



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 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 Biosciences 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 Biosciences 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 Biosciences retains the right to reject samples that do not meet its standards for testing.
10. The Next Biosciences 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 Biosciences may store test data to perform analysis for research purposes. Next Biosciences 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 Biosciences, 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 Biosciences, 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 Biosciences (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 Biosciences under any and all circumstances shall be the total amount paid by the client to Next Biosciences as set out hereunder.

ADDITIONAL HISTOLOGY TESTING OPTION

This test is performed at the Path Point referral laboratory, Pretoria, under pathologist Dr Nemukongwe & Partners and is offered as a test send out service. You give permission and consent to share relevant information for the histology analysis of tissue isolated from the products submitted for testing and understand that the referral laboratory will bill you/your medical funder directly for the cost of processing.

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

- You understand that Next Biosciences 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 Biosciences team for the purposes of providing services.
- You acknowledge that your personal information may be disclosed by Next Biosciences 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 Biosciences has ensured that all information transferred is done in an encrypted format.
- Next Biosciences 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 Biosciences, you consent to the use of information as above.
- You warrant that you are entitled to provide Next Biosciences with the information and data that you provide and you indemnify Next Biosciences against any claims of a data breach by a third party.