services to you, certain personal information may be transferred outside of South Africa. Next Genetics has ensured that all information transferred is done in an encrypted format.
- Next Genetics will collate the information shared to provide you with information on other services which may be relevant to you personally and may also use this information to inform you about any changes to the services offered from any of the companies forming part of the Next Biosciences group of companies.
- By sharing information with Next Genetics, you consent to the use of information as above.